# Top Food and Drug Cases, 2022, & Cases to Watch, 2023

*Edited by August T. Horvath*

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# TOP FOOD AND DRUG CASES, 2022 & CASES TO WATCH, 2023

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# Introduction

**AUGUST T. HORVATH***

Welcome, readers, to the 2023 edition of the Food and Drug Law Institute's Top Food and Drug Cases volume, covering a selection of the most important decisions and other developments in the food and drug sector. Given the spirit of these times, it seems worth boasting that this introduction, and indeed the whole volume to the best of our knowledge, is "All Natural"—that is, created without any artificial colors, flavors, or intelligence. One almost suspects that any brief or publication that one reads without at least a partial contribution by generative AI may be the last. For now, though, although we retain the ebook format for this year's publication, we are still firmly old-school in relying on the unique, meatware-generated insights of our roster of exceptional authors from law firms, industry, and academe to bring you the key cases of 2022 and the controversies to keep an eye on for the balance of 2023 and beyond.

The eleven chapters of this volume on specific legal developments, as always, range across all aspects of the food, drug, and medical device sectors, including those in other areas of law that have significant implications for the food and drug community. On behalf of the book's panel of authors, we hope that the FDLI membership continues to find this volume informative, interesting, and worth archiving for future reference.

As far afield as we sometimes wander, we inevitably return to FDA as the wellspring of law and guidance on food and drug issues. In this volume, Brigid DeCoursey Bondoc and KB Do tell us about *Vanda Pharmaceuticals v. FDA*, a case challenging FDA's ability to shield review records relating to pending or unapproved drug applications from Freedom of Information Act disclosure. Anne Walsh reports on FDA's efforts to stop a clinic from performing certain stem cell treatments by characterizing stem cells as drugs subject to premarket review and approval.

Other chapters report on cases where FDA is not a party, but that directly implicate industry's relations with the agency. Sara Koblitz reviews the *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals* case, a challenge to the types of patents that can be listed in the Orange Book that plays a central role in the Hatch-Waxman system of balancing the interest between innovator and generic pharmaceutical producers. Lynn Tyler analyzes limitations that can apply in False Claims Act whistleblower cases accusing a company of falsifying records in connection with pre-approval inspection of a pharmaceutical manufacturing facility. Mital Patel and Francisco Cabrera Lopez cover a case about the extent of preemption of consumer class action suits involving FDA-regulated labeling and packaging elements. And James Beck deserves special mention for not only taking on the important and controversial Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, but for updating the chapter to account for frequent developments in the litigation challenges to FDA's authority to

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approve abortifacient drugs in the wake of *Dobbs* in the weeks immediately prior to publication of this volume.

*Dobbs* is not the only high-profile 2022 case discussed in this year's volume. Justine Lenehan and Dan Logan walk us through the implications of the Supreme Court's use of the Major Question Doctrine in *West Virginia v. EPA* for its imminent review of *Chevron* deference, a question of major importance for all government agencies, including FDA. Bryant Godfrey and Tina Papagiannopoulos report on the criminal convictions of the executives of the now-infamous Theranos medical device company.

Several of our chapters always cover private litigation in the food and drug areas. Bill Janssen covers a class action alleging that a drugstore misleadingly implied that homeopathic products are comparable in efficacy to OTC drugs by shelving them in the same area. Rene Befurt, Anne Cai, Rebecca Kirk Fair, and Helene Rowland explore private class action litigation asserting "greenwashing" claims against major food and beverage companies. Anand Agneshwar and Jocelyn Wiesner describe an important Circuit Court development in the burdens of proof in private medical device product liability suits.

Our two perennial composite chapters summarizing important non-court-decision developments have plenty to report as always. Lauren Farruggia is joined by Stephanie Philbin and Steven Tjoe to describe this year's important regulatory and enforcement developments from the past year, and Vanessa Fulton covers significant settlements negotiated with enforcement agencies in 2022. For our final chapter, our author team nominated in-progress cases that we think are worth watching for the balance of 2023. As always, there is more than a little to interest any active practitioner in the food, drug, and related spaces in these pages.

Not only are our chapters purely human-intelligence derived, there is also nothing artificial about the appreciation I and FDLI express for the contributions of our 2023 authors, some veteran, some new to this volume. We hope this summary of important 2022 matters in the food and drug area provides you with the same education and enjoyment as our previous volumes. On behalf of the entire Top Cases team, we wish our audience a happy, healthy, and safe year.

# Vanda Pharmaceuticals, Inc. v. Food and Drug Administration

**BRIGID DECOURSEY BONDOC & KEUNBONG DO***

## I. WHY IT MADE THE LIST

The Freedom of Information Act (FOIA) has allowed public to access government-held information upon request, while providing exemptions to protect certain information from disclosure. Over time, however, concerns that some agencies are overusing these FOIA exemptions have grown. To address the concerns, Congress enacted the FOIA Improvement Act of 2016, creating additional requirements for the agencies to withhold information and thereby increasing the burden on the agencies to sustain a FOIA denial. This case[1] is one of the first challenges of a FOIA denial by the U.S. Food and Drug Administration (FDA) since the FOIA Improvement Act went into effect, where the denial is based on the deliberative process privilege that the agency has frequently invoked. Against FDA's general policy of not disclosing review records associated with unapproved or pending drug applications, the district court in this case found that the agency should disclose certain review documents associated with a pending drug application that received a complete response letter from the agency.

## II. DISCUSSION

### *A. Legal Background*

In 1966, FOIA amended Section 3 of the Administrative Procedure Act (codified as 5 U.S.C. § 552),[2] requiring federal agencies to disclose certain information in response to a proper request under FOIA. FOIA provides that this disclosure requirement does not apply to information protected by one or more of the nine exemptions enumerated in 5 U.S.C. §§ 552(b)(1) to (9). Among these nine exemptions, agencies have frequently invoked the exemption under 5 U.S.C. § 552(b)(5) to deny FOIA requests. This exemption category is often referred to as "Exemption 5," which protects "inter-agency or intra-agency memorandums or letters

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1 Vanda Pharms., Inc. v. FDA, Case No. 22-cv-938 (D.D.C. Mar. 27, 2023).

2 Freedom of Information Act, Pub. L. No. 89-487, 80 Stat. 250 (July 4, 1966).

that would not be available by law to a party other than an agency in litigation with the agency."[3]

The Supreme Court has observed that Exemption 5 includes the attorney–client privilege, attorney work-product privilege, and deliberative process privilege.[4] The Supreme Court has required the information be both "predecisional" and "deliberative" to be protected under the deliberative process privilege.[5]

Since 1967, Congress has revised 5 U.S.C. § 552 multiple times, most recently in the FOIA Improvement Act of 2016.[6] With this most recent legislation, Congress tried to address concerns that some agencies are overusing FOIA exemptions, particularly Exemption 5.[7] To address such concerns, the FOIA Improvement Act added 5 U.S.C. § 552(a)(8)(A)(i), requiring agencies to withhold information only if "the agency reasonably foresees that disclosure would harm an interest protected by an exemption" or "disclosure is protected by law."[8]

Section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) requires FDA's approval of a new drug application (NDA) under subsection 505(b) or an abbreviated new drug application (ANDA) under subsection 505(j) before introducing a new drug into interstate commerce. According to 21 C.F.R. § 314.70(b)(2)(v)(A), certain changes in labeling, e.g., to amend the indications and usage in the prescribing information of an approved drug, require a supplemental submission and approval prior to distribution of the drug with those changes. FDA refers to such supplemental submission as a supplemental new drug application (sNDA). After review of an NDA or an sNDA, FDA may issue a complete response letter if the agency determines not to approve the application. The sponsor may respond to a complete response letter with a resubmission that addresses the deficiencies set forth in the complete response letter. However, FDA generally has not disclosed the underlying review documents until it approves the application.

### *B. Factual Background*

FDA approved Vanda's NDA for the drug Hetlioz® (tasimelteon) in January 2014 for the treatment of "Non-24-Hour Sleep-Wake Disorder."[9] In October 2018, Vanda filed an sNDA to add "Jet Lag Disorder" to the label. In August 2019, FDA issued a complete response letter declining to approve this sNDA. In December 2019, Vanda submitted a FOIA request to FDA requesting disclosure of FDA's clinical and statistical review documents that supported FDA's complete response letter. In a letter dated January 15, 2020, FDA denied Vanda's FOIA request, invoking Exemption 5. Vanda appealed that same month, and in May 2021, the Department of Health and Human Services (HHS) upheld FDA's FOIA denial. In the decision letter, HHS acknowledged that the requested review documents do not contain information exempt under the attorney–client privilege or attorney work-product privilege. Nevertheless,

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3 5 U.S.C. § 552(b)(5).

4 *See, e.g.*, United States Fish & Wildlife Serv. v. Sierra Club, Inc., 141 S. Ct. 777, 785 (2021).

5 *Id.* at 785–86.

6 FOIA Improvement Act of 2016, Pub. L. No. 114-185, 130 Stat. 538 (2016).

7 *See* S. REP. NO. 4, 114th Cong., 1st Sess. 2 (2015); H.R. REP. NO. 391, 114th Cong., 2d Sess. 10 (2016).

8 5 U.S.C. § 552(a)(8)(A)(i).

9 NDA 205677.

HHS concluded that FDA properly withheld the requested documents based on the deliberative process privilege under Exemption 5.

### *C. Court Decision*

Vanda filed a complaint against FDA in the U.S. District Court for the District of Columbia in April 2022, alleging that Exemption 5 does not apply to FDA's review documents it requested and demanded an injunctive relief directing FDA to produce the requested documents. Vanda pointed out that HHS acknowledged that the attorney–client and work-product privileges do not apply to the requested documents and argued that the deliberative process privilege does not apply to the requested documents because they are neither predecisional nor deliberative. From a policy standpoint, Vanda argued that disclosure of such information would foster drug development by enabling the sponsors to make informed product development decisions and to meaningfully respond to FDA's adverse actions.

In a summary judgment motion, FDA contended that the requested documents are subject to the deliberative process privilege because they are predecisional and deliberative. Further, attempting to meet the "foreseeable harm" requirement under 5 U.S.C. § 552(a)(8)(A)(i)(I), FDA contended that it reasonably foresees that disclosure of the requested documents would harm an interest protected by Exemption 5. In support of this contention, FDA argued that disclosing review documents such as those Vanda is requesting would have a chilling effect on FDA's internal deliberations ("chilling effect" argument). FDA further argued that disclosing the review documents for an unapproved application may confuse consumers and medical practitioners, raising public health and safety concerns ("public health" argument).

In a cross motion for summary judgment, Vanda maintained that the requested documents do not enjoy the deliberative process privilege because they are neither predecisional nor deliberative. Vanda further argued that FDA failed to meet the "foreseeable harm" requirement, and therefore that FDA should disclose the requested documents regardless of whether the deliberative process privilege applies.

In a decision issued on March 27, 2023, the court denied FDA's motion for summary judgment and granted Vanda's cross motion for summary judgment. The court agreed with Vanda that FDA did not meet the "foreseeable harm" requirement, mooting the issue of whether the requested documents are predecisional or deliberative. Regarding FDA's "chilling effect" argument, the court found that FDA's reviewers do not reasonably expect their deliberations to be kept private and reasoned that a disclosure cannot have a chilling effect in such case. As to FDA's "public health" argument, the court found it to be based on speculated harm, i.e., that "could" happen rather than harm that "would" happen as required by 5 U.S.C. § 552(a)(8)(A)(i)(I). The court therefore concluded that FDA failed to meet the "foreseeable harm" requirement.

## III. IMPACT OF THE DECISION

This case is one of the first cases challenging FDA's FOIA denial based on the deliberation process privilege since the FOIA Improvement Act went into effect on June 30, 2016. The district court decision collides with FDA's general policy of not disclosing review documents associated with unapproved or pending applications. While FDA has been publishing review documents associated with approved NDAs pursuant to FDCA § 505(l)(2), it has taken the position that disclosure of unapproved or pending applications raises public health and safety concerns due to potential public

confusion. However, under this decision, FDA may need to disclose certain review documents associated with unapproved or pending applications in response to a FOIA request.

As Vanda argued in its complaint, access to review documents associated with FDA's adverse actions may allow sponsors to make more informed decisions on future drug development. Further, with such access, sponsors may have the opportunity to scrutinize FDA's decision-making process that led to an adverse action, thereby engaging with FDA in a more meaningful way. Also, the possibility of the disclosure would further promote accountability and transparency.

This case, however, does not suggest that FDA would need to disclose internal review documents before issuing a complete response letter for an application. Although Vanda's sNDA at issue was pending when Vanda submitted the FOIA request, the request was made after FDA issued a complete response letter, indicating that its deliberative process had ended. It would be less likely for a court to mandate disclosure of review documents, for example, when FDA issues a discipline review letter (DRL). FDA may issue a DRL before issuing a complete response letter or an approval letter to communicate *potential* deficiencies in the application. A DRL may allow the sponsor to address an issue without receiving a complete response letter or to start early in the preparation of a resubmission in case a complete response letter follows. There, it would be less likely for a court to mandate disclosure of review documents because FDA has not taken any action with respect to an application that decisively end the deliberative process.

This case showed that the FOIA Improvement Act has indeed increased the burden on the agency to sustain a FOIA denial that is based on the deliberative process privilege and may signal the beginning of a line of Exemption 5 FOIA lawsuits against FDA or more careful handling of such requests by the agency.

# United States v. California Stem Cell Treatment Center

**ANNE K. WALSH***

## I. WHY IT MADE THE LIST

Any case that FDA loses is significant. But this case is extra special because it tees up a potential circuit split that could jeopardize FDA's regulatory authority over regenerative medicines. FDA has appealed this decision, so next year's publication may include a sequel to this matter.

In *United States v. California Stem Cell Treatment Center*,[1] FDA sought to stop a stem cell clinic from performing various stem cell treatments on patients on the ground that the stem cells were drugs that required FDA approval before they could be sold. FDA argued that the stem cells constituted human cells, tissues, and cellular or tissue-based products (HCT/Ps), and that the exemptions for premarket review set forth in Section 361 of the Public Health Service Act did not apply. The clinic argued that the products were not drugs and not subject to premarket review. The district court in California sided with the clinic and held that two of the clinic's procedures were subject to an exemption from FDA regulation. In short, the court determined that these products were not drugs and not subject to FDA premarket review, in almost direct conflict with a 2021 decision from the Eleventh Circuit, *United States v. U.S. Stem Cell Clinic, LLC*, 998 F.3d 1302 (11th Cir. 2021).

## II. DISCUSSION

### *A. Regulatory Background*

Although the practice of medicine is generally known to be outside the scope of FDA's jurisdiction, FDA has sought to curb physicians from conducting procedures that involve the use of stem cells to treat a variety of conditions. FDA's position is that the physician's removal of cells from a patient, processing of those cells, and reinsertion of those cells, involves the creation of a "drug" within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA). In 2017, FDA set forth a framework for determining whether HCT/Ps are a "drug" that requires premarket review and approval before they can be marketed. Industry was given until May 2021 to align its practices with the new requirements.

HCT/Ps are defined in Section 1271.3(d) as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or

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[1] *United States v. Cal. Stem Cell Treatment Ctr.*, No. EDCV 18-1005 JGB, 2022 U.S. Dist. LEXIS 156714 (C.D. Cal. Aug. 30, 2022).

transfer into a human recipient."[2] HCT/Ps that meet the requirements set forth in Section 361 of the Public Health Service Act (PHSA) and corresponding regulations are not regulated as "drugs" and do not require FDA premarket approval.[3] Among other criteria, the HCT/P cannot be more than "minimally manipulated" and it must be intended for "homologous use." Most of the questions related to HCT/P regulation surround whether a product is for "homologous use," meaning that the procedure is for the "repair, construction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipients as in the donor."[4]

HCT/Ps that do not meet the 361 criteria are regulated under Section 351 of the PHSA and require FDA approval before marketing. These products are subject to other FDA requirements for registration, listing, and compliance with good manufacturing practices.

There are some exceptions to the HCT/P regulations. The SSP Exception exempts from FDA oversight any "establishment that removes HCT/Ps from an individual and implants such HCT/Ps into the same individual during the same surgical procedure."[5] In creating this exemption, FDA determined that the risk to a patient for removal and reimplantation of the patient's own cells did not increase risks beyond those typically associated with surgery.[6]

### *B. Factual Background*

The U.S. Department of Justice (DOJ) filed a complaint in May 2018 seeking to permanently enjoin California Stem Cell Treatment Center, Cell Surgical Network Corporation, and two physicians (Elliot Lander and Mark Berman) from performing various stem cell treatments on patients. The government alleged that the treatments violated the FDCA by causing the adulteration and misbranding of drugs and the receipt of misbranded drugs. The alleged violative products all were derived from Stromal Vascular Fraction (SVF) cells taken from a patient's adipose (fat) tissue. These SVF cells were used in three different procedures:

> (1) SVF Surgical Procedures—These procedures involve the collection of a patient's SVF cells through liposuction of adipose tissue, mechanical separation of the cells from the tissue, filtration, suspension in a saline solution, and reinsertion into the same patient's body. The purpose of the procedure is to increase the number of available SVF cells in circulation around an injured area.
>
> (2) Expanded MSC Surgical Procedures—In these procedures, the physician collects a patient's adipose tissue and sends it to a tissue bank to isolate the mesenchymal stem cells (MSC). The tissue bank then places the MSC cells in a culture that causes then to naturally replicate ("expand"), so that the cells can be used in multiple treatments for a

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2 21 C.F.R. § 1271.3(d).

3 42 U.S.C. § 264.

4 21 C.F.R. § 1271.3(c).

5 21 C.F.R. § 1271.15.

6 U.S. FOOD & DRUG ADMIN., SAME SURGICAL PROCEDURE EXCEPTION UNDER 21 CFR 1271.15(B): QUESTIONS AND ANSWERS REGARDING THE SCOPE OF THE EXCEPTION: GUIDANCE FOR INDUSTRY (Nov. 2017), https://www.fda.gov/media/89920/download.

> patient who is unable to undergo multiple liposuctions to remove tissue. The cells are intended for autologous use (meaning that the cells are returned "back into the individual from whom the cells or tissue were recovered"[7]).
>
> (3) SVF/ACAM2000 Treatment—ACAM2000 is an FDA-approved vaccine, and this treatment was used on patients with terminal cancer to deliver the ACAM2000 to the area of the cancer cells. The physician removed the adipose tissue and prepared the SVF cells, and added the ACAM2000 to the SVF cells before deploying them into the same patient's body.

### *C. Decision*

After a bench trial, Judge Jesus Bernal of the Central District of California made specific rulings about each of the treatments at issue.

For the SVF Surgical Procedure, the court ruled that the SVF cells were HCT/Ps, that they were not regulated as "drugs" within the meaning of the FDCA, and that the procedure satisfied the "same surgical procedure" exception. The court focused on the "same surgical procedure" exception, which provided a complete defense to the DOJ's claims because it removed the procedures from FDA jurisdiction. According to the court, the "same surgical procedure" exception "unambiguously" states that the focus is on the target of the removal, and that cells can only be removed from a patient along with larger systems, such as the tissues. The court rejected FDA's argument that the "tissue" being removed from the patient was not the same as the "cells" that were reinserted, and reasoned that FDA's interpretation eliminated the word "cells" from the definition of HCT/P. The court ruled that the removal and reinsertion of the SVF cells satisfied the "same surgical procedure" exception to apply to these products.

Even though unnecessary to the exception, the court also examined whether the SVF surgical procedure fundamentally changed the cells. It found that the reinserted cells were the same autologous cells removed from, belonging to, and returned back to the patient. Therefore, the court concluded that the SVF Surgical Procedure was not governed by the FDCA.

For the Expanded MSC Procedure, the court ruled that the cells involved were not drugs. "They are human cells removed from patients and then reintroduced into those same patients. They are not fungible goods that can be sold, mass produced, or patented."[8] The court concluded that the defendants were engaged in the practice of medicine, which is carved out from FDA statutory authority, and not the manufacture of drugs.

Last, the court ruled that the SVF/ACAM2000 Treatment did involve a "drug" under the FDCA, but that injunctive relief was not warranted because the defendants had discontinued the treatment before initiation of the litigation.

The court declined to award defendants' attorneys fees because the United States had a reasonable basis to commence the lawsuit. The court noted that other courts have concluded that the procedures can be regulated by FDA, citing a 2019 case in Florida involving a similar stem cell clinic and procedures.[9]

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[7] 21 C.F.R. § 1271.3(a).

[8] Cal. Stem Cell Treatment Ctr., 2022 U.S. Dist. LEXIS 156714, at *23.

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

## III. IMPACT OF THE DECISION

As of May 31, 2021, FDA "expects all establishments that manufacture HCT/Ps regulated as drugs or biological products to have an approved biologics license application (BLA) or an investigational new drug application (IND) in effect."[10] This case directly challenges whether certain products qualify as HCT/Ps that require premarket approval, thus undermining FDA's oversight of these regenerative medicine products.

As reported in last year's *Top Food and Drug Cases* publication,[11] the Eleventh Circuit upheld a lower court's holding that a clinic conducting similar SVF procedures were subject to FDA regulation.[12] Unlike the California court, the Eleventh Circuit found that the products did not meet the "same surgical procedure" exemption nor did they meet the criteria to be marketed as 361 HCT/Ps. At the time, the Eleventh Circuit decision was touted as a big victory for FDA and its enforcement efforts against stem cell clinics. Now, with the California verdict going the opposite way, providers of stem cell therapies are betwixt and between conflicting findings on essentially identical treatments and issues.

FDA filed its notice of appeal in October 2022, and the latest briefing schedule requires the United States to file its opening brief by April 25, the clinics and the individuals to file their briefs by May 25, 2023, and an optional reply brief to be filed twenty-one days after service of the answering brief. Parties completed initial briefing by March 8, 2023. Stay tuned for the 2023 edition of the *Top Food and Drug Cases* publication for the fall-out from that appeal.

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[10] Questions and Answers Regarding the End of the Compliance and Enforcement Policy for Certain Human Cells, Tissues, or Cellular or Tissue-Based Products (HCT/Ps), U.S. FOOD & DRUG ADMIN. (July 9, 2021), https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/questions-and-answers-regarding-end-compliance-and-enforcement-policy-certain-human-cells-tissues-or.

[11] Naomi Igra & Emily Marden, *United States v. U.S. Stem Cell Clinic, LLC*, *in* TOP FOOD AND DRUG CASES, 2021, & CASES TO WATCH 2022 (Food & Drug Law Inst., May 2022), https://www.fdli.org/wp-content/uploads/2022/07/United-States-v.-US-Stem-Cell-Clinic-LLC.pdf.

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

# Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC

**SARA W. KOBLITZ***

## I. WHY THIS CASE MADE THE LIST

Patents listed in FDA's List of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") play a critical role in maintaining the balance between access and innovation that underscores the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or "Hatch-Waxman").[1] Indeed, each patent listed in the Orange Book requires a certification in any filed follow-on application—Abbreviated New Drug Applications (ANDA) or 505(b)(2) New Drug Applications (NDA)—seeking approval of a proposed drug referencing an innovator product.[2] Those listed patents are eligible for assertion prior to generic launch,[3] along with a thirty-month stay of follow-on approval,[4] preventing an onslaught of potentially infringing product from flooding the market during the pendency of litigation. Consequently, the patents that can be listed in the Orange Book are of significant concern, and industry has been asking FDA to opine on the proper patents for listing for many years. While FDA has asked for public opinion on the types of patents that should be listed in the Orange Book,[5] the agency itself has remained silent.[6]

With little guidance from FDA, companies have listed all sorts of patents in the Orange Book that could be asserted against a potential generic, including patents covering Risk Evaluation and Mitigation Strategies (REMS). However, because these patents do not necessarily cover the drug product itself, such listings have been controversial. In *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, the

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1 Pub. L. No. 98-417, 98 Stat. 1585 (1984).

2 21 U.S.C. § 355(b)(2)(A); 21 U.S.C. § 355(j)(2)(A)(vii).

3 35 U.S.C. § 271(e)(2).

4 21 U.S.C. § 355(c)(3)(C); 21 U.S.C. § 355(j)(5)(B)(iii).

5 Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 33,169, 33,170 (June 1, 2020).

6 *See* Request for Advisory Op. by GlaxoSmithKline, Docket No. FDA-2005-A-0476 (formerly 2005A-0015) (Jan. 10, 2005); Request for Advisory Op. by AstraZeneca, Docket No. FDA-2006-A-0063 (formerly 2006A-0318) (Aug. 10, 2006); Request for Advisory Op. by AstraZeneca, Docket No. FDA-2007-A-0099 (formerly 2007A-0261) (June 21, 2007); Request for Advisory Op. by Forest Lab'ys, Inc., Docket No. FDA-2011-A-0363 (May 12, 2011); Request for Advisory Op. by Novo Nordisk Inc., Docket No. FDA-2012-A-1169 (Nov. 26, 2012); *see also* Letter from Douglas C. Throckmorton, CDER, to James Ford, GlaxoSmithKline, et al., Docket Nos. FDA-2005-A-0476, FDA-2006-A-0063, FDA-2007-A-0099, FDA-2011-A-0363, and FDA-2012-A-1169 (June 1, 2020).

courts had the opportunity to address the listing of REMS patents in the Orange Book.[7] Ultimately, the court decided that the patent at issue in this case could not be listed in the Orange Book—and ordered the delisting of that patent—because the patent claimed a "system" rather than a "method" of using the drug.

Generally, *Jazz v. Avadel* addresses questions that have long gone unanswered related to listing patents in, and FDA's role in administering, the Orange Book. While the court's narrow interpretation of a method of use patent implicitly limits listable patents, it both stops short of limiting patent listings more generally and embraces FDA's hands-off approach to listing decisions. But aside from the implications as to the propriety of listing REMS patents, this case is also notable because of the intervention of the Federal Trade Commission (FTC) and its strong *amicus* brief arguing that the listing of a REMS patent generally is anticompetitive. No government agency has taken that strong a position related to patent listings, even with industry prodding, making the filing of the FTC brief notable.

## II. DISCUSSION

### *A. 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.[8] 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.[9] To that end, the FDCA establishes the procedure for obtaining FDA approval to sell pharmaceutical products through an NDA, which requires the submission of clinical trial data establishing the proposed new drug's safety and efficacy for its intended use under the conditions of its proposed labeling.[10] Upon approval, the NDA sponsor must file with FDA "the patent number and the expiration date of each 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 . . . ."[11] The statute then obligates FDA to "publish" and regularly "revise" a list of all such patent data.[12] That listing of patent data is published in FDA's Orange Book alongside the NDA with which it is associated.

The FDCA also authorizes FDA to review and approve "abbreviated" or "follow-on" versions of approved drug products. A generic version of a previously approved drug may be approved under an ANDA so long as the ANDA includes data to establish that the proposed generic drug is "the same as" a previously approved Reference Listed Drug (RLD) in certain key respects.[13] The FDCA also provides for an additional type of abbreviated applicated—a 505(b)(2) NDA—which permits the submission of

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[7] Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:21-cv-00691 (D. Del. 2021); No. 1:21-cv-01594 (D. Del. 2021); No. 1:22-cv-00941 (D. Del. 2022); No. 23-1186 (Fed. Cir. 2022).

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

[9] *See* 21 U.S.C. § 355.

[10] *Id.*

[11] 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.50(h).

[12] 21 U.S.C. § 355(j)(7)(A)(i)–(iii); *see also id.* § 355(c)(2).

[13] *Id.* § 355(j)(2)(A).

an NDA for a drug that is not a duplicate of a previously approved RLD, and where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.[14] In practice, this enables the applicant to rely, in part, on FDA's findings of safety and/or effectiveness for the RLD or on published literature reports of studies rather than re-conducting certain studies in support of its application.

Both ANDA and 505(b)(2) NDA applicants relying on FDA's findings of safety or efficacy for an approved product must certify to any patents listed in the Orange Book for the RLD it is referencing.[15] Specifically, the applicant must certify to each patent in one of the following ways:

> (i) the required patent information has not been filed;
>
> (ii) the listed patent has expired;
>
> (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or
>
> (iv) the listed patent is invalid or will not be infringed by the new product.

A Paragraph IV certification also requires the ANDA or 505(b)(2) NDA sponsor to provide notice of the application and patent certification 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 application.[16] Should the RLD holder file an infringement suit against a follow-on applicant, approval of that ANDA is stayed for thirty months as the patent litigation is resolved.[17]

When an applicant believes that a patent has been wrongly listed in the Orange Book, the applicant can dispute the listing and ask the RLD sponsor, through FDA, to remove it from the Orange Book.[18] Should the RLD sponsor decline to remove or update the patent listing, the patent remains listed in the Orange Book, and any follow-on applicant must certify to that patent.[19] The only remaining remedy for the applicant to address an alleged improper listing is to file a counterclaim to the patent litigation initiated by the RLD sponsor "seeking an order requiring [the RLD sponsor] to correct or delete" from the Orange Book the relevant patent information.[20]

Importantly, FDA has enumerated—and thereby limited—the types of patents to be listed in the Orange Book and consequently the types of patents for which certifications are required upon submission of an ANDA or a 505(b)(2) NDA. Specifically, these patents are limited by FDA regulation to patents that claim the drug substance (active ingredient), drug product (formulation and composition), or methods of using the drug.[21] The scope of the limitations on patent listing are not entirely clear, however. FDA has not taken a position on whether certain patents should be listed, including drug delivery systems for combination products and patents covering REMS

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[14] *Id.* § 355(b)(2).

[15] *Id.* § 355(b)(2)(A); *id.* § 355(j)(2)(A)(vii).

[16] *Id.* § 355(c)(3)(C); *id.* § 355(j)(5)(B)(iii).

[17] *Id.*

[18] 21 C.F.R. § 314.53(f).

[19] *Id.* § 314.53(f)(1)(i).

[20] 21 U.S.C. § 355(c)(3)(D)(ii)(I); *id.* § 355(j)(5)(C)(ii)(I).

[21] 21 C.F.R. § 314.53(b)(1).

where FDA has determined such a REMS is necessary to ensure that the benefits of a drug outweigh its risks.[22] Absent FDA input, certain RLD sponsors have decided to list REMS patents in the Orange Book, requiring ANDA and 505(b)(2) sponsors referencing those products to certify to such patents.

Patents listed in the Orange Book as "method of use" patents do not necessarily require 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), as detailed in the "use code" selected by the RLD sponsor.[23] 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 (or "carved-out") from the proposed product labeling to avoid infringement.[24]

### *B. Factual Background*

Used for the treatment of cataplexy and excessive daytime sleepiness associated with narcolepsy, Jazz Pharmaceuticals, Inc. ("Jazz") has marketed immediate release formulations of sodium oxybate in the United States since 2002. Given its potential for abuse, all sodium oxybate products are subject to a REMS that requires a limited distribution system involving a single, central pharmacy.[25] Jazz's two sodium oxybate products, Xyrem and Xywav, are subject to its own REMS, and Jazz obtained a patent covering the REMS.[26] Jazz listed that patent, U.S. Patent Number 8,731,963 ("the '963 patent"), in the Orange Book with the associated use code U-1110, "method of treating a patient with a prescription drug using a computer database in a computer system for distribution."[27]

Avadel CNS Pharmaceuticals, LLC ("Avadel") developed its own sodium oxybate product, called Lumryz, that is dosed once nightly, in contrast to the Jazz products, which require a second dose in the middle of the night.[28] Avadel submitted a 505(b)(2) NDA referencing Xyrem in December 2020.[29] Because Avadel proposed to use its own REMS rather than Jazz's patented system, Avadel did not certify to the '963 patent but instead submitted a section viii statement asserting that the patent "does not

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[22] *See* 85 Fed. Reg. at 33,172, 33,173 (soliciting comments on the types of patents that should be listed in the Orange Book).

[23] 21 U.S.C. § 355(b)(2)(B), (j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(8)(iv); 21 C.F.R. § 314.53(f)(1)(i)(B).

[24] 85 Fed. Reg. at 33,170; *see* 21 C.F.R. § 314.53(f)(1)(i)(B).

[25] Op. at 2–3, Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 23-1186 (Fed. Cir. Feb. 24, 2023), ECF No. 59.

[26] *Id.*

[27] U.S. DEP'T OF HEALTH & HUM. SERVS., *Prescription and OTC Drug Product Patent and Exclusivity List*, *in* ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, at ADA 369 (43rd ed., 2023).

[28] Jazz v. Avadel, No. 23-1186, at 6 (Fed. Cir. Feb. 24, 2023).

[29] *Id.*

claim a use for such drug for which the applicant is seeking approval."[30] Nonetheless, Jazz sued Avadel for infringement of the '963 patent, as well as infringement of other listed patents.

Notwithstanding Avadel's section viii statement submitted with the 505(b)(2) NDA more than a year and a half earlier, FDA, in May 2022, ordered Avadel to certify to the '963 patent based on the conclusion that the Lumryz REMS's use of four computer databases for distribution overlaps with the U-1110 use code.[31] Avadel certified to the '963 patent "under protest" in June 2022, and Jazz initiated a second lawsuit against Avadel for infringement of the '963 patent on July 15, 2022. Because Jazz timely sued Avadel, the lawsuit triggered a thirty-month stay, effectively barring Lumryz from coming to market until the June 2023 expiration of the '963 patent and its associated pediatric exclusivity.[32]

In the interim, FDA tentatively approved the Lumryz 505(b)(2) NDA on July 18, 2022, and Avadel sued the agency in the District Court of the District of Columbia alleging that it violated the Administrative Procedure Act (APA) by requiring a certification to the '963 patent.[33] Avadel reasoned that the decision whether to file a patent certification or a section viii statement rests solely in the "opinion" of the new drug "applicant" under the plain language of the statute set forth in 21 U.S.C. § 355(b)(2), and FDA therefore lacked the statutory authority to "second-guess Avadel's decision to file a patent statement rather than a patent certification."[34] Accordingly, Avadel argued that FDA does not have legal basis to compel a patent certification to the '963 patent.[35] Thus, Avadel concluded its 505(b)(2) is entitled to final approval now—not after the pendency of the thirty-month stay or expiration of the '963 patent. However, because the APA authorizes review only when there is no adequate remedy for a plaintiff's injury, the district court dismissed Avadel's suit against FDA citing the pending delisting counterclaim as a potential remedy.[36]

After the dismissal, Avadel responded to both of Jazz's infringement lawsuits with a counterclaim seeking an order that Jazz delist the '963 patent for failure to claim a drug or method of use.[37]

While litigation was ongoing, the FTC filed an *amicus* brief in the case detailing the abuse arising from improper listing of patents in the Orange Book.[38] Because FDA has no tools to "remove improperly listed patents," the FTC explained that there is "no gatekeeper to prevent a company from inappropriately listing patents that do not meet

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[30] Mem. of P. & A. in Supp. of Pl.'s Mot. for a Prelim. Inj. or in the Alternative Summ. J. at 3, Avadel CNS Pharms., LLC v. Becerra, Docket No. 1:22-cv-2159 (D.D.C. July 21, 2022), ECF No. 2-1; 21 U.S.C. § 355(b)(2)(B).

[31] Compl. for Declaratory and Injunctive Relief at 4, Avadel CNS Pharms., LLC v. Becerra, No. 1:22-cv-2159 (D.D.C. July 21, 2022), ECF No. 1.

[32] *Id.* at 5.

[33] *Id.*; *id.* at 24.

[34] *Id.* at 24.

[35] *Id.*

[36] Mem. Op., Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:21-cv-00691 (D. Del. Nov. 18, 2022), ECF No. 231.

[37] *Id.* at 2.

[38] Federal Trade Commission's Br. as Amicus Curiae, Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:21-cv-0691 (D. Del. Nov. 10, 2022), ECF No. 222-3.

the Orange Book criteria."[39] A brand can therefore list a patent—even if it does not adhere to FDA listing regulations—and sue, triggering an automatic thirty-month stay, with no oversight.[40] This, FTC explained, is anticompetitive.[41] While the FTC took no position on Jazz's specific patent, it argued that patents only covering drug distribution systems "do not meet the Orange Book listing criteria; to the extent they claim a method at all, it is a method of *distributing* a drug rather than a method of *using* one. This is an important distinction."[42] The FTC also argued that listing REMS patents not only contravenes the plain text of the Orange Book listing statute, but it also may violate the REMS statute by blocking or delaying follow-on approval.[43]

### *C. Court Decision*

Jazz and Avadel engaged in two separate sets of lawsuits; the first lawsuit proceeded to claim construction in which Avadel argued that the '963 patents are directed to systems—not methods—while Jazz argued that the terms systems and methods are interchangeable.[44] On November 18, 2022, the District Court of Delaware agreed with Avadel, construing the '963 patent claims to be directed to systems, not methods.[45] Because it does not cover a method of using the drug, the district court issued a second Memorandum Opinion on the same day ordering the delisting of the '963 system patent.[46] Jazz appealed.

On February 24, 2023, the Court of Appeals for the Federal Circuit upheld the district court's decision that the patent should be delisted.[47] The Federal Circuit looked to both the adequacy of the claim construction and to the proper interpretation of the term "'an approved method of using the drug' under 21 U.S.C. § 355(c)(2) and § 355(c)(3)(D)(ii)(I)."[48]

Based on the description in the patent specification and prosecution history, the Federal Circuit determined that the '963 patent claimed a system rather than a method.[49] Specifically, the court explained, Jazz's claims to a system comprising computer memory and a data processor are not method claims; that the system can be used to treat patients "does not alter the fact that these are system claims."[50] The court

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[39] *Id.* at 13.

[40] *Id.* at 13–14.

[41] *See id.* ("An improper listing harms competition and consumers: By listing a patent in the Orange Book and then filing an infringement suit, a brand can block competition for up to two-and-a-half years regardless of the scope or validity of the patent and regardless of whether it meets the statutory listing criteria.").

[42] *Id.* at 2 (emphasis added).

[43] *Id.* at 20.

[44] Mem. Op., Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:21-cv-01594 (D. Del. Nov. 18, 2022), ECF No. 146.

[45] *Id.*

[46] *Jazz v. Avadel*, No. 1:21-cv-00691 (D. Del. Nov. 18, 2022).

[47] *Jazz v. Avadel*, No. 23-1186 (Fed. Cir. Feb. 24, 2023).

[48] *Id.* at 11.

[49] *Id.* at 10.

[50] *Id.*

therefore determined that the district court properly construed the claims as system—rather than method—claims.[51]

The court next looked at whether the system claimed in the '963 patent qualified as "an approved method of using the drug" under 21 U.S.C. § 355(c)(2) and § 355(c)(3)(D)(ii)(I).[52] Jazz argued that the FDA regulation 21 C.F.R. § 314.53(b)(1) requires a broader definition of the term "method" than permitted by the language of patent law and that this broader definition encompasses the claims of the '963 patent.[53] Because prescribing Xyrem required following a REMS, Jazz argued that the REMS computer system described in the '963 patent was a "condition of use" for which approval had been granted in the NDA.[54] The court rejected this argument, explaining that the patent still needed to claim a method of use to be eligible for listing.[55] And because the '963 patent does not claim a method of use, the court found 21 C.F.R. § 314.53(b)(1) inapplicable.[56]

Jazz also argued that the patent was permissibly listed in 2014 because the patent was neither required nor forbidden from listing.[57] Thus, Jazz argued, Avadel could not compel Jazz to delist it.[58] The Federal Circuit again disagreed, explaining that whether the patent was eligible for listing when it was initially listed does not control whether a court could order delisting now.[59] Thus, the Federal Circuit concluded that the district court was correct in ordering the '963 patent delisted.[60]

## III. IMPACT OF THE DECISION

While limited to the delisting of the '963 patent, this case has significant implications as to the listing of certain patents in the Orange Book. Because FDA historically has declined to opine on the propriety of listing certain patents in the Orange Book, including REMS patents, RLD sponsors have taken a broad approach to Orange Book listing by including patents that do not reference specific drug products.[61] The decision in *Jazz v. Avadel* implicitly limits the types of patents listable by narrowly interpreting a "method" of use.[62] Indeed, that a condition of use is recited in the patent does not render the patent a "method of use" patent covering the drug product eligible for Orange Book listing; consequently, RLD sponsors will need to carefully draft claims so that they undeniably claim a ***method*** of using the drug, which can be challenging since REMS typically involve strategies for educating patients and practitioners or limiting distribution of drug products rather than an actual use of the

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[51] *Id.*

[52] *Id.* at 11.

[53] *Id.*

[54] *Id.* at 12.

[55] *Id.* at 11–12.

[56] *Id.*

[57] *Id.* at 14.

[58] *Id.*

[59] *Id.*

[60] *Id.*

[61] *See In re* Lantus Direct Purchaser Antitrust Litigation, No. 18-2086 (1st Cir. 2020) .

[62] *Jazz v. Avadel*, No. 23-1186, at 11–12 (Fed. Cir. Feb. 24, 2023).

drug product. Whether this means that the patent must include a claim covering use of the drug itself is still unclear, leaving unanswered the question of whether other types of patents, like device patents, can be properly listed in the Orange Book even if they do not expressly claim the drug.

Additionally, that both the district court and the Federal Circuit determined that the listability of the '963 patent in the Orange Book hinged on claim construction legitimizes FDA's position that its role in administering the Orange Book is merely ministerial.[63] Because claim construction is squarely within the purview of the courts and the U.S. Patent and Trademark Office,[64] the decision allows FDA to avoid any responsibility for monitoring and administering the Orange Book with an eye toward improper listings. In other words, FDA can continue to avoid intervening in patent listing disputes by directing applicants to the delisting counterclaim provisions in the Hatch-Waxman Amendments, leaving all Orange Book listing concerns to the discretion of the courts.

With the procedural history of this case and the delay in approval of the Lumryz 505(b)(2) NDA, this case suggests that FDA's refusal of responsibility for proper Orange Book listing can cause a significant roadblock for applicants. It took Avadel several years to get to the point where a court finally made a delisting decision, delaying market entry for reasons that were ultimately baseless. Admittedly, claim construction clearly is not in the purview of FDA, but because there is no mechanism by which FDA can or will interpret a patent or compel its removal from the Orange Book without a sponsor undertaking costly and lengthy litigation—and because FDA had refused to address the question of listability of REMS patents—Avadel was forced to certify to a questionably listed patent. In turn, and even though Lumryz was ready for approval, the compelled certification triggered a second round of patent litigation and an automatic thirty-month stay of approval that theoretically would block Avadel from marketing until the expiration of the relevant patent. A clever—and completely legal—listing strategy consumed significant time, money, and court resources. And importantly, this was not even a direct copy of the Jazz product, which means that such a listing strategy ***prevented innovation*** rather that encouraged it.

It is also notable that FTC took a strong position in its *amicus* brief that the listing of certain patents in the Orange Book is anticompetitive. While neither court expressly agreed with the FTC, it is clear that the reasoning presented in the FTC's brief permeated the courts' decision. Indeed, the FTC argued that patents claiming a method of *distributing* a drug do not cover the drug itself or a method of *using* the drug, which is similar to the reasoning the Federal Circuit used in holding that the Jazz system of distribution was not listable; the court stopped just short of the pronouncement made by the FTC. The FTC further argued that listing REMS patents not only contravenes the plain text of the Orange Book listing statute, but it also may violate the REMS statute by blocking or delaying follow-on approval. While the courts may not have addressed that point, that the enforcer of the antitrust statutes believes that listing REMS patents in the Orange Book is anticompetitive is significant and may serve as

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[63] 85 Fed. Reg. at 33,170 ("We note that FDA has a ministerial role with regard to the listing of patent information.").

[64] *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, U.S. FOOD & DRUG ADMIN. (Feb. 4, 2020), https://tinyurl.com/FDAPTE ("FDA defers to PTO on all matters involving the construction and validity of patent claims.").

the impetus for FDA to announce its perspective on listing REMS patents in the Orange Book.

Finally, Avadel made interesting arguments in the APA litigation that the District Court for the District of Columbia did not have an opportunity to address. Avadel argued that FDA does not have the authority to compel a patent certification rather than a section viii statement based on the plain language of 21 U.S.C. § 355(b)(2), which calls for certification based on "the opinion of the applicant and to the best of his knowledge."[65] This language seems to delegate decision-making authority regarding the proper patent certification to the applicant. This raises an interesting question—whether the applicant alone can determine the proper certification—a decision on which could upend the patent certification process. Additionally, Avadel explained that FDA's review of the Lumryz REMS document to assess the use code overlap—rather than the Prescribing Information alone—violated FDA regulations. Avadel argues that FDA regulations state that a patent certification is necessary "[i]f the *labeling* of the drug product for which the application is seeking approval includes an indication or other condition of use that, according to the patent information submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 or in the opinion of the applicant, is claimed by a method-of-use patent," which thereby limits FDA to review of the labeling for use code overlap.[66] This is an important question because FDA frequently assesses the propriety of use code carve-outs in Citizen Petitions by looking at the *impact* of the labeling carve-out on doctors' prescribing decisions. If FDA is not permitted to look beyond the confines of the Prescribing Information to assess a carve-out, FDA likely could not rely on the *implications* of the omission of that carved-out language beyond the actual instructions for use in the labeling to the foreseeable use of those instructions. Of course, no court has reached these questions yet.

Ultimately, the Federal Circuit decision stands, and in March 2023, Jazz delisted the '963 patent at the direction of the Federal Circuit.

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[65] Complaint for Declaratory and Injunctive Relief, Avadel CNS Pharms., LLC v. Becerra, No. 1:22-cv-2159 (D.D.C. July 21, 2022) (Doc. 1), at 10.

[66] Mem. of P. & A. in Supp. of Pl.'s Mot. for a Prelim. Inj. or in the Alternative Summ. J. at 3, Avadel CNS Pharms., LLC v. Becerra, Docket No. 1:22-cv-2159 (D.D.C. July 21, 2022), ECF No. 2-1 (citing 21 C.F.R. § 314.50(i)(1)(iii)(B)) (emphasis added).

# (Alleged) False Statements to FDA Do Not Necessarily a False Claim Make

**LYNN C. TYLER***

In connection with an FDA pre-approval inspection of a pharmaceutical manufacturing facility, a company makes false statements and provides false records to FDA inspectors. The company passes the inspection, which allows it to manufacture and sell the product, including to government healthcare programs. Sounds like the makings of a good False Claims Act case, right? Although making false statements and providing false records to FDA can have a variety of serious adverse consequences, the answer in this case is "not necessarily" based on the Second Circuit's decision in *United States ex rel. Yu v. Grifols USA, LLC*.

## I. WHY IT MADE THE LIST

In light of the eye-popping recoveries that sometimes arise out of False Claims Act (FCA) cases, they often garner a lot of attention and it is important to know the metes and bounds of their elements. This case illustrates some of the limitations that can stand in the way of (or prevent) one of those recoveries.

## II. DISCUSSION

### *A. Factual Background*

Because the case was dismissed for failure to state a claim, the facts are taken from the Amended Complaint as summarized in the district court's opinion. The relator, Allen Timothy Yu, was a resident of California and a former employee of the defendants. The defendants (collectively, "Grifols") were commonly-owned suppliers of plasma-derived products and pharmaceuticals. Specifically, Yu worked for Grifols Biologicals, LLC, which manufactures intravenous immunoglobulin (IVIG).

In 2011, Grifols converted a manufacturing facility in Los Angeles to produce Gamunex, a pharmaceutical for treating chronic inflammatory demyelinating polyneuropathy and other autoimmune disorders. The Los Angeles plant conversion required Grifols to have FDA conduct a pre-approval inspection of the facility and its equipment and also review Grifols' manufacturing validation records for IVIG products. Grifols hired Yu in 2011 during the plant approval process to serve as a quality assurance project manager. His job was to perform routine and ad hoc quality assurance reviews of qualifications, investigations, documentation, audits, protocols, and final reports on topics that FDA would review.

In January, 2014, months before FDA planned to inspect the Los Angeles plant, Yu discovered a discrepancy in the signed Installation Qualification (IQ/OQ) Final Report

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for CIP-14, one of thirteen Clean-In-Place (CIP) systems used to clean IVIG manufacturing equipment. During his examination of CIP-14, Yu noticed that a specific diaphragm control valve, which controlled the emission of certain cleaning chemicals, had been validated as stainless steel when in fact it was made of plastic. After raising that discrepancy with his supervisor, Yu inspected the CIP-14 further and found at least another nineteen signed and dated entries in the CIP-14 IQ/OQ Report that did not agree with the actual equipment on the cleaning system. He told his supervisor about those discrepancies and was asked to investigate other CIP systems.

In the course of his inspections, Yu found over one hundred "discrepancies" in the CIP systems' hardware, components, and utilities. These errors consisted primarily of incorrectly validated amperage for various parts; parts that had been previously validated with incorrect part numbers and model numbers that were either not specified, not documented, or were documented but not actually found on the equipment; and missing, incorrectly documented, or undocumented identification tags on various parts. For instance, a phase reactor that supplied power to a pump motor drive "had 18 fundamental amps and not the 25 fundamental amps as required" by relevant protocol specifications. In addition, three large valves were "incorrectly documented as having been tri-clamped, but Yu found that they were actually welded."

According to Yu's Amended Complaint, those and other discrepancies "may lead to contamination of the IVIG equipment;" "may lead and [are likely] to lead to inaccurate testing results;" "may lead to contamination;" and "could impact [the CIP systems'] maintenance, service and, [sic] overall performance, thereby reducing the systems' efficacies, and leading over time to adulterated IVIG product and the significant risk of patient harm."

Yu presented his findings to his supervisor again and they were reported to at least three others further up the chain. The Director of Validation reported that the department might have been understaffed and the validation engineers probably did not do their work correctly. The Vice-President of Quality Assurance stated that he did not want Yu's findings to be documented as a deviation or a corrective and preventative action, though Grifols' validation procedures required such documentation. Yu was never interviewed by anyone at Grifols about his findings, nor was he aware of any investigation conducted by Grifols after he presented his findings.

In March, 2014, Yu was asked to approve various IQ/OQ reports that allegedly had been corrected. Because the updated reports attributed the current Good Manufacturing Practice (cGMP) discrepancies to "inadvertent error," Yu refused to approve them. Later, during employment litigation Yu brought against Grifols, Yu saw both 1) reports that appeared to contain his forged initials indicating his approval, and 2) errors that he had originally identified that had still not been corrected. "To the best of Yu's knowledge," Grifols made these falsified Final Reports available to FDA for its pre-approval inspection of the Los Angeles plant and used them to create the summaries that were submitted to FDA.

Further, Yu "learned about significant fraud" regarding rabbit bacterial endotoxin tests. Rabbits that had been injected with Gamunex had developed a fever. In a conversation with his supervisor, Yu came to believe that Grifols had concealed the results of these rabbit tests. According to Yu, two of his superiors were apparently successful in fraudulently deleting data sets regarding the rabbit testing from Grifols' laboratory information management system and thereby concealed them from FDA. FDA approved the Los Angeles plant in January 2015. Several confidential witnesses also reported ongoing cGMP violations at the Los Angeles plant, some of which were

allegedly related to a 2019 recall. Nevertheless, Yu did not allege that FDA had ever withdrawn the plant's approval.

### *B. Legal Framework*

To manufacture and sell a drug in the United States, a company must submit a new drug application (NDA) to FDA. An NDA asks FDA to approve a new drug for sale and marketing in the United States based on information submitted from the drug manufacturer, including clinical trial data and test results establishing the quality of the drugs manufactured at a specified facility. One element of an NDA requires the manufacturer to identify the production facilities and certify that they comply with the cGMP regulations set forth in 21 C.F.R. Parts 210 and 211.

The Federal Food, Drug, and Cosmetic Act (FDCA) provides that FDA "shall issue an order refusing to approve the application" if:

> the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.[1]

The FDCA's definition of an adulterated drug uses this same language.[2] In addition, FDA may withdraw its approval of an NDA if the NDA "contains any untrue statement of material fact."[3] FDA's regulations also provide that the failure of a drug to comply with cGMP regulations, "shall render such drug to be adulterated" under the FDCA.[4]

### *C. Court's Analysis*

The district court dismissed Yu's Amended Complaint because it did not adequately allege that the false statements or falsified records were material to a claim for payment from a government healthcare program. Thus, the Second Circuit applied the standards under Fed. R. Civ. P. 12(b)(6) when reviewing the district court's decision. Under Rule 12(b)(6), a complaint must plead enough facts to "state a claim to relief that is plausible on its face." The requirement to accept all factual allegations as true does not extend to allegations that are "naked assertions" or "conclusory statements."[5] In addition, when alleging fraud, a plaintiff must meet both the plausibility standard of Fed. R. Civ. P. 8 and satisfy the heightened pleading standard of Fed. R. Civ. P. 9(b), which requires the complaint to state with "particularity the circumstances constituting fraud."

The False Claims Act imposes civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[6] The Supreme Court has held that in some circumstances "implied false

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[1] 21 U.S.C. §§ 351(a), 355(d).

[2] 21 U.S.C. § 351(a).

[3] 21 U.S.C. § 331(a).

[4] 21 C.F.R. § 210.1.

[5] Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). *See also* Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

[6] 31 U.S.C. § 3729(a)(1)(A).

certification" can amount to a false or fraudulent claim.[7] In particular, at least where a claim for payment makes specific representations about the goods or services provided, but then fails to disclose noncompliance with material statutory, regulatory, or contractual requirements, the omission may render the representations "misleading half-truths."[8]

In addition to alleging a particular misrepresentation, a plaintiff must plead sufficient facts to allege plausibly that the misrepresentation is *material*.[9] The FCA defines materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[10] The Supreme Court has identified three factors relevant to the materiality assessment: "(1) whether the government expressly designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; (2) the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision; and (3) whether the defendants' alleged noncompliance was 'minor or insubstantial.'"[11]

As to the first *Escobar* factor, the court said a contract that merely incorporates by reference and lacks a provision that "specifically identifies any of the contractual or regulatory requirements" that Grifols allegedly violated as an express condition of payment, "at most, weighs neutrally in the materiality analysis" for this factor.[12] The court found Yu did not identify any provisions in the contracts that expressly conditioned payment by the government healthcare programs on Grifols' compliance with any specific cGMPs.

On the second *Escobar* factor, the Supreme Court has explained that evidence the government "consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" at issue can prove materiality.[13] The court found that Yu had failed to support his claims with any non-conclusory factual assertions plausibly alleging that in other cases with comparable cGMP violations, the government healthcare programs declined to pay claims, or that in cases with comparable cGMP violations, FDA declined to approve, or withdrew approval of, the manufacture of a drug.

Finally, the third *Escobar* factor is the degree of the defendants' non-compliance. In this case, the court found that Yu failed to allege plausibly that the alleged violations substantially comprised the government's goal to obtain safe and effective Gamunex or, in other words, that Yu had only alleged the cGMP violations "may" or "could" cause negative consequences, in part because he mostly alleged errors in documentation. The court concluded that Yu did not suggest that Grifols' alleged violations have resulted in "significant financial cost to the government" or demonstrate that the violations go to the "heart of the bargain," this factor weighed against a finding of materiality.

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[7] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 186 (2016) ("Escobar").

[8] *Id.* at 190.

[9] United States *ex rel.* Foreman v. AECOM, 19 F.4th 85, 109 (2d Cir. 2021) ("Foreman").

[10] 31 U.S.C. § 3729(b)(4).

[11] *Foreman*, 19 F.4th at 110.

[12] *Id.* at 110.

[13] *Escobar*, 579 U.S. at 195.

In short, Yu's allegations did not move the needle on any of the three materiality factors identified in *Escobar*, so the Second Circuit affirmed the district court's dismissal of the case.

## III. IMPACT OF THE CASE

As is often true of Supreme Court decisions, there has been debate about the breadth of the *Escobar* decision construing the False Claims Act. The Second Circuit's decision in this case shows that at least in that jurisdiction, the Act's materiality requirement will be strictly construed. It is a meaningful requirement that a plaintiff must allege, and ultimately be prepared to prove, with particularity in the words of Fed. R. Civ. P. 9(b). Not every misrepresentation at some point in the process of securing FDA approval for a drug will sustain a claim under the False Claims Act. The case is also a powerful reminder of the impact of the Supreme Court's decisions in *Twombly* and *Iqbal*. It is unthinkable that Yu's Amended Compliant would have been dismissed under the notice pleading standards that prevailed before *Twombly* and *Iqbal*.

# The Rapid Dissolution of Sapienza v. Albertson's Companies, Inc.

**MITAL PATEL & FRANCISCO CABRERA LÓPEZ***

## I. WHY IT MADE THE LIST

*Sapienza v. Albertson's Companies, Inc.*[1] makes the list of "top food and drug cases" in 2022 because the court shut down yet another improper effort by the plaintiffs' bar to turn an alleged labeling case related to an FDA-regulated product into a consumer class action. It is illustrative of two trends. The first is the continuing efforts by class action attorneys to test the bounds of state consumer protection statutes as it relates to over-the-counter (OTC) drugs and medical devices. The second is an expansion of efforts by consumers attempting civil action redress relating to alleged labeling of regulated products. *Sapienza* is nearly a textbook case of why and how regulated products are managed and how and why the labeling of such products is not properly addressed by traditional consumer class actions.

The key issue in *Sapienza* was the labeling statements regarding the speed of release for a pain medication. According to supposed "independent testing" by the plaintiff, this OTC acetaminophen marketed as "rapid release" allegedly dissolved slower than cheaper non-"rapid release" products.[2] Despite the FDA standards that govern the labeling of such OTC drugs, including dissolution standards, Sapienza, a Massachusetts resident, sought to represent a nationwide class for supposedly being deceived into paying a price premium for the "rapid release" drug.[3] Sapienza's own "independent testing" confirmed the OTC drug met the FDA's dissolution standards.[4] To hold the defendants liable would be to impose "requirements" that are "different from or in addition" to those adopted by FDA, and thus the court held the claims were expressly preempted under the Federal Food, Drug, and Cosmetic Act (FDCA).[5] The rest of the complaint consisted of the usual boilerplate economic loss/"premium" pricing claims. Because Sapienza asserted economic loss, rather than personal injury claims, the "product liability" exception to OTC express preemption in 21 U.S.C. § 379r(a) was applicable, and as a result, Sapienza was duly dispatched on a motion to dismiss, rather than lingering until summary judgment like several other similar

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1 No. CV 22-10968-RGS, 2022 WL 17404919 (D. Mass. Dec. 2, 2022).

2 *Sapienza*, 2022 WL 17404919, at *1.

3 *Id.* at *1–3.

4 *Id.* at *3.

5 *Id.*

cases—or escaping preemption altogether as in *In re Acetaminophen—ASD-ADHD Products Liability Litigation*, 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022).

## II. DISCUSSION

Sapienza asserted six consumer fraud-type claims against several defendants that manufactured and distributed acetaminophen, a popular pain reliever sold generically by many retailers. She claimed the defendants, grocery store operators Albertsons Companies, misrepresented the OTC drug as "rapid release" because independent testing demonstrated it dissolved slower than a comparable non-"rapid release" version. According to her, she and a putative nationwide class would not have purchased the drug had they not been deceived by the "rapid release" language.[6]

The supermarket chain moved to dismiss all six of Sapienza's claims, arguing that the drug met the definition of "immediate release" and "rapidly dissolving" given by FDA and thus the claims were preempted by the National Uniformity for Nonprescription Drugs provision of the FDCA, which states the following:

> [N]o State or political subdivision of a State may establish or continue in effect any **requirement**—
>
> (1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title [i.e., an over-the-counter drug like the one at issue in *Sapienza*]; and
>
> (2) that is **different from or in addition to**, or that is otherwise not identical with, a requirement under this chapter . . . .[7]

"Requirements" subject to preemption include successful common law claims, like those asserted by Sapienza.[8]

In its motion to dismiss, the defendants explained the FDA's thorough regulatory scheme governing the labeling of OTC drugs. Through a 1988 tentative final monograph (TFM) that had the full force and effect as a final monograph, FDA established the "conditions under which a category of [OTC] drugs or specific OTC drugs [including acetaminophen] are generally recognized as safe and effective and not misbranded."[9] These conditions included the labeling and disclosure requirements for acetaminophen—the drug at issue in *Sapienza*. The TFM also incorporated dissolution standards for acetaminophen promulgated in the United States Pharmacopeia (USP).[10]

The USP identified acetaminophen tablets as "immediate release" if the tablet dissolves by at least 80% after thirty minutes.[11] Separately, an FDA guidance identified acetaminophen tablets as "rapidly dissolving" if it dissolved more than 85%

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6 *Id.* at *1.

7 21 U.S.C. § 379r(a) (emphasis added).

8 *See* Cipollone v. Liggett Grp., 505 U.S. 504, 521 (1992).

9 *Sapienza*, 2022 WL 17404919, at *2.

10 *Id.*

11 *Id.*

or more within thirty minutes, and "very rapidly dissolving" if it dissolved more than 85% or more within fifteen minutes.[12]

Thus, fatal to Sapienza's claims was her own alleged independent testing that confirmed the subject acetaminophen dissolved by 85% in twelve minutes.[13] In other words, the OTC drug she claimed was deceiving complied with standards adopted by FDA and could be called "immediate release," "rapidly dissolving," or "very rapidly dissolving" under FDA regulations and guidance. Holding defendants to a different standard would clearly impose standards "different from or in addition to" federal standards, so Sapienza's claims were expressly preempted.[14]

Sapienza unsuccessfully argued her claims should not be preempted because the USP and FDA guidance relied on by the defendants did not sanction the specific phrase "rapid release."[15] The court rebuffed the argument, emphasizing that "FDA preemption regulates dissolution standards generally – the subject matter of Sapienza's state-law claims – even if the words slightly differ."[16] This "commonsense interpretation" was supported by recent case law, which held similar claims attacking marketing statements as misleading were expressly preempted under comparable preemption provisions because "while the FDA may not have considered the exact language . . . it had clearly addressed the substance of the claims at issue."[17] The court noted the that other products not so labeled "may dissolve just as (or even more) rapidly is no more relevant as a comparison than is a bag of ice labeled 'frozen' as opposed to one simply branded as 'ice.'"[18]

The court was also not convinced by the inapposite case law Sapienza cited to argue that "rapid release" would need to appear verbatim in FDA and USP regulations for preemption to apply. In *Lee*, a putative class action asserted consumer fraud claims based on a food manufacturer's label that stated a product was "100% Natural" when, in fact, it contained genetically modified organisms.[19] The manufacturer argued that the plaintiff's claims were preempted because FDA had an "informal policy not to restrict the use of the term natural."[20] The court there disagreed because the informal policy was not the same as defining "natural" and had never become binding.[21] In *Sapienza*, on the other hand, the TFM that adopted the USP standards that the subject acetaminophen complied with had been formally adopted by congressional fiat.

Lastly, the court described the unworkable consequences of Sapienza's argument that preemption should only apply if the challenged phrase appeared verbatim in FDA regulations. FDA would have to list every possible permutation of similar words to have preemptive effect, which would undermine the FDCA's express preemption provision (and thus, Congress' intent). Permitting Sapienza's argument would also

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12 *Id.*

13 *Id.* at *3.

14 *Id.*

15 *Id.*

16 *Id.*

17 *Id.* (citations omitted).

18 *Id*.

19 Lee v. Conagra Brands, Inc., 958 F.3d 70, 74 (1st Cir. 2020).

20 *Id.* at 77.

21 *Id.*

undermine "the latitude Congress gives agencies to have authority over matters in which they have subject matter expertise – here the FDA's responsibility to evaluate and regulate drugs."[22]

## III. IMPACT

This case, and others like it, inform and limit the ways consumer class action lawyers and consumers themselves can seek redress for labeling and other product issues. Where FDA has been involved in the specific qualities of a product or language for labeling, typical class actions will not fly.

*Sapienza* emphasizes the importance of preemption for FDA-regulated products:

> Congress's adoption of a preemptive scheme . . . ensures that the legal rules governing complex areas of the economy or products are formulated by expert regulators with a broad national perspective and needed scientific or technical expertise, rather than by decision makers—such as municipal officials, elected state judges, and lay juries—who may have a far more parochial perspective and limited set of information.[23]

This preemptive scheme is even more important in the context of potential class actions, where the threat of large nationwide classes can be devastating for business and innovation.

Decisions on the preemptive scope of FDA regulations have been slow to grow in consumer class action false advertising cases, including in food labeling cases, because courts tend to dismiss these cases on other grounds.[24] *Sapienza* adds to a growing body of case law in which courts have applied the doctrine of preemption when a label claim that complies with federal regulations is nonetheless challenged on grounds that it is misleading to consumers that companies can rely on to shield themselves from threats of class action suits.[25]

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[22] *Sapienza*, 2022 WL 17404919, at *4.

[23] *Id.*

[24] *See, e.g.*, Barreto v. Westbrae Nat., Inc., 518 F. Supp. 3d 795, 806 (S.D.N.Y. 2021) ("Because the Court concludes that the product's labeling would not mislead a reasonable consumer, . . . [i]t is unnecessary to reach Westbrae's argument that Barreto's state claims are preempted by federal law."); Bernstein v. Conopco, Inc., No. 3:21-cv-10160-KAR, 2022 U.S. Dist. LEXIS 106579, at *14 (D. Mass. June 15, 2022) ("Because the court has determined that Plaintiff has not stated a claim for a violation of Chapter 93A, it need not reach the question of whether the Product label violates the FDCA, as Plaintiff contends.").

[25] Campbell v. Ariz. Beverages USA LLC, No. 22-cv-02752-JST, 2023 U.S. Dist. LEXIS 60515, at *9–10 (N.D. Cal. Mar. 31, 2023) (holding false advertising claims preempted to the extent they challenge claims or language required by federal regulations); Chong v. Kind LLC, 585 F. Supp. 3d 1215, 1219–20 (N.D. Cal. 2022); Reid v. Johnson & Johnson, 780 F.3d 952, 959 (9th Cir. 2015) ("The preemption analysis turns on whether the challenged statements are authorized by the FDA's regulations or other pronouncements of similar legal effect."); Henry v. Gerber Prods. Co., No. 3:15-cv-02201-HZ, 2016 U.S. Dist. LEXIS 52638, at *23 (D. Or. Apr. 18, 2016) ("Courts have repeatedly found that state law claims challenging 'natural flavors' labels, accompanied by images or names of fruit, are preempted, because such labeling references the characterizing flavor of the food and is permitted by § 101.22."); Hi-Tech Pharms., Inc. v. HBS Int'l Corp., 910 F.3d 1186, 1195–96 (11th Cir. 2018) (holding that state law claims were preempted if viable because plaintiff did not dispute that the labeling at issue complied with federal regulations); Reynolds v. Wal-Mart Stores, Inc., No. 4:14CV381-MW/CAS, 2015 U.S. Dist. LEXIS 53405, 2015 WL 1879615, at *12 (N.D. Fla. Apr. 23, 2015) ("[W]here challenged conduct is expressly required or permitted by FDA regulations, the claims fall within the core of the preemption provision because they would 'impose different requirements on precisely those aspects . . . that the FDA had approved.'" (quoting Altria Grp., Inc. v. Good, 555 U.S. 70, 86, 129 S. Ct. 538, 172 L. Ed. 2d 398 (2008)); *In re* PepsiCo,

Inc., Bottled Water Mktg. & Sales Pracs. Litig., 588 F. Supp. 2d 527, 537 (S.D.N.Y. Dec. 8, 2008) (granting motion to dismiss state law claims alleging mislabeling of bottled water on preemption grounds because bottled water label "complies with the FDCA's requirements"); Savalli v. Gerber Prods. Co., No. 15-61554-CIV-ZLOCH, 2016 U.S. Dist. LEXIS 138014, at *10 (S.D. Fla. Sept. 20, 2016); Willard v. Tropicana Mfg. Co., 577 F. Supp. 3d 814, 830 (N.D. Ill. 2021).

# Dobbs v. Jackson Women's Health Organization

**JAMES M. BECK***

## I. WHY IT MADE THE LIST

The monumental fallout from the Supreme Court's first abolition of a constitutional right in modern times places FDA squarely in the crosshairs of the ongoing American culture wars. Already we have seen state-law attempts to ban distribution, prescription, and use of FDA-approved abortifacient drugs,[1] as well as an unprecedented attack on the FDA's ability to approve such drugs.[2]

On the other hand, supporters of reproductive choice have affirmatively interposed FDA drug regulation, such as Risk Evaluation and Mitigation Strategy (REMS) requirements, against state actions to restrict abortion.[3] The President of the United States directed the Secretary of Health and Human Services (HHS), which oversees FDA, to "protect women's access to critical medications for reproductive health care that are approved by the Food and Drug Administration—including . . . medication abortion."[4] Depending on their political proclivities, future presidents could do the same or could demand that FDA do precisely the opposite.

Because of its likely impact on FDA over the coming years and decades, the Supreme Court's decision in *Dobbs v. Jackson Women's Health Org.*[5] makes our list of the top Federal Food, Drug, and Cosmetic Act (FDCA)-related cases of 2022 even though it does not mention the FDA. One measure of *Dobbs*' ongoing impact is that portions of this Article may well have become obsolete by the time it is published and distributed.

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1 *See*, *e.g.*, Wyo. Stat. §35-6-120(a) ("it shall be unlawful to prescribe, dispense, distribute, sell or use any drug for the purpose of procuring or performing an abortion"); La. R.S. § 14:87.9 ("Criminal abortion by means of an abortion-inducing drug is committed when a person knowingly causes an abortion to occur by means of delivering, dispensing, distributing, or providing a pregnant woman with an abortion-inducing drug.").

2 All. for Hippocratic Med. v. FDA, ___ F. Supp. 3d ___, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) (purporting to invalidate FDA's 1994 approval of mifepristone) (*AHM I*), *stayed in part*, 2023 WL 2913725 (5th Cir. Apr. 12, 2023) (*AHM II*), *fully stayed sub nom.* Danco Lab'ys, LLC v. All. for Hippocratic Med., ___ S. Ct. ___, 2023 WL 3033177 (U.S. Apr. 21, 2023). *See* discussion *infra* notes 45–58.

3 *E.g.*, Genbiopro, Inc., v. Sorsaia, 2023 WL 3211847 (S.D.W. Va. May 2, 2023) (rejecting standing and other non-preemption dismissal arguments); Bryant v. Stein, No. 1:23-cv-00077 (M.D.N.C., filed Jan. 25, 2023) (subsequently voluntarily dismissed).

4 Press Relase, The White House, FACT SHEET: President Biden Announces Actions in Light of Today's Supreme Court Decision on Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/24/fact-sheet-president-biden-announces-actions-in-light-of-todays-supreme-court-decision-on-dobbs-v-jackson-womens-health-organization/.

5 142 S. Ct. 2228 (2022) (*Dobbs*).

## II. DISCUSSION OF THE FACTS, HOLDING, AND RATIONALE

From the moment that the United States Supreme Court first recognized a federal constitutional right to privacy in matters pertaining to abortion in *Roe v. Wade*,[6] powerful political forces have sought to reverse that decision and once again to make abortion illegal, first in those states that these forces control, and eventually nationwide. It took almost fifty years, but the addition of three new anti-abortion justices to the Supreme Court during the administration of Donald J. Trump augmented the Court's *Roe* opponents sufficiently that the 5–4 *Dobbs* decision resulted.

*Dobbs* was a challenge to a gestational-age-based Mississippi statute that prohibited all abortions after fifteen weeks of gestation[7] brought by the Jackson Women's Health Organization (JWHO), which at the time was the sole remaining abortion provider in Mississippi,[8] and one of its physicians. The defendant was the state, in the person of certain state officials.[9] The district court, on the strength of *Roe* and its progeny, enjoined enforcement of the statute, and the Fifth Circuit affirmed.[10]

The Supreme Court reversed, expressly overruling *Roe* and several other Supreme Court decisions based on *Roe*.[11] The key holding in *Dobbs* was stark: the Constitution no longer supports any right of a pregnant woman to obtain an abortion.[12] All authority to regulate abortion now belongs to "the people," through their elected representatives, both federal and state.[13] One of the regulating entities, although not mentioned in *Dobbs*, is FDA.

While the Constitution contains no express reference to a right to obtain an abortion,[14] it does confer a "liberty" interest against state restrictions under the Fourteenth Amendment.[15] Other constitutional provisions viewed as sources of a generalized individual right to privacy include the First, Fourth, Fifth, Ninth, and Fourteenth Amendments.

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[6] 410 U.S. 113 (1973).

[7] Miss. Code §41-41-191.

[8] Jackson Women's Health Org. v. Currier, 349 F. Supp. 3d 536, 538 (S.D. Miss. 2018), *aff'd*, 945 F.3d 265 (5th Cir. 2019), *rev'd*, 142 S. Ct. 2228 (2022) ("*Jackson I*").

[9] Initially, the lead defendant was Mary Currier, chief officer of the Mississippi Department of Health, who was then succeeded in that position by Thomas E. Dobbs.

[10] *Jackson I*, 349 F. Supp. 3d at 543–44; Jackson Women's Health Org. v. Dobbs, 945 F.3d 265, 276–77 (5th Cir. 2019), *rev'd*, 142 S. Ct. 2228 (2022).

[11] *Dobbs*, 142 S. Ct. at 2242. In addition to *Roe v. Wade*, 410 U.S. 113 (1973), the *Dobbs* majority overruled or abrogated: *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103 (2020); *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582 (2016); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992); *Colautti v. Franklin*, 439 U.S. 379 (1979); and *Doe v. Bolton*, 410 U.S. 179 (1973).

[12] *Dobbs*, 142 S. Ct. at 2242.

[13] *Id.* at 2257.

[14] *Id.* at 2245.

[15] The Fourteenth Amendment's equal protection provision is not part of the analysis. *See* Bray v. Alexandria Women's Health Clinic, 506 U.S. 263, 273–74 (1993); Geduldig v. Aiello, 417 U.S. 484, 496 n. 20 (1974).

*Dobbs* examined Due Process-related protections for abortion in a historical context, as whether they were "essential to our Nation's scheme of ordered liberty,"[16] and found no satisfactory basis in American history and tradition.[17] Finding a direct appeal to "liberty" interests inadequate, as "liberty" provided little guidance,[18] the Court's historical analysis centered on abortion historically being considered a crime, both under English common law[19] and under state law at the time that the Fourteenth Amendment was enacted in 1868.[20] That straitjacket allowed the majority to enact its "own ardent views . . . about the liberty that Americans should enjoy" into law,[21] through its reasoning that the Court should be "reluctant" to recognize rights not mentioned in the Constitution.[22] The Court's historical analysis supported its decision to overrule *Roe* and to allow states to re-criminalize abortion.

Appeals to grounds other than the majority's historical analysis fell on deaf ears. While "the great common-law authorities" of earlier centuries—Bracton, Coke, Hale, and Blackstone—only confirmed criminalization of abortion after "quickening,"[23] that absence of evidence was not evidence of absence, since these authorities did not suggest any limit on the power of the states to ban pre-quickening abortions as well.[24]

Nor was the *Dobbs* majority willing to consider constitutional protection for abortion as part of a broader "right" of personal "privacy" for "intimate and personal choices" that are "central to personal dignity and autonomy."[25] Instead, "ordered liberty" prevailed, with the Court concluding that whatever "particular balance" the people of any particular state struck, through their political representatives, would suffice.[26] The notion of ordered liberty does not prevent "elected representatives from deciding how abortion should be regulated."[27]

Further, no right to obtain an abortion could be justified as a component of a broader right to personal autonomy.[28] Such a right was too general to be cabined in any meaningful fashion.[29] Abortion is different because of the state's converse "critical

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[16] *Dobbs*, 142 S. Ct. at 2246 (quoting Timbs v. Indiana, 139 S. Ct. 682, 686, 203 L.Ed.2d 11 (2019)) (internal quotations omitted).

[17] *Id.* at 2248–54.

[18] *Id.* at 2247.

[19] *Id.* at 2249–51.

[20] *Id.* at 2254 (concluding that when the Fourteenth Amendment was adopted in 1868, three-quarters of the states criminalized abortion at any stage of pregnancy). *Cf. id.* at 2241 (observing that twenty states had liberalized their laws by the time *Roe* was decided).

[21] *Id.* at 2247.

[22] *Id.* (citing Collins v. Harker Heights, 503 U.S. 115, 125 (1992)).

[23] *Id.* at 2249–50.

[24] *Id.* at 2250 (citing a "proto-felony-murder rule" as "a way in which a pre-quickening abortion could rise to the level of a homicide").

[25] *Id.* at 2257 (citations and quotation marks omitted).

[26] *Id.*

[27] *Id.*

[28] *Id.* at 2258.

[29] *Id.* ("Those criteria, at a high level of generality, could license fundamental rights to illicit drug use, prostitution, and the like.").

moral" interest in protection of the "potential life" represented by "unborn human beings."[30]

Nor could constitutional protection of services be justified any longer by the doctrine of *stare decisis*. *Dobbs* considered five factors in deciding to overrule *Roe* and *Casey*:

- The nature of the claimed error—deciding that *Roe* was "egregiously wrong and on a collision course with the Constitution from the day it was decided" and "short-circuited the democratic process."[31]
- Quality of the reasoning—finding that *Roe* created an "arbitrary" trimester scheme by engaging in judicial fact-finding rather than following the constitutional text, history, or precedent, while ignoring the effect of abortion on "potential life."[32]
- Workability of the result—holding that the previous "undue burden" test made it "impossible" to draw a "line between" permissible versus unconstitutional restrictions in an "evenhanded, predictable, and consistent" manner.[33]
- Spillover effects—asserting that the *Roe* line of precedent distorted other "important but unrelated legal doctrines," such as facial constitutional challenges, standing, *res judicata*, severability, statutory construction, and the First Amendment.[34]
- Reliance on existing precedent—minimizing any reliance interest in the right *Roe* recognized as involving "unplanned activity" while discounting any attempts to weigh the relative importance of the interests of the fetus and the mother as both "speculative" and "substitut[ing judicial] social and economic beliefs for the judgment of legislative bodies."[35]

Finally, the majority refused to be "affected" by what it considered the "extraneous" concern that the *Dobbs* decision would be viewed as an exercise of political, rather than judicial, power.[36] Because the prior *Roe* and *Casey* decisions had "fail[ed]" to "end the[] national division" regarding the abortion issue, that "national controversy" justified overruling those decisions because "there is no reason to think that another decision sticking with *Roe* would achieve what *Casey* could not."[37]

Having overruled *Roe* and decided that procuring an abortion was not a "fundamental" constitutional right,[38] the *Dobbs* majority held that state abortion

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[30] *Id.* at 2261 ("The exercise of the rights at issue in [other Fourteenth Amendment due process decisions] does not destroy a 'potential life,' but an abortion has that effect.").

[31] *Id.* at 2265.

[32] *Id.* at 2265–72.

[33] *Id.* at 2272–75.

[34] *Id.* at 2275–76.

[35] *Id.* at 2276–78.

[36] *Id.* at 2278.

[37] *Id.* at 2280.

[38] *Id.* at 2279.

regulations were subject only to "rational basis" review, even though the issue itself was a matter of great social significance and moral substance. State abortion-related restrictions, like other health and welfare laws, enjoy a "strong presumption of validity."[39] Courts should sustain such laws as long as they can find a rational basis between them and legitimate state interests. Because the Mississippi statute was supported by specific legislative findings, including that state's interest in "protecting the life of the unborn,"[40] the necessary rational basis existed, and the challenge failed.

## III. IMPACT

The decision in *Dobbs* to abolish the previous constitutional protection afforded to abortion exposes FDA fully to that "national controversy," since FDA approval is the basis for the availability of the drugs commonly used for medication abortions, chiefly mifepristone, misoprostol, and to a lesser extent, methotrexate.[41] Medication abortions now account for over half of all abortions in the United States.[42] Until 2023, FDA's Risk Evaluation and Mitigation Strategy (REMS) for mifepristone imposed a requirement that patients obtain the drug in person at a certified provider, but the agency, under pressure of litigation,[43] eliminated in-person delivery, so that the drug can be dispensed by mail.[44]

Anti-abortion forces have commenced their own litigation, an unprecedented challenge to FDA's approval, over two decades ago in 2000, of mifepristone,[45] which as of this writing remains pending. In *Alliance for Hippocratic Medicine v. FDA* (*AHM*), the plaintiffs allege that a Nineteenth Century statute, the so-called "Comstock Act,"[46] makes it illegal for FDA to approve any abortifacient drug—even though the FDCA post-dates that 1873 statute. Enacted primarily to exclude indecent material from being mailed, the Comstock Act made unmailable "[e]very article or thing . . . intended for producing abortion," including any "drug" or "medicine."[47]

Long before *Roe*, appellate courts had interpreted the Comstock Act as applying only to otherwise "illegal" matter.[48] Since Congress subsequently granted FDA the power to approve drugs for marketing in interstate commerce without abortion-

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[39] *Id.* at 2284 (citing Heller v. Doe, 509 U.S. 312, 319 (1993)).

[40] Miss. Code §41-41-191(2)(b)(i).

[41] *See Medication Abortion*, GUTTMACHER INST. (Apr. 13, 2023), https://www.guttmacher.org/state-policy/explore/medication-abortion#.

[42] Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin & Marielle Kirstein, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Feb. 24, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

[43] *See* Am. Coll. of Obstetricians & Gynecologists v. FDA, 506 F. Supp. 3d 328 (D. Md. 2020) (maintaining injunction against in-person requirement).

[44] *See Questions and Answers on Mifepristone for Medical Termination of Pregnacy Thorugh Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.

[45] *See supra* note 2.

[46] 18 U.S.C. §§ 1461–62.

[47] *Id.* § 1461.

[48] *E.g.*, Davis v. United States, 62 F.2d 473, 475 (6th Cir. 1933); Youngs Rubber Corp. v. C.I. Lee, 45 F.2d 103, 108 (2d Cir. 1930).

specific limitations,[49] that would seem to put the Comstock Act to rest.[50] Nonetheless, the district court[51] in *AHM* relied on the Comstock Act as prohibiting interstate sale of this FDA-approved drug.[52] The district court also excused the *AHM* plaintiffs' extremely belated regulatory challenges to the original FDA approval of mifepristone.[53] However, the six-year applicable limitation period was reinstated on appeal.[54] Both the district court and Fifth Circuit opinions, however, took an extremely liberal approach to standing, potentially exposing future FDA drug approvals to collateral attack by any physician who might be inconvenienced by having to treat patients with adverse drug reactions.[55]

Both courts also disregarded an extensive 2008 investigation into FDA's approval process that concluded FDA acted appropriately,[56] indicating their unprecedented willingness to disregard the usually rigorous arbitrary and capricious standard of review and thereby substitute their judgments for FDA's scientific conclusions.[57]

As of this writing, the *AHM* decisions have been temporarily stayed,[58] but should the above aspects of those decisions stand, it would set a dangerous precedent that non-expert courts can essentially ignore FDA's expert scientific judgments, reweigh the scientific evidence as they see fit, and retroactively revoke FDA marketing approval of regulated products. Given that mifepristone has been approved since 2000, the implication of such a decision on industry reliance interests and product innovation could be profound.

Abortion defenders are also seeking to utilize FDA decisions to advance their positions. Pursuant to FDA's mandate to "promot[e] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products,"[59] it has approved abortion-related drugs as safe and effective and has created REMS and other requirements governing their use. Both FDA, under the current administration, and entities distributing these drugs are using FDCA

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[49] *E.g.*, 21 U.S.C.A. § 355(d) (listing grounds for refusing a new drug application).

[50] *See GenBioPro v. Sorsaia*, 2023 WL 3211847, at *7 (describing Comstock Act as a "widely abrogated 19th century statute which the federal government will not enforce").

[51] The *AHM* litigation is before Judge Matthew J. Kacsmaryk, a Trump appointee, with a reputation as an activist conservative jurist, particularly opposed to legal abortion.

[52] *AHM I*, 2023 WL 2825871, at *18–19.

[53] *Id.* at *9–12.

[54] *AHM II*, 2023 WL 2913725, at *12–15.

[55] *AHM II*, 2023 WL 2913725, at *7 (plaintiff "doctors have had to devote significant time and resources to caring for women experiencing [the drug's] harmful effects. This harm is sufficiently concrete"); *AHM I*, 2023 WL 2825871, at *4 (plaintiff physicians, and by extension the associational plaintiffs in which they are members, "have standing because they allege adverse events . . . from [the drug] can . . . place enormous pressure and stress on doctors during emergencies and complications") (quotation marks and footnote omitted).

[56] U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX (Aug. 2008) ("The approval process for [the brand-name version of mifepristone] was consistent with the processes for the other [similarly] restricted drugs.").

[57] *AHM II*, 2023 WL 2913725, at *16–18; *AHM I*, 2023 WL 2825871, at *24–28.

[58] *Danco Lab'ys*, 2023 WL 3033177, at *1. Two justices would have denied the stay and thus allowed partial nullification of FDA's regulation of mifepristone to go into effect. *Id.* at *1–2 (Alito & Thomas, JJ., dissenting).

[59] 21 U.S.C. § 393(b)(1).

preemption as a means to combat state restrictions on medication abortions post-*Dobbs*.[60]

Federal law can preempt even implied obstacles to FDA's regulatory mandate.[61] "[N]ormally Congress would not want States to forbid, or to impair significantly, the exercise of a power that Congress explicitly granted."[62] States cannot exercise their powers "to regulate the administration of drugs by the health professions . . . in a way that is inconsistent with federal law."[63] State power to restrict distribution of disfavored, yet federally approved drugs has been subject to federal preemption as an obstacle to FDA power to issue such approvals.[64] Justice Alito, author of *Dobbs*, has recognized that "[w]here the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' our conflict pre-emption cases prohibit any state from countermanding that determination."[65]

In particular, recent state private bounty laws[66] can affect distribution of FDA-approved abortion-related drugs similar to the tort claims held preempted in *Buckman*.[67] Drug marketers' "ability to comply with state law [would] depend[] on uncertain . . . third-party decisions,"[68] thereby impeding the prescription of FDA-approved drugs for FDA-approved indications. State-law citizen suits over drugs prescribed for FDA-approved indications likewise could create litigation-driven "skew[ing]" of "[t]he balance sought by the [FDA]" in a much more direct way than the claims in *Buckman* affected off-label use of FDA-approved drugs.[69] The same regulatory concerns that the Court expressed in *Buckman* would also support preemption of state-law claims that would impose liability for prescribing drugs for uses explicitly considered and approved by FDA.[70]

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[60] FDA drug approval "is tantamount to a required license to sell the drug or device in the United States." Talley v. Danek Med., Inc., 179 F.3d 154, 160 (4th Cir. 1999).

[61] *E.g.*, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001) ("fraud claims attacking submissions to FDA presented an obstacle to FDA's regulatory scheme by "skew[ing]" the "delicate balance of statutory objectives" that FDA pursued); United States v. Sullivan, 332 U.S. 689, 698 (1948) (states cannot impose prohibitory labeling requirements on FDA-approved drugs ).

[62] Barnett Bank of Marion Cnty., N.A. v. Nelson, 517 U.S. 25, 33 (1996).

[63] Zogenix, Inc. v. Patrick, 2014 WL 3339610, at *4 (D. Mass. July 8, 2014), *vacated in part on other grounds*, 2014 WL 4273251 (D. Mass. Aug. 28, 2014). In *Zogenix*, state regulations that effectively "banned [the drug's] prescribing, ordering, dispensing or administration" were preempted because they interfered with FDA's previous balance of competing safety and availability factors for an opiate drug. *Id.* at *1, 5. After the state repealed the offending regulations, the injunction against their enforcement was lifted. Zogenix, Inc. v. Patrick, 2014 WL 4273251 (D. Mass. Aug. 28, 2014).

[64] *See* Pharm. Rsch. & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56 (D.D.C. 2005) (state law creating a private right for any "any affected party" to sue for excessive drug prices preempted due to conflict with the purpose and execution of federal patent laws governing drugs).

[65] Wyeth v. Levine, 555 U.S. 555, 609 (2009) (citing *Buckman*, 531 U.S. at 348) (dissenting opinion).

[66] *See* Tex. 2022 SB 8 (permitting citizens to file suit against anyone who knowingly aids or abets an abortion).

[67] *Buckman*, 531 U.S. at 353.

[68] PLIVA, Inc. v. Mensing, 564 U.S. 604, 623 (2011) (plurality opinion).

[69] *Buckman*, 531 U.S. at 348.

[70] *Id.* at 350–51.

An independent basis of FDCA-based preemption has arisen in product liability litigation. *Mutual Pharmaceutical Co. v. Bartlett*[71] held preempted any purported state-law duties that allegedly required FDA-regulated entities to cease distribution of FDA-approved products altogether. "Even in the absence of an express pre-emption provision," state law will "be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'"[72] While a drug manufacturer "could escape the impossibility of complying with both its federal- and state-law duties by 'choos[ing] not to make [its FDA-approved drug] at all," *Bartlett* "reject[ed] this 'stop-selling' rationale as incompatible without our pre-emption jurisprudence."[73]

> Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.
>
> The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.[74]

Because "statutory 'mandate[s]' do precisely the same thing" as tort suits insofar as they "require a manufacturer to choose between leaving the market and accepting the consequences of its actions,"[75] *Bartlett* analogized stop-selling tort liability to a state's "directly prohibiting the product's sale."[76] Given FDA approval of prescription drugs, even one of the two *Bartlett* dissents expressed discomfort with stop-selling claims in this context.[77]

Since *Bartlett*, "'an outright ban' cannot be a viable alternative to sustain a [state-law] claim."[78] Following *Bartlett*, courts across the country have almost universally rejected claims "that the defendants should never have sold the FDA-approved formulation of [their drug, because] such claims have been explicitly repudiated by the Supreme Court."[79] Any claim that the defendant's drug "should have been banned . . . constitutes a 'stop-selling' theory, which courts have consistently found to

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[71] 570 U.S. 472 (2013).

[72] *Id.* at 480 (citations and quotation marks omitted); see also *id.* at 493 ("the FDCA's treatment of prescription drugs includes neither an express pre-emption clause," but "[t]hat federal law forbids [a drug manufacturer] to take actions required of it by state tort law evinces an intent to preempt").

[73] *Id.* at 488.

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

[75] *Id.* at 491.

[76] *Id.* at 489, n.5.

[77] *Bartlett*, 570 U.S. at 494 ("The FDA is responsible for administering the relevant federal statutes. And the question of pre-emption may call for considerable drug-related expertise. Indeed, one might infer that, the more medically valuable the drug, the less likely Congress intended to permit a State to drive it from the marketplace.") (Breyer & Kagan, JJ., dissenting).

[78] Trisvan v. Heyman, 305 F. Supp. 3d 381, 405 (E.D.N.Y. 2018).

[79] Utts v. Bristol-Myers Squibb Co., 226 F. Supp. 3d 166, 186 (S.D.N.Y. 2016).

be preempted by federal law,"[80] and "any argument that [defendant] should have stopped selling the drug is unavailing."[81] Numerous courts have rejected allegations that state law can prohibit the sale of FDA-approved drugs.[82]

Under the *Bartlett*-based stop-selling rationale—"a straightforward application of pre-emption law"[83]—state efforts to prohibit or restrict mifepristone or other FDA-approved drugs used in medication abortions will be subject to substantial preemption challenge. What the Constitution prohibits states from doing indirectly through product liability litigation is even more problematic when done via "statutory legal mandate."[84]

Express FDCA preemption will also find itself in the culture war crosshairs, should states seek to interfere with the availability of over-the-counter (OTC) emergency contraceptive drugs. OTC drugs receive protection from an express preemption provision,[85] but preemption is limited by a series of exceptions that states may attempt to rely on to maintain restrictions on emergency contraception. The most significant of these exceptions allows state regulation "that relates to the practice of pharmacy" or "that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such a drug."[86]

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[80] Silver v. Bayer Healthcare Pharms., Inc., 2021 WL 4472857, at *4 (D.S.C. Sept. 30, 2021) (recognizing that "[t]he Supreme Court has rejected the 'stop-selling' theory as incompatible with preemption jurisprudence because if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless") (quoting *Bartlett*, 570 U.S. at 488) (internal quotation marks omitted).

[81] Hernandez v. Aurobindo Pharma USA, Inc., 582 F. Supp. 3d 1192, 1213 (M.D. Fla. 2022).

[82] Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281, 300 (6th Cir. 2015) (claim "that defendants should never have sold the[ir] FDA-approved [product] in the first place" preempted under *Bartlett*); Drager v. PLIVA USA, Inc., 741 F.3d 470, 476 (4th Cir. 2014) (state law cannot "require[]" the manufacturer of an FDA-approved drug "to exit the market"); Trejo v. Johnson & Johnson, 13 Cal. App.5th 110, 147 (2017) ("claim that defendants should have withdrawn [the drug] from the market is preempted"); Beaver v. Pfizer, Inc., 2023 WL 2386776, at *3 (W.D.N.C. Mar. 6, 2023) ("no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce"); *In re* Zantac (Ranitidine) Prods. Liab. Litig., 548 F. Supp. 3d 1225, 1252–53 (S.D. Fla. 2021) (defendants "not required to stop selling ranitidine in order to comply with federal law while avoiding liability under state law"); Evans v. Gilead Scis., Inc., 2020 WL 5189995, at *9–10 (D. Haw. Aug. 31, 2020) (quoting and following *Bartlett*); Javens v. GE Healthcare, Inc., 2020 WL 2783581, at *6 (Mag. D. Del. May 29, 2020) (claim that defendants should have marketed a different product was "clearly preempted" by federal law), *adopted*, 2020 WL 7051642 (D. Del. June 18, 2020); Drescher v. Bracco Diagnostics, Inc., 2020 WL 1466296, at *5 (D. Ariz. March 26, 2020) (quoting and following *Bartlett*); Mahnke v. Bayer Corp., 2019 WL 8621437, at *5 (C.D. Cal. Dec. 10, 2019) (same); *In re* Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig., 185 F. Supp. 3d 761, 771 (D.S.C. 2016) ("any claims that Defendant should have simply stopped selling the drug to women . . . is preempted"); Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 678 (S.D.N.Y. 2017) (claims that "challenge[] the FDA's approval of . . . [an] indication . . . are preempted") (quoting 73 Fed. Reg. 49603, 49606 (FDA Aug. 22, 2008)), *aff'd*, 919 F.3d 699 (2d Cir. 2019); *In re* Fosamax Prods. Liab. Litig., 965 F. Supp. 2d 413, 420 (S.D.N.Y. 2013) (*Bartlett* "preempted the possibility of [state law] claims based on a [drug manufacturer's] failure to stop selling the product").

[83] *Bartlett*, 570 U.S. at 493.

[84] *Id.* at 491.

[85] 21 U.S.C. § 379r.

[86] 21 U.S.C. § 379r(c)(1). This subsection has yet to be addressed, or even cited, in any judicial opinion. Whether subsection (c)(1) would permit a state to require a prescription for an OTC drug that, like some forms of emergency contraception, FDA has specifically determined should be available without a prescription is uncertain. Even without express preemption, however, implied conflict preemption could also apply in such circumstances. *Buckman*, 531 U.S. at 352 ("neither an express pre-emption provision nor

Even before *Dobbs*, abortion-related political pressures have affected FDA's science-based regulation of both abortifacient and contraceptive drugs.[87] *Dobbs* only ups the political ante. Just as abortion opponents will seek to prevent FDA from approving abortion-related drugs at all, conversely, supporters of reproductive freedom will seek to leverage the preemptive effect of FDA drug approval to nullify restrictive state laws. These pressures are not going to abate any time soon, so *Dobbs* deserves its place in the most significant food and drug cases of 2022.

a saving clause 'bar[s] the ordinary working of conflict pre-emption principles'") (quoting Geier v. American Honda Motor Co., 529 U.S. 861, 869 (2000)).

[87] U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-109, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 13 (Nov. 2005).

# West Virginia v. Environmental Protection Agency

**JUSTINE E. LENEHAN & T. DANIEL LOGAN***

## I. WHY IT MADE THE LIST

Although this case does not directly implicate the U.S. Food and Drug Administration (FDA) or its authorities, it has been included for two reasons. First, the Major Questions Doctrine (MQD) has the potential, if employed broadly by courts, to upend the traditional *Chevron* deference accorded to agency interpretation of statutes. While the doctrine has been previously deployed by the Supreme Court, the instant case is the first instance of it being *referred to by name*. Second, the provenance of the MQD traces back to a seminal case in FDA history—*FDA v. Brown & Williamson Tobacco Corp.*

## II. DISCUSSION

### *A. Background and Procedural History*

Section 111 of the Clean Air Act authorizes the U.S. Environmental Protection Agency (EPA) to establish "standards of performance" for stationary sources of pollutants that cause or contribute to air pollution that can endanger public health or welfare.[1] These standards reflect limitations of air pollution emissions that are achievable through application of the "best system of emission reduction" (BSER) that has been "adequately demonstrated" by the EPA.[2]

In 2015, EPA adopted the Clean Power Plan (CPP), a regulation promulgated pursuant to Section 111(d) of the Clean Air Act, to reduce greenhouse gas emissions from existing power plants.[3] Under the CPP, EPA determined that the BSER would involve shifting power generation from higher emission sources (e.g., coal) to lower emission sources (e.g., solar and wind), rather than traditional methods aimed at reducing emissions from existing sources (for example, through heat-rate improvements allowing for more efficient fuel consumption). As written, the emission limits specified in the CPP were such that no existing coal plant could comply with the standard absent some form of generation shifting. In other words, EPA effectively mandated existing plant operators to change their electricity generation inputs, such as

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1 42 U.S.C. § 7411(b), (d) (relating to new and existing sources of air pollution, respectively).

2 42 U.S.C. § 7411(a).

3 Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, 80 Fed. Reg. 64,662 (Oct. 23, 2015).

from coal to natural gas or from natural gas to solar. The CPP presented a novel strategy to limit emissions in that it attempted to regulate net pollution across the national system rather than individual sources of pollution.

Immediately following the CPP's promulgation, West Virginia, other states, utilities, and coal mining companies challenged EPA's authority to issue the CPP. The DC Circuit refused to stay the rule, but the Supreme Court did so in 2016 pending judicial review.[4] Following a change in Presidential administration, EPA repealed the CPP in 2019.[5] Finding that the CPP exceeded its authority under the Clean Air Act, EPA concluded that the determination as to whether generation shifting could serve as the BSER fell under the MQD pursuant to which courts "expect Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'"[6] In the same rulemaking, EPA promulgated the Affordable Clean Energy (ACE) rule. EPA based the ACE rule on a new reading of the Clean Air Act, which involved BSER measures that could be adopted at each stationary source (e.g., equipment upgrades and operating practices) as opposed to the generation-shifting approach of the CPP.

The challenges to the CPP pending at the DC Circuit were dismissed as moot and various states and private parties challenged EPA's repeal of the CPP and issuance of the ACE rule. The DC Circuit vacated the ACE rule in January 2021, effectively reviving the CPP, finding that generation shifting could reasonably qualify as the BSER under Section 111(d) of the Clean Air Act.[7] Following yet another change in Presidential administration, EPA stated that it intended to refrain from enforcing the CPP and instead replace it with a new rule. The DC Circuit granted a partial stay of its repeal of the ACE rule to provide EPA an opportunity to do so.[8] Nevertheless, West Virginia and the American Coal Corporation, among others, filed petitions for certiorari with the Supreme Court appealing the DC Circuit's decision.[9]

### *B. The Supreme Court's Analysis and Holding*

In a 6–3 opinion, the Court invalidated the CPP, holding that Section 111(d) of the Clean Air Act did not authorize EPA to create a standard setting emissions caps based on generation shifting. The Court's reasoning rested on a doctrine that had never before been explicitly invoked in a majority opinion—the so-called "Major Questions Doctrine."

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[4] West Virginia v. EPA, 577 U.S. 1126, 136 S. Ct. 1000 (2016).

[5] Repeal of the Clean Power Plan; Emission Guidelines for Greenhouse Gas Emissions From Existing Electric Utility Generating Units; Revisions to Emission Guidelines Implementing Regulations, 84 Fed. Reg. 32,520 (July 8, 2019).

[6] *Id.* at 32,529 (citing Utility Air Regul. Grp. v. EPA, 573 U.S. 302, 324 (2014) (quoting FDA v. Brown & Williamson Corp., 529 U.S. 120, 159 (2000))).

[7] *See* West Virginia v. EPA, 142 S. Ct. 2,587, 2,605–06 (prior history omitted).

[8] *See id.* at 2,606.

[9] The keen reader may question whether this case was justiciable in the first place given that EPA informed the DC Circuit that it intended to replace the CPP and not enforce it. The Court's analysis extends beyond the bounds of this Article; however, in brief, the Court clarified that the case was not mooted as a result of EPA's statements. Specifically, notwithstanding the agency's voluntary non-enforcement of the CPP, there remained a possibility that the alleged wrongful behavior could recur (as the CPP remained on the books). *See id.* at 2,607.

### *1. The Major Questions Doctrine*

Tracing a direct line from the decision in *FDA v. Brown & Williamson Tobacco Corp.*,[10] the Court's decision explained that while the starting point for most statutory construction analyses is the text of the statute, there are "extraordinary cases . . . in which the history and the breadth of the authority that [the agency] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority."[11] The Court highlighted that the MQD was developed to address "a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted."[12]

In such "extraordinary cases," an agency must be able to point to "clear congressional authorization" for its initiative.[13] In circumstances where the doctrine applies, a "merely plausible textual basis" for an agency's action will not suffice.[14] In fact, the majority opinion counsels that lower courts should "hesitate" before concluding that Congress intended to confer transformative authority on the agency.

Although not explicitly mentioned in a majority opinion prior to *West Virginia v. EPA*, the Court cited to numerous cases in which the MQD was namelessly invoked.[15]

Far from a model of clarity, the Court did not clearly define the contours of the MQD—that is, when an agency's action raises a "Major Question" and what legislative acts constitute clear congressional authorization. Nevertheless, the majority and concurring opinions shed light on how lower courts *could* embark on an MQD analysis.

### *2. What is a "Major Question"?*

The majority opinion offered several non-exhaustive factors to determine whether an agency action raises a "Major Question": 1) whether the agency "discover[ed] in a long-extant statute an unheralded power" that represents a "transformative expansion" of its regulatory authority; 2) whether the agency relies upon an "ancillary," "gap filler," or "rarely used" provision of the statute; and 3) whether the agency adopted a regulatory program that "Congress had conspicuously and repeatedly declined to enact itself."[16]

Perhaps in an attempt to elucidate more concrete guidance for lower courts, Justice Gorsuch's concurrence enumerated several additional factors: 1) whether an agency attempted to resolve a matter of "great political significance" (which might be discerned from Congress failing to enact similar actions); 2) whether the issue

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[10] 529 U.S. 120 (2000) (concerning FDA's attempt to regulate or ban tobacco products).

[11] 142 S. Ct. at 2,608 (internal quotations omitted).

[12] *Id.* at 2,609.

[13] *Id.*

[14] *Id.*

[15] *See, e.g.*, Gonzalez v. Oregon, 549 U.S. 243 (2006) (U.S. Attorney General's regulation of physician administration of assisted suicide drugs under Controlled Substances Act); Ala. Assn. of Relators v. Dep't of Health & Hum. Servs., 594 U.S. ___ (2021) (the Centers for Disease Control and Prevention's attempt to impose an eviction moratorium in response to the COVID-19 pandemic); Nat'l Fed'n of Indep. Bus. v. Occupational Safety & Health Admin., 595 U.S. ____ (2022) (the Occupational Safety and Health Administration's attempt to impose a vaccine or testing mandate on private employers).

[16] 142 S. Ct. at 2,610 (internal citations and quotations omitted).

represents a "significant portion of the American economy" or requires significant spending by those being regulated; or 3) whether the agency's action intrudes into an area of state law.[17]

Here, the Court determined that the case presented a major question because it represented a "transformative expansion" of EPA's regulatory authority discovered in the "vague language of an 'ancillary provision'" of the Clean Air Act that was "designed to function as a gap filler" and had "rarely been used in the preceding decade."[18] The Court noted that Congress had historically rejected proposals to amend the Clean Air Act to create a cap-and-trade scheme for carbon (which, according to the Court, is the essence of the CPP) and similar measures such as a carbon tax.[19]

Additionally, the Court found that the Clean Air Act's charge to EPA to implement the "best system of emission reduction" was not a sufficiently clear congressional mandate to impose emissions caps based on generation shifting as under the CPP. In arriving at this conclusion, it relied heavily on how EPA had historically interpreted and used Section 111(d) since its enactment decades prior.[20] In particular, the Court found the changes in EPA's use of the Clean Air Act's provision (from regulating single sources of pollution to multiple sources) to be "not only unprecedented," but also a "'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind."[21]

The Court further found fault in EPA's own characterizations that broader regulation of energy generation markets was beyond its traditional scope, noting that the agency's appropriations requests related to the generation-shifting approach sought special funding for "technical and policy expertise *not* traditionally needed in EPA regulatory development."[22]

Justice Gorsuch noted that the size of the electric power sector and the potential effects the CPP could have on this industry and on consumers—the closure of dozens of power plants, the elimination of thousands of jobs, and the rise of electricity costs by over $200 billion—reinforced the magnitude of the impact the EPA's action could have on the American economy.[23]

### *3. Clear Congressional Authorization*

The Court was even less clear on what language Congress must employ in order to provide its clear authorization for agency action, essentially invoking the Justice Potter Stewart obscenity test ("we'll know it when we see it").[24]

The concurrence provided some level of guidance, recommending that courts examine legislative provisions, the "age and focus of the statute" in relation to the problem the action seeks to address, the agency's past interpretations of the statute,

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[17] *Id.* at 2,620–21 (internal citations and quotations omitted).

[18] *Id.* at 2,610.

[19] *Id.* at 2,614.

[20] *See id.* at 2,610–12.

[21] *Id.* at 2,612 (quoting MCI Telecomm. Corp. v. Am. Telephone & Telegraph Co., 512 U.S. 218, 231 (1994)).

[22] *Id.* (citing U.S. ENV'T PROT. AGENCY, EPA-190-R-15-001, FISCAL YEAR 2016: JUSTIFICATION OF APPROPRIATION ESTIMATES FOR THE COMMITTEE ON APPROPRIATIONS 213 (Feb. 2015)).

[23] *Id.* at 2,622.

[24] Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

and any "mismatch between an agency's challenged action and its congressionally assigned mission and expertise."[25]

Here, the Court rejected EPA's position that Congress conferred its clear authorization for the CPP based on inclusion of the term "system" in Section 111, explaining that the term is merely an "empty vessel" and too "vague" to authorize a transformational program such as the generation-shifting approach.[26] In its closing, the majority opinion acknowledged that setting emission limits in a manner that would necessitate a nationwide exodus from coal as a source of electricity generation might be a "sensible 'solution to the crisis of the day,'" but ultimately emphasized that a "decision of such magnitude and consequence rests with Congress itself, or an agency acting pursuant to a clear delegation" from Congress.[27]

Writing for the dissent, Justice Kagan took issue with the majority's conclusion that a generation-shifting approach is beyond the bounds of EPA authority, arguing that it deprives EPA of the power it needs, and the power Congress granted it, to curb greenhouse gas emissions.[28] In a particularly critical passage of the dissent, Justice Kagan alleged that the Court is "textualist only when being so suits it . . . [w]hen that method would frustrate broader goals, special canons like the 'major questions doctrine' magically appear as get-out-of-text-free cards."[29]

## III. IMPACT OF THE DECISION

Names have power—this is a lesson demonstrated by the likes of Rumpelstiltskin, Polyphemus, and Voldemort. The Supreme Court has, for many years, alluded to the idea that "Major Questions" obviate the need for deference to an agency where it has asserted an authority in which it has neither expertise nor experience. Now, the "thing" has been named, given a nascent structure, and can be referred to directly without indirect case citation. Indeed, a lower court scrutinizing an agency action can now begin its analysis with the question: does the Major Questions Doctrine apply?

In many ways, the majority opinion is a warning—an agency should stay in its lane. Thus, as an initial matter, any agency policymaker, attorney, or regulatory counsel must, in advance of developing new rulemaking, consider whether the scope of such rulemaking risks "rais[ing] the eyebrow" of a court.[30] Additionally, given the Court's examination of past agency interpretation and practice, agency policymakers would be wise to consider whether past agency treatment of a statutory delegation provision may affect present initiatives.

Following the outcome here, the $64,000 question remains: what about *Chevron* deference*?*

Under *Chevron*, courts defer to agency interpretations of ambiguous statutory language where that interpretation is reasonable. This framework functions not based on clear congressional authorization, but through Congress' broad delegations of authority that implicitly allow agencies to resolve statutory ambiguities or fill in

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[25] 142 S. Ct. at 2,623.

[26] *See id.* at 2,614–15.

[27] *Id.* at 2,616.

[28] *Id.* at 2,628.

[29] *Id.* at 2,641.

[30] *Id.* at 2,613.

statutory holes using their specialized knowledge that Congress lacks. The MQD dictates, however, that even where an agency's interpretation is textually plausible, courts should not necessarily defer to agency interpretations where questions of vast economic or political significance are involved.

The Court did not engage with *Chevron* in the three most recent cases applying the MQD, suggesting that the doctrine is an entirely independent principle of statutory interpretation and not merely an exception to *Chevron*. For "major" agency actions, the MQD doctrine appears to effectively precede or supplant ordinary statutory construction principles, but the precise relationship between the doctrines has not, as of yet, been elucidated.

With relatively minimal guidance defining the contours of the MQD and the Court's use of vague terms such as "economic and political significance" and "extraordinary cases," lower courts are left to use their own judgment in assessing when and how to apply this doctrine. One might reasonably anticipate, however, that courts may elect to invoke the MQD where an agency's action will have a meaningful impact on the economy or national policy, represents a new area of regulation by the agency, and/or stems from an agency's novel use of the delegating statute. While one might expect, then, that only a small portion of agency actions will implicate "major" questions, these actions will, by definition, be "major"—initiatives implicating broad or "transformative" powers involving large portions of the population and the economy or having great political significance.

In the context of food and drug law, especially, the *West Virginia v. EPA* decision could have profound impacts. As an agency broadly known for scientific expertise, FDA may be especially vulnerable to allegations that any ambitious assertions of its authority must be examined under the MQD. Because Congress often lacks the expertise necessary for legislation to comprehensively address the complex and nuanced substantive issues under the ambit of the FDA, it relies on the agency to deploy scientific and regulatory expertise to effectuate its legislative objectives (which are not always entirely crystal clear).

In addition to its implementation of congressional directives, FDA's initiatives and efforts are often motivated by trends and crises that require it to clarify or adapt policies in response to evolving circumstances (pandemics, technological advances, etc.) where congressional action is delayed or infeasible. The MQD could, if used more frequently by courts, result in greater scrutiny of policies intended to address such rapidly evolving situations, and ultimately, FDA reluctance to engage in ambitious rulemaking. Further, Congress' broad delegations of authority to FDA allow the agency to adopt science-driven policies and rules that the agency intends to benefit the public health. Moving forward, FDA may find it more difficult to defend such actions against challenge, particularly where the agency's action amounts to assertions of authority over a new product type (such as in the case of electronic cigarettes) or novel areas not expressly contemplated by the Federal Food, Drug, and Cosmetic Act. Finally, as FDA's routine operations, such as review and approval of new drug applications, are increasingly politicized, there remains the possibility that the MQD may find broader application in judicial scrutiny of such decisions.

# United States v. Elizabeth Holmes and Ramesh Balwani

**BRYANT GODFREY & TINA PAPAGIANNOPOULOS***

## I. WHY THIS CASE MADE THE LIST

A highly publicized and long-running multi-agency action against the former Chief Executive Officer and the former Chief Operating Officer of Theranos Inc. resulted in criminal convictions last year against both executives for their roles in deceiving investors, doctors, and patients about the Company's failed diagnostic tests. While this case is not premised upon violations of the Federal Food, Drug, and Cosmetic Act (FDCA)—and might even be considered by some industry observers to be ancient history at this point—the case is nevertheless important, and not only because the individuals at the helm were held personally and criminally accountable for their conduct. The case remains relevant because it has attracted the attention of lawmakers, and regulators are pointing to the underlying facts as a cautionary tale to promote a change in the regulatory landscape surrounding diagnostics.

## II. SUMMARY OF THE CASE

Former Chief Executive Officer (CEO) of Theranos Inc. (Theranos or the Company), Elizabeth Holmes, and former President and Chief Operating Officer (COO), Ramesh "Sunny" Balwani, were indicted in June 2018 for defrauding investors, doctors, and patients by lying about the performance of the Company's blood testing technology and about the Company's financial condition, key business dealings, and future prospects.[1] Charges were brought by the U.S. Department of Justice (DOJ) in the Northern District of California based on an investigation conducted by the Federal Bureau of Investigation (FBI), U.S. Food and Drug Administration (FDA), and the U.S. Postal Inspection Service (USPIS). Each defendant was charged with two counts of conspiracy to commit wire fraud, in violation of 18 U.S.C. § 1349, and nine counts of wire fraud, in violation of 18 U.S.C. § 1343.

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[1] The original indictment was superseded on July 14, 2020, and the second indictment was superseded on July 28, 2020. The summary below discusses the allegations that were made in the operative indictment dated July 28, 2020. *See* Third Superseding Indictment, United States v. Elizabeth Holmes & Ramesh "Sunny" Balwani, No. 5:18-CR-0258-EJD, Doc. No. 469 (N.D. Cal., July 28, 2020).

In essence, the defendants were charged with making false statements in advertisements and using other methods to persuade doctors and patients to use the Company's tests, even though they were aware that the tests were not capable of providing accurate and reliable results. For example, the executives claimed (or directed the Company to claim) that Theranos could quickly and accurately run a combination of tests at once from a single blood sample comprised of a few drops of blood collected from a fingerstick. Defendants made these representations despite their personal knowledge that the technology was not capable of consistently producing accurate and reliable results for certain blood tests, including tests for calcium, cholesterol, gonorrhea, glucose, HbA1c, HIV, testosterone, and TSH. To induce individuals to purchase the tests, the advertisements also falsely claimed that the Theranos tests were cheaper than blood tests from conventional laboratories.

The defendants were also alleged to have made numerous material misrepresentations to potential investors (though direct communications, marketing materials, media statements, financial statements, etc.) about the Company's business relationships with Walgreens and the U.S. Department of Defense (DoD), the regulatory status of the analyzer and tests, and the quality of the tests. The executives claimed that the TSPU (Theranos' proprietary analyzer) was capable of performing the full range of clinical tests using fingerstick samples while producing better results and at a faster speed than conventional methods. In reality, the TSPU performed a limited number of tests, was slower than some competing analyzers, and could not compete in terms of throughput or simultaneous testing against larger, conventional machines. The indictment alleges that the defendants were aware of the accuracy, reliability, and performance limitations of the analyzer when they touted the technology's performance.

In addition to misrepresenting the technology's performance capabilities, the indictment alleges that the executives misrepresented to investors the Company's revenue potential and made a number of false representations, including that 1) its business partnership with Walgreens was expanding when, in fact, the rollout was stalled due to Walgreens' concern with the performance of the technology; 2) the Company had a profitable relationship with the DoD when, in fact, the revenue from military contracts was limited; 3) the DoD had deployed the technology to the battlefield, when in fact, it had not; 4) the Company had conducted certain tests on patient samples using the Company's proprietary technology, when in fact, the patient samples were tested using other commercially available analyzers; 5) the Company's proprietary technology had been validated by several pharmaceutical companies and research institutions, when in fact, it had not; 6) patient samples were being run using the Company's proprietary technology during certain demonstrations to investors, when in fact, the demonstration was faked; and 7) FDA clearance or approval of the proprietary analyzer and tests was not required but that Theranos was planning to make a submission to the FDA voluntarily because FDA clearance or approval was considered the "gold standard" in the industry. In reality, the indictment alleges that the executives knew that FDA was requiring Theranos to make a submission.

The case against Holmes and Balwani was bifurcated into separate trials for each defendant. The trial against Holmes commenced in September 2021. After a fifteen-week trial, the jury found Holmes guilty of conspiracy to commit wire fraud against the Company's investors and three counts of wire fraud related to the scheme to

defraud investors.[2] Holmes was acquitted of the patient-related fraud conspiracy count and the three counts of fraud against individual patients. The jury could not reach a unanimous verdict with respect to three individual investor fraud counts against Holmes. An additional count of wire fraud relating to a Theranos patient had been dismissed during trial. On November 18, 2022, Holmes was sentenced to over eleven years (135 months) in federal prison and was ordered to surrender to begin serving her sentence on April 27, 2023.[3]

Balwani's trial commenced in March 2022, and he was convicted in July 2022 on all counts of investor and patient fraud.[4] In December 2022, Balwani was sentenced to almost thirteen years (155 months) in federal prison for his role in perpetuating the fraud.[5] A hearing on the amount of restitution that each defendant will owe is still pending. Both defendants have appealed their convictions.[6]

Aside from the criminal action, the individual defendants and the Company have suffered additional fallout from their actions. Holmes and Theranos previously settled a civil complaint by the U.S. Securities and Exchange Commission (SEC) related to the fraud whereby Holmes agreed to pay a $500,000 penalty, return 18.9 million shares of Theranos, relinquish her voting control in the Company, and be barred from serving as an officer or director of a publicly owned company for ten years.[7] (Balwani's SEC case was stayed pending resolution of the criminal case.[8]) In addition, Theranos settled consumer law violation claims made by the Arizona Attorney General alleging that the Company made false, deceptive, misleading, and unfair claims to consumers regarding the tests.[9] Walgreens and Safeway ended their business relationships with Theranos, and Walgreens sued the Company, which resulted in a settlement for an

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2 Final Verdict Form, United States v. Holmes, Case No. 5:18-CR-00258-EJD, Doc. No. 1235 (N.D. Cal. Jan. 3, 2022).

3 Order on Sentencing, United States v. Holmes, Doc. 1712 (Jan. 10. 2023).

4 Final Verdict Form, United States v. Balwani, Doc. 1507 (July 7, 2022).

5 Order on Sentencing, United States v. Balwani, Doc. 1730 (Feb. 16, 2023).

6 Holmes Notice of Appeal, United States v. Holmes, Doc. 1670 (Dec. 2, 2022); Balwani Notice of Appeal, United States v. Balwani, Doc. 1705 (Dec. 21, 2022).

7 Press Release, U.S. Sec. & Exchange Comm'n, Theranos, CEO Holmes, and Former President Balwani Charged with Massive Fraud (Mar. 14, 2018), https://www.sec.gov/news/press-release/2018-41.

8 Order Staying and Administratively Closing Action, Sec. & Exchange Comm'n v. Ramesh Sunny Balwani, Case No. 5:18-CV-01603-EJD (N.D. Cal. June 30, 2021).

9 Press Release, Az. Att'y General, AG Brnovich Obtains $4.65 Million for Arizonans Who Purchased Theranos Blood Tests (Apr. 18, 2017), https://www.azag.gov/press-releases/ag-brnovich-obtains-465-million-arizonans-who-purchased-theranos-blood-tests; Ken Alltucker, *Theranos Reaches $4.65 Million Fraud Settlement with Arizona*, AZCENTRAL (Apr. 18, 2017), https://www.azcentral.com/story/money/business/health/2017/04/18/theranos-reaches-465-million-settlement-arizona-blood-testing/100582618/.

undisclosed amount.[10] In the face of these and other legal actions, the Company eventually closed its labs, laid off its employees, and dissolved.[11]

## III. CMS AND FDA CONCERNS ABOUT THE TESTS

The indictment did not include any charges under the Federal Food, Drug, and Cosmetic Act (FDCA), nor were any charges brought alleging any violations of the Clinical Laboratory Improvement Amendments (CLIA). The government nevertheless was permitted to introduce some evidence related to the Company's failure to comply with these laws and related regulations. The Company had received reports from the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the California Department of Public Health (CDPH) detailing their respective observations from regulatory inspections. When ruling against Holmes' motion to exclude such evidence, the court explained that the evidence was probative of Holmes' state of mind, intent, and knowledge. In particular, the court found that:

> the evidence has a tendency to show Holmes' state of mind regarding Theranos' interactions with the regulatory agencies, the extent to which Holmes knew or should have known that Theranos was failing to meet certain federal regulations, and whether Holmes intended to mislead investors regarding the accuracy and reliability of Theranos' technology.[12]

Consequently, the jury was instructed that it could consider evidence of regulatory violations in light of the specific elements that must be proved in connection with the counts charged in the indictment.[13]

The evidence of regulatory violations presented to the jury included a redacted report from CMS outlining deficiencies it observed during a recertification and survey of Theranos' Newark, California laboratory in September 2015. The report pointed out multiple deficiencies, including failure to ensure acceptable quality control (QC) for the proprietary system prior to reporting patient test results, failure to institute a quality assessment (QA) procedure to identify and correct problems when the system failed to meet precision requirements, and failure to establish a QA procedure to identify and correct problems with the QC program. The report listed several examples where large percentages of QC samples reported values that called into question the ability of the system to produce accurate results.

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[10] *Walgreens Officially Breaks-Up with Theranos*, FDANEWS (June 17, 2016), https://www.fdanews.com/articles/10158-walgreens-officially-breaks-up-with-theranos; Christopher Weaver, John Carreyrou & Michael Siconolfi, *Walgreen Sues Theranos, Seeks $140 Million in Damages*, WALL ST. J. (Nov. 8, 2016), https://www.wsj.com/articles/walgreens-seeks-to-recover-140-million-investment-from-theranos-1478642410; Emily Wasserman, *Safeway Severs Ties with Theranos as $350M Deal Collapses*, FIERCE BIOTECH (Nov. 11, 2015), https://www.fiercebiotech.com/medical-devices/safeway-severs-ties-theranos-as-350m-deal-collapses.

[11] *Theranos Calls It Quits*, FDANEWS (Sept. 6, 2018), https://www.fdanews.com/articles/188300-theranos-calls-it-quits; *Embattled Blood-Testing Firm Theranos to Dissolve: WSJ*, REUTERS (Sept. 4, 2018), https://www.reuters.com/article/us-theranos-bankruptcy/embattled-blood-testing-firm-theranos-to-dissolve-wsj-idUSKCN1LL077.

[12] Order re Motions in Limine at 13, United States v. Holmes, Doc. 798 (May 22, 2021).

[13] Final Jury Instructions at 33, United States v. Holmes, Doc. 1206 (Dec. 9, 2021).

CMS sent a letter to Theranos dated January 25, 2016 informing the company that following the November 20, 2015 survey of the laboratory, CMS determined that 1) the facility was not in compliance with all of the Conditions required for certification in the CLIA program; and 2) that based on the condition-level requirement at 42 C.F.R. § 493.1215, Hematology, the laboratory's deficient practices posed "immediate jeopardy to patient health and safety."[14] As a result, immediate corrective action was necessary because the non-compliance "has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."[15] The letter notified Theranos that the Company had ten calendar days in which to provide a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy had been removed. Theranos submitted a response to this letter on February 12, 2016, but CMS concluded that the submission did not demonstrate that the laboratory had come into compliance and abated the immediate jeopardy. After some additional back and forth between Theranos and the agency, CMS revoked Theranos' CLIA certificates, imposed a civil money penalty, and levied other sanctions on the Company.[16] Theranos appealed the revocation but subsequently reached a global settlement agreement with CMS, whereby CMS withdrew the revocation of the CLIA certificates and reduced the civil monetary penalty, and Theranos agreed not to operate a clinical laboratory for two years.[17] Evidence pertaining to the settlement with CMS was excluded from the trial.[18]

FDA also inspected the Newark facility in August and September 2015, and it issued a Form FDA-483 inspectional observation report outlining nine observations of objectionable conditions.[19] Of note, the Company was cited for shipping an uncleared medical device in interstate commerce. According to the 483 report, FDA identified the Company's capillary tube nanotainer (a blood specimen collection device) as a Class II medical device, but the Company had identified it as a Class I exempt medical device. FDA also uncovered several systemic issues and cited the Company for failing to: have adequate procedures for evaluating complaints, evaluate and document complaints, document corrective and preventive action (CAPA) activities, document software validation activities, evaluate potential suppliers, maintain adequate records of acceptable suppliers, establish procedures for device history records, and perform quality audits.

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[14] Letter from CMS to Theranos dated Jan. 25, 2016, Trial Exh. 4621a.

[15] *Id.*

[16] Letter from Ctrs. for Medicare & Medicaid Servs. to Sunil Dhawan, Director, Elizabeth Holmes, Owner & Ramesh Balwani, Owner, Theranos (July 7, 2016), https://www.wsj.com/public/resources/documents/r_Theranos_Inc_CMS_07-07-2016_Letter.pdf.

[17] Settlement Agreement, Exhibit 29 to Declaration of Amy Mason Saharia in Support of Ms. Holmes' Motions in Limine and Daubert Motions to Exclude Expert Testimony, United States v. Holmes, Doc. 583-3 (Nov. 20, 2020); *Theranos Reaches Resolution with Centers for Medicare & Medicaid Services*, BUSINESS WIRE (Apr. 17, 2017), https://www.businesswire.com/news/home/20170417005931/en/CORRECTING-and-REPLACING-Theranos-Reaches-Resolution-with-Centers-for-Medicare-Medicaid-Services.

[18] Order re Motions in Limine at 16, United States v. Balwani, Doc. 1326 (Feb. 28, 2022).

[19] U.S. FOOD & DRUG ADMIN., THERANOS INC. (NEWARK) FORM FDA-483 (Sept. 16, 2015), https://www.fda.gov/files/about%20fda/published/Theranos--Inc.--Newark--CA-483-Issued-09-16-2015.pdf.

FDA contemporaneously inspected the Company's Palo Alto facility and issued a separate Form FDA-483 inspectional observation report outlining five observations of objectionable conduct.[20] FDA found that the Company's design validation did not ensure that the device conformed to defined user needs and intended uses, the design was not validated under actual or simulated use conditions, the Company failed to adequately document design input requirements and design risk analysis, and designated individuals did not review and approve important regulatory documents (such as a hazard analysis) prior to issuance.

## IV. IMPACT OF FAULTY TESTS ON PATIENTS

In response to the CMS investigation observational findings, the Company performed a patient impact assessment, which concluded that the laboratory performed poorly and exhibited abrupt shifts in quality control target means. Since the Company could not discern the magnitude of the bias on patient results, the laboratory concluded that there was a "possible patient impact for every test reported" from the proprietary instruments.[21] The laboratory consequently "voided" all patient test results reported from these instruments, but according to the Company's lab director at the time, Theranos did not communicate that it had voided the results to all the affected patients.[22]

The government also provided specific examples of patients who had received inaccurate test results. For example, one patient testified that she received test results from Theranos that falsely indicated that she had HIV antibodies, causing her emotional distress.[23] Another patient testified that he received test results from Theranos that falsely indicated that he could have aggressive prostate cancer. After two of the three fingerstick tests he received from Theranos showed high prostate-specific antigen (PSA) levels, the patient took a fourth test taken venously by another company, which showed that his PSA levels were normal.[24] Another patient testified that a Theranos test falsely showed that she had experienced a sudden drop in hCG hormones, which would suggest a miscarriage. This was particularly concerning to the patient since she had previously had three miscarriages. Because the results were inconsistent with other clinical findings, her practitioner ordered another hormone test from another company, which revealed that the Theranos test was inaccurate. The patient eventually gave birth to a healthy baby.[25]

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[20] U.S. FOOD & DRUG ADMIN., THERNANOS INC. (PALTO ALTO) FORM FDA-483 (Sept. 16, 2015), https://www.fda.gov/media/94721/download.

[21] Patient Impact Assessment, Trial Exh. 4943.

[22] Dorothy Atkins, *Ex-Theranos Lab Chief Doubted Holmes' Implausible Takes*, LAW360 (Nov. 9, 2021), https://www.law360.com/articles/1439134/ex-theranos-lab-chief-doubted-holmes-implausible-takes.

[23] Dorothy Atkins, *Theranos Patient Got Incorrect HIV Test Result, Jury Told*, LAW360 (Nov. 17, 2021), https://www.law360.com/articles/1441334/theranos-patient-got-incorrect-hiv-test-result-jury-told.

[24] Dorothy Atkins, *Fortune Writer Claims Holmes Duped Him as DOJ Wraps Case*, LAW 360 (Nov. 18, 2021), https://www.law360.com/articles/1441736/fortune-writer-claims-holmes-duped-him-as-doj-wraps-case.

[25] Dorothy Atkins, *Theranos Test Wrongly Suggested Miscarriage, Jury Hears*, LAW360 (Sept. 21, 2021), https://www.law360.com/articles/1423718.

The government argued that the evidence of patient harm justified enhanced sentences for the defendants, but the court disagreed. Since Holmes was acquitted from the patient-related fraud, the judge declined to enhance her sentence to account for the harm to patients that may have resulted from her false statements.[26] The court also declined to enhance Balwani's sentence to account for patient harm. One factor in this decision was the fact that the "vast majority" of the samples that Theranos tested in its labs were run using other FDA-approved technology, not Theranos' platform, and that no evidence was offered to suggest that the FDA-approved devices had produced inaccurate results. With respect to patients who were tested using the Theranos technology, the court found that it was a "close question" whether Balwani consciously disregarded the risk of death or serious bodily injury to these patients, since Balwani tended to defer to the judgment of Theranos scientists. Although the evidence was consistent with a finding that Balwani "was aware of inaccuracies and intended to deprive patients of the benefit of their bargain," the court found that on balance, the evidence did not weigh in favor of imposing an enhancement to Balwani's sentence on these grounds.[27]

## V. IMPLICATIONS ON REGULATORY LANDSCAPE

The criminal case against the former Theranos executives was not an FDA or CMS case, but rather it was a wire fraud and conspiracy case that was focused largely on misrepresentations about the performance of the tests that defrauded investors and patients. In many aspects, the allegations made here were likely simpler for a jury to understand than any allegations of regulatory misconduct that could have been made with the same set of facts. Evidence of regulatory violations was presented to demonstrate that the defendants had knowledge that the tests were plagued with difficulties yet continued to make false statements to secure business advantage. The regulatory status of Theranos' tests would have added a layer of complexity to the government's case, however, had the government sought a cause of action under the FDCA. Ultimately, the strategy paid off, since the prosecutors in this case succeeded in securing guilty verdicts and lengthy criminal sentences, making an example of high-profile executives and holding them personally accountable for their actions.

Although the potential for patient harm did not factor into the court's sentencing decisions, it was clearly a factor in the government's motivation to prosecute this case. According to an FDA press release about the case:

> The conduct alleged in these charges erodes public trust in the safety and effectiveness of medical products, including diagnostics. The FDA would like to extend our thanks to our federal law enforcement partners for sending a strong message to Theranos executives and others that these types of actions will not be tolerated.[28]

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[26] Order on Sentencing, United States v. Holmes, Doc. 1712 (Jan. 10, 2023).

[27] Order on Sentencing, United States v. Balwani, Doc. 1730 (Feb. 16, 2023).

[28] Press Release, U.S. Food & Drug Admin., Theranos Founder and Former Chief Operating Officer Charged in Alleged Wire Fraud Schemes (June 15, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/june-15-2018-theranos-founder-and-former-chief-operating-officer-charged-alleged-wire-fraud-schemes.

When Balwani was prosecuted, FDA put out a similar statement warning that FDA "will vigilantly investigate and bring to justice individuals and companies responsible for putting the public health at risk."[29]

The timing of this case is noteworthy because the regulatory regime governing laboratory developed tests (LDTs) has been under scrutiny in recent years, particularly in light of the increasing complexity of some LDTs as well as the quality of some LDTs that were developed in response to the COVID-19 pandemic. FDA has historically maintained that it has regulatory authority over LDTs (which are in vitro diagnostic (IVD) tests that are designed, manufactured, and used within a single laboratory) but that it had decided to exercise enforcement discretion and not require most LDTs to undergo premarket review or be subject to other regulatory requirements. In contrast, FDA has to date focused its regulatory oversight on commercial IVD tests pursuant to its authority to regulate medical devices and biological products under the FDCA. FDA regulates the safety and effectiveness of IVDs through a variety of premarket and postmarket controls, including requiring premarket submissions to allow FDA to assess the analytical and clinical validity as well as the quality of the design and manufacture of the test.[30] Clinical laboratories are regulated by CMS pursuant to its authority under CLIA, which requires laboratories to establish certain performance characteristics to assure analytical validity for use of the test system in the laboratory's environment.[31]

Lawmakers, regulators, and other stakeholders have pointed to this case as evidence for the need for additional regulatory oversight over laboratories.[32] For example, The Pew Charitable Trusts sent a letter to Xavier Becerra, the Secretary of the Department of Health and Human Services (HHS), in April 2021 advocating, among other things, for legislation to "update FDA's regulatory oversight of diagnostic tests and to provide regulatory certainty."[33] The letter acknowledged that Theranos "was not representative of the broader laboratory industry" but noted that the company had an incentive to offer its tests under the LDT framework in order to avoid FDA's premarket requirements. Pew argued that the example highlights "the risks associated with CLIA, which does not require premarket review even for high-risk tests," cautioning that "patients may be exposed to unreliable tests for years before regulators learn of any potential issues." Pew is advocating for Congress to enact the Verifying Accurate, Leading-edge IVCT Development (VALID Act) in order to close the "loophole" that Theranos' leaders exploited to avoid independent review of their devices.[34]

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[29] Press Release, U.S. Food & Drug Admin., Theranos Chief Operating Officer Ramesh "Sunny" Balwani Found Guilty of Conspiracy, Wire Fraud (July 27, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/theranos-chief-operating-officer-ramesh-sunny-balwani-found-guilty-conspiracy-wire-fraud.

[30] *See* FDA REGULATION OF LABORATORY-DEVELOPED TESTS (LDTS), CONG. RSCH. SERV.: IN FOCUS (Dec. 7, 2022), https://crsreports.congress.gov/product/pdf/IF/IF11389.

[31] 42 C.F.R. Part 493.

[32] *The Theranos Saga: A Wake-Up Call for the Lab-Developed Test Market*, MED. DEVICE NETWORK (Jan. 25, 2022), https://www.medicaldevice-network.com/features/theranos-ldt-regulation/.

[33] Letter from Liz Richardson, Project Director, Pew Charitable Trusts to The Hon. Xavier Becerra, Secretary, U.S. Dep't of Health & Human Svcs. (Apr. 28, 2021), https://www.pewtrusts.org/-/media/assets/2021/04/pew-urges-reversal-of-federal-policies-limiting-diagnostic-test-oversight.pdf

[34] Liz Richardson, *The Theranos Problem Congress Must Still Solve—Patients Need Protection*, THE PEW CHARITABLE TRUSTS: TRUST MAGAZINE (May 27, 2022),

The VALID Act would create a new regulatory pathway for in vitro clinical tests (ICVTs), which would regulate both LDTs and commercial IVD kits under a risk-based framework. Variations of this bill have been introduced in Congress during the past few years. Last year, the bill was included as a rider in an amendment to a Senate FDA user fee bill, the Food and Drug Administration Safety and Landmark Advancements (FDASLA), which had been approved by the Senate Health, Education, Labor, and Pensions (HELP) Committee but was not voted on by the Senate. VALID was ultimately not included as a rider in the Food and Drug Omnibus Reform Act (FDORA), which passed at the end of 2022 and authorized a number of FDA programs and initiatives that were considered by Congress during user fee negotiations.[35]

VALID was recently re-introduced in the U.S. House of Representatives by Reps. Larry Bucshon (R-Ind.) and Diana DeGette (D-Col.).[36] According to a press release by Rep. Bucshon, the legislation "comes in the wake of several high-profile scandals—including companies such as Theranos—that have led to increased demand among public health officials for greater oversight of diagnostic tests being used to screen patients in the United States."[37] Rep. DeGette has actively followed the Theranos testing scandal as part of her role as Energy and Commerce Committee Oversight and Investigations Subcommittee Ranking Member. Along with other Committee leaders, DeGette had previously sent letters to the Company as well as to FDA and CMS requesting information about the situation.[38]

FDA Commissioner Robert Califf has testified before Congress in favor of the VALID Act.[39] In the absence of legislation, FDA officials have indicated that the agency would consider administrative action, which could include rulemaking, to impose additional requirements on LDTs.[40]

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https://www.pewtrusts.org/en/trust/archive/spring-2022/the-theranos-problem-congress-must-still-solve-patients-need-protection.

[35] David Lim, *VALID Act Left Out of Year-End Omnibus*, POLITICO PRO (Dec. 20, 2022), https://subscriber.politicopro.com/article/2022/12/valid-act-left-out-of-year-end-omnibus-00074748;

[36] Verifying Accurate Leading-edge IVCT Development Act of 2023 or the "VALID Act of 2023", H.R. 2369, 118th Cong. (2023).

[37] Press Release, Larry Bucshon, M.D., Lawmakers Move to Reform Diagnostic Testing in United States (Mar. 29, 2023), https://bucshon.house.gov/news/documentsingle.aspx?DocumentID=4402.

[38] Press Release, Energy & Com. Comm. Democrats, Democratic Committee Leaders Request Information from FDA and CMS on Theranos' Inaccurate Blood Tests (July 26, 2016), https://democrats-energycommerce.house.gov/newsroom/press-releases/democratic-committee-leaders-request-information-from-fda-and-cms-on.

[39] *See, e.g.*, *Hearing on the Federal Response to COVID-19 Before the H. Comm. on Energy and Commerce Subcommittees on Health and Oversight & Investigations*, 118th Cong. (Feb. 8, 2023), https://energycommerce.house.gov/events/joint-oversight-and-investigations-subcommittee-and-health-subcommittee-hearing-titled-the-federal-response-to-covid-19-1 (statement of Dr. Robert Califf, Commissioner of Food and Drugs, U.S. Food and Drug Administration).

[40] Nick Paul Taylor, *FDA Moving Ahead with Rulemaking on Lab Developed Tests Without Waiting for Congress: BioWorld*, MEDTECH DIVE (Mar. 2, 2023), https://www.medtechdive.com/news/fda-rulemaking-lab-developed-tests-hillebrenner/643972/.

# Center for Inquiry Inc. v. Walmart, Inc.

**WILLIAM M. JANSSEN***

## I. WHY IT MADE THE LIST

"Get ready to match the stars—as we play the star-studded, big money *Match Game*! And here's your host, Gene Rayburn!"

Anyone born in the 1960s likely remembers this TV opening with its funky, synthesized musical theme, opening each episode of the popular televised game show of the 1970s. What made it so well watched? It probably wasn't the "stars" (with apologies to Brett Somers, Nipsey Russell, Fannie Flagg, and Charles Nelson Reilly). Many were no longer quite "A"-listers. Richard Dawson's *Family Feud* enjoyed a robust popularity as well, with family members trying, for years, to match the top five answers. Perhaps these shows' success can be traced to their similar, intrinsically appealing premise: matching things.

It seems we, as humans, are pretty much hot-wired to search for matches. As toddlers, our favorite games probably included Tic-Tac-Toe's matching of Xs and Os. As early students, our haunting nightmares may have involved matching tests. When old enough to start picking out our own clothes for the day, we almost certainly remember being told that blue pants and brown shoes just don't match. In middle-of-the-street neighborhood stickball games, most can recall matching up players. Back then, our sports team adversaries were "no match" for our favored squad, unless of course they were equally matched and then fandom panic set in. Into adulthood, we began the search for our perfect match—the special someone whose likes, interests, and aspirations aligned (matched) with our own.

As career approached, little changed. Looking for an internship? You'd match your resume to that job's posted credentials. Thinking medical school? Prepare for residency "match-day" angst. A career in pharmaceutical science? Show an affinity for detecting patterns in clinical data. A criminal law specialist? Matching offense criteria to sentencing guidelines is a must.

If, indeed, all of life is matching, last September's *Center for Inquiry Inc. v. Walmart, Inc.* decision[1] ought to feel quite familiar. The plaintiff there contended that pharmacies had violated the District of Columbia's consumer protection/unfair trade practices statute in their marketing of homeopathic products. Why? Because they were shelved alongside FDA-approved medicines, allegedly imparting the misleading impression that the products were functionally similar—in effect, interchangeable matches.

The District of Columbia Court of Appeals ruled that this contention survived the pharmacies' pleadings-based challenge, and in so doing, held that the manner in which a product is displayed for customer viewing can, itself, constitute a deceptive trade

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[1] 283 A.3d 109 (D.C. Ct. App. Sept. 29, 2022).

practice. Because this litigation may widen the inventory of products liability theories, it qualifies as one of the top food and drug cases of 2022.

## II. DISCUSSION

Two lawsuits filed in the District of Columbia Superior Court prompted this appeal. In both lawsuits, the trial judges had dismissed the complaints. The lawsuits were filed against, respectively, Walmart, Inc. and CVS Pharmacy, Inc., and sought declaratory, injunctive, and monetary relief for claimed violations of D.C.'s Consumer Protection Procedures Act ("trade practices act").[2] The lawsuits contended that the stores engaged in unfair and deceptive trade practices by displaying homeopathic products alongside "science-based" medicines in their "Cold, Cough & Flu Relief" physical store aisles and Internet product pages. The litigating theory was that, through such product placement, Walmart and CVS Pharmacy had falsely represented to consumers that the two product types were "equivalent" to one another and "effective in treating specific diseases and symptoms."[3] The complaints pleaded that neither representation was true.

### *A. A Primer on Homeopathic Products*

Homeopathic products are not approved as medicines by the U.S. Food and Drug Administration (FDA).[4] Yet FDA retains regulatory authority over them, as it does with other non-prescription, over-the-counter products.[5]

Homeopathy is an alternative approach to healthcare remedies grounded in the belief that the human body can be prompted to cure itself. Tracing its roots back to ancient Egypt and Greece, homeopathy was systematized in the 1700s by a German physician.[6] It is anchored in two theories—"like-cures-like," the view that diseases can be treated successfully with substances that trigger similar symptoms in healthy persons; and "law-of-infinitesimals," the view that significantly diluted aqueous solutions created from those triggering substances will be "imprinted" with the memory of the therapeutic properties of that substance.[7]

Whether homeopathic treatments are effective in treating health conditions remains a vigorously debated question. Some research suggests that they might be effective in certain contexts, while other research concludes they are not.[8] An often-cited 2010

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[2] D.C. Code §§ 28-3901–13.

[3] *Center for Inquiry*, 283 A.3d at 112.

[4] *See Homeopathic Products*, U.S. Food & Drug Admin. (Dec. 7, 2022), https://www.fda.gov/drugs/information-drug-class/homeopathic-products ("There are no FDA-approved products labeled as homeopathic; this means that any product labeled as homeopathic is being marketed in the U.S. without FDA evaluation for safety or effectiveness.").

[5] *See* 21 U.S.C. § 321(g)(1)(A) (defining the term "drug" as used in FDCA to include "articles recognized in the . . . official Homoeopathic Pharmacopoeia of the United States").

[6] *See id.*

[7] *See* U.S. FOOD & DRUG ADMIN., HOMEOPATHIC DRUG PRODUCTS—GUIDANCE FOR FDA STAFF AND INDUSTRY 1–2 (Dec. 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry [hereinafter FDA, HOMEOPATHIC DRUG PRODUCTS].

[8] *Compare, e.g.*, *What is Homeopathy?—Does It Work?*, WEBMD (Mar. 22, 2021), https://www.webmd.com/balance/what-is-homeopathy ("Research is mixed. Some studies show that homeopathic remedies are helpful, while others don't. Critics chalk up the benefits to the placebo effect."), *with Homeopathy: What You Need to Know*, NAT'L INSTS. OF HEALTH: NAT'L CTR. FOR COMPLEMENTARY

report released in the United Kingdom by the House of Commons Science and Technology Committee pronounced "the settled view of medical science" that the central homeopathic principle ("like-cures-like") is "theoretically weak" and lacking "a credible physiological mode of action"; that the "imprinting" theory of substance dilutions is "scientifically implausible"; and that "systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos."[9] Seven years later, the English National Health Service announced that it would no longer fund homeopathic treatments.[10]

Historically, homeopathic remedies were prepared specially for individual patients by those physicians who personally embraced homeopathy. But that changed. More recently, demand for homeopathic products increased meaningfully.[11] Estimates valued the global homeopathy market at nearly $18 billion in 2021 with growth forecasted to more than $50 billion by 2028.[12] Predictably, this rising demand led to mass manufacture and broad marketing of homeopathic products as over-the-counter remedies.[13] Enter Walmart and CVS Pharmacy.

### *B. The Plaintiff—Center for Inquiry, Inc.*

The Center for Inquiry, Inc. (CFI) is a nonprofit 501(c)(3) organization committed to the mission of "foster[ing] a secular society based on reason, science, freedom of inquiry, and humanist values."[14] CFI insists that homeopathy "is a pseudoscience and that the concepts on which it is based 'contradict the most fundamental understanding of science.'"[15] Motivated by a longstanding objective of "discouraging reliance on pseudoscience and pseudoscientific products"—a category to which it contends homeopathic products belong—CFI has evidently committed itself to having homeopathic products removed from the marketplace.[16]

CFI's two complaints claimed that, by shelving homeopathic products alongside "science-based" medicines in aisles labeled for cold, cough, and flu relief, Walmart

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& INTEGRATIVE HEALTH, https://www.nccih.nih.gov/health/homeopathy ("There's little evidence to support homeopathy as an effective treatment for any specific health condition.") (last updated Apr. 2021).

[9] House of Commons—Science & Technology Comm.—Fourth Report ¶¶ 54, 61 & 70 (2010), https://publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4504.htm#a11.

[10] *See Homeopathy*, NAT'L HEALTH SERV., https://www.nhs.uk/conditions/homeopathy/ (last updated Apr. 7, 2021).

[11] *See Homeopathy: What You Need to Know*, *supra* note 8 (citing 2012 survey to estimate that in 2011, 5 million adults and 1 million children used homeopathic products, most without guidance from homeopathic practitioners; instead, analysis suggests that adults mostly "self-prescribe[d] them for colds and musculoskeletal pain").

[12] *See Insights on Global Homeopathy Products Market Size & Share Projected to Hit at USD 50,203.3 Million and Rise at a CAGR of 18.7% By 2028: Industry Trends, Demand, Value, Analysis & Forecast Report*, CISION PR NEWSWIRE (Zion Market Research May 17, 2022), https://www.prnewswire.com/news-releases/insights-on-global-homeopathy-products-market-size--share-projected-to-hit-at-usd-50-203-3-million-and-rise-at-a-cagr-of-18-7-by-2028-industry-trends-demand-value-analysis--forecast-report--zion-market-research-301549050.html.

[13] *See* FDA, HOMEOPATHIC DRUG PRODUCTS, *supra* note 7.

[14] *Our Mission*, CTR. FOR INQUIRY, https://centerforinquiry.org/about/. *See also id.* ("To move forward, we need to discard old superstitions, prejudices, and magical thinking and embrace facts, evidence, and critical thinking.").

[15] *Center for Inquiry*, 283 A.3d at 112.

[16] *See id.* at 115–17.

and CVS Pharmacy violated the codified rights of consumers to truthful information about products purchased within the District of Columbia.[17] More precisely, CFI charged that the two stores violated D.C.'s unfair or deceptive trade practices statute, which provides a remedy ("whether or not any consumer is in fact misled, deceived, or damaged thereby") for: representing that goods have "characteristics, ingredients, uses, benefits, or quantities that they do not have . . . [or] are of particular standard, quality, grade, style, or model, if in fact they are of another"; misrepresentations "as to a material fact which has a tendency to mislead"; failing "to state a material fact if such failure tends to mislead"; or using "innuendo or ambiguity as to a material fact, which has a tendency to mislead."[18]

### *C. The Court Rulings*

The D.C. trial judges dismissed the two CFI complaints for lack of statutory standing and for failing to state a cognizable civil claim. After the two dismissals were consolidated for appeal, the District of Columbia Court of Appeals reversed and remanded. Preliminarily, the appeals court ruled that CFI had demonstrated an adequate nexus to the interests of District of Columbia cold, cough, and flu product customers sufficient to establish statutory standing. While that is interesting, it is the appeals court's second ruling on the tenability of the CFI complaints' claims that merits our attention.

Walmart and CVS Pharmacy faulted the complaints' failure to state a claim upon which relief could be granted, noting that neither complaint indicted the content of the homeopathic products' labeling or otherwise suggested some labeling inadequacy.[19] Indeed, the record seemed to establish that the products at issue all properly contained the word "homeopathic" on their carton labeling and bore the federally required statements that the products had not been evaluated by FDA.[20] CFI's challenge was different, limited solely to product placement—that the shelving of homeopathic products alongside "science-based medicines" had the tendency to mislead D.C. customers into believing that the products were comparable in effectiveness. It was that theory that the stores challenged as a deficient claim under the D.C. unfair trade practices statute.

To test the pleaded adequacy of a civil claim, the District of Columbia applies the familiar *Twiqbal* "plausibility"[21] approach:

> To survive a motion to dismiss for failure to state a claim, a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," and the "factual allegations must be enough to raise a right to relief above the speculative level." "A claim has facial plausibility when the plaintiff pleads factual content that allows the

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[17] *See id.* at 116.

[18] D.C. Code §§ 28-3904(a), (d), (e), (f) & (f-1).

[19] *See Center for Inquiry*, 283 A.3d at 121 n.13.

[20] *See id.* at 113.

[21] "Twiqbal" has become the handy moniker to refer collectively to the U.S. Supreme Court's federal pleading decisions in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *See, e.g.*, RHJ Med. Ctr., Inc. v. City of DuBois, 754 F. Supp. 2d 723, 730 (W.D. Pa. 2010) (identifying "Twiqbal" as how the Supreme Court's *Iqbal* and *Twombly* decisions are now "commonly known").

> court to draw the reasonable inference that the defendant is liable for the misconduct alleged." To permit such an inference, the factual allegations must "nudge[ ] [the plaintiff's] claims across the line from conceivable to plausible." In reviewing whether dismissal of a complaint was warranted, "we accept the allegations of the complaint as true, and construe all facts and inferences in favor of the plaintiff."
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> "[N]aked assertion[s] devoid of further factual enhancement" will not survive a motion to dismiss. Still, at the pleading stage, a plaintiff's burden "is not onerous." The issue presented by a motion to dismiss "is not whether [the] plaintiff will ultimately prevail but whether [it] is entitled to offer evidence to support the claims. Indeed it may appear on the face of the pleadings that a recovery is very remote and unlikely but that is not the test." "[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely."[22]

The trial judges ruled that the complaints failed this plausibility inquiry, thus warranting their dismissals, because the stores' product-placement practices: 1) did not amount to a "representation" of product efficacy within the meaning of the D.C. trade practices statute; and 2) did not have a tendency to mislead consumers within the meaning of that statute. In reversing, the appeals court disagreed with the first conclusion and deferred the second conclusion to the province of the jury.

First, to be actionable under the D.C. statute, the appeals court ruled that a "representation" need not be verbal: "'acts,' not just words or statements, fall within the scope of the unfair or deceptive trade practices prohibited by the" D.C. statute.[23] Such a construction was found to be consistent both with this statute's liberal, remedial purpose and with the reach given by other courts interpreting similar trade practices statutes so as to encompass "practices such as product placement, misleading imagery, and other non-verbal cues."[24]

Second, the appeals court explained that a tendency-to-mislead is assessed "in terms of how the practice would be viewed and understood by a reasonable consumer," questions ordinarily reserved for a factfinder.[25] While acknowledging that, in an unusual case, the context-specific task of assessing plausibility might allow for a dismissal as a matter of law, the appeals court was persuaded that the complaints' pleaded facts, combined with the judicially noticeable public record, established the requisite plausibility to survive dismissal.

As for the pleaded facts, the appeals court noted that CFI alleged: that both stores market themselves as selling products to aid in customer health; that customers routinely turn to the stores' pharmacies for such relief; that research and experience establishes that homeopathic products are ineffective; that homeopathic products are displayed in both stores alongside FDA-approved products; that aisle signage directs

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[22] *See Center for Inquiry*, 283 A.3d at 117–18 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009)) (cleaned up).

[23] *See id.* at 118–19.

[24] *See id.* at 118.

[25] *See id.* at 120.

customers to the displayed products for illness relief; and that the stores fail to inform customers that scientific evidence does not support homeopathic product efficacy.[26]

Regarding the public record, the appeals court noted that the U.S. Federal Trade Commission had published an official enforcement policy that corroborated the complaints' plausibility. The FTC policy commented that many consumers are unfamiliar with "homeopathy" and, as such, merely noting a product's homeopathic nature would not adequately afford consumers notice that the product's efficacy was "not backed by scientific evidence." And even that notice would be inadequate, reasoned the Commission, because not-supported-by-scientific-evidence "does not convey the truly limited basis for the efficacy claim and that, to avoid deceiving consumers, it is likely necessary to explain that [homeopathy] is not accepted by modern medicine."[27]

In the end, the appeals court wrote that it could not find it implausible that a reasonable consumer might understand the stores' shelving decisions as a nonverbal representation "that the homeopathic products are efficacious or are equivalent alternatives to the FDA-approved over-the-counter drugs alongside which they are displayed."[28] Thereupon, although reversing the trial judges' dismissals, the appeals court was quick to add that CFI's allegations might not suffice "to defeat summary judgment or to prevail at trial."[29]

## III. IMPACT

Assessing the jurisprudential impact of *Center for Inquiry Inc. v. Walmart, Inc.* leads to at least three important observations: 1) an adventuresome reliance on nonverbal, product placement representations can (sometimes) support a cognizable unfair trade practices claim; 2) notwithstanding its many well-placed critics, the *Twiqbal* plausibility test can (sometimes) prove quite formidable; and 3) the "reasonable consumer" deception standard is (often) impervious to pleadings-based attacks.

### *A. Product Placement (Shelving) Can Constitute a "Representation"*

Modern products law rests typically on proving that a claimant's injury or loss was caused by one (or more) defects in the challenged product: that the product's design was defective, or its production/manufacture/assembly was defective, or its warnings

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[26] *See id.* at 122.

[27] *See id.* at 122–23 (quoting Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs, 81 Fed. Reg. 90,122, 90,123 n.15 (Dec. 13, 2016)). *See also id.* at 90,123 (proffering this tepid safe-harbor: "the promotion of an OTC homeopathic product for an indication that is not substantiated by competent and reliable scientific evidence may not be deceptive if that promotion effectively communicates to consumers that: (1) There is no scientific evidence that the product works and (2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts").

[28] *See Center for Inquiry*, 283 A.3d at 123.

[29] *See id.* at 123 & n.17 ("Summary judgment is the proverbial 'put up or shut up' moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of events.") (citation omitted). *See also* Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs, 81 Fed. Reg. at 90,123 n.15 ("Marketers are advised to develop extrinsic evidence, such as consumer surveys, to determine the net impressions communicated by their marketing materials.").

or instructions were defective.[30] CFI alleged no such product defect. Instead, its claim rested on how and where the homeopathic products were displayed to customers. At first blush, the theory feels viscerally specious.[31] Yet it is not without some conceptual grounding.

The D.C. Court of Appeals surveyed case law from other jurisdictions that accepted, at least at the pleading stage, that nonverbal product conduct could be legally consequential. For example, a Missouri federal court had earlier ruled that the shelving of obsolete motor oils next to non-obsolete motor oils could deceptively induce unsophisticated customers into buying a cheaper but valueless, and potentially vehicle-damaging, product in violation of the state's consumer protection statute.[32] The D.C. court also noted, in the trademark infringement context, a federal court's musings that product shelf positioning could be a purposeful strategy to drive customer product selection.[33] The appeals court need not have stopped with these two citations; further grounding in products theory exists generally.

Much of today's products litigation is fought with common law principles—negligence, strict liability, misrepresentation, and warranty, with a formidable smattering of federal and state statutory tools sprinkled in. Most jurisdictions, for example, have enacted statute-based unfair trade practices laws, as the District of Columbia did in this case. Although this array of product liability litigating approaches may seem disparate, it is quite wrong to consider them each hermetically cordoned off from one another. To the contrary, there is a healthy degree of theoretical cross-pollination. Thus, evolution and developments in one products sector are often harbingers of change in others.

The law of tortious misrepresentation, for example, hinges on the communication of information to another in a manner that the law finds actionable. The obvious starting predicate for this tort is a "representation," just as it is in the D.C. unfair trade practices statute. In the common law of tortious misrepresentation, "[i]nformation usually is communicated by spoken or written word, but it may also be conveyed pictorially or by conduct."[34] Thus, nonverbal communications can be instruments of tortious misrepresentation.

So, too, the law of express warranty lies in "affirmative assertions, made by a seller in connection with a sales transaction, that a product possesses certain characteristics." This type of warranty "springs from a seller's words or other forms of communication"; while the law ordinarily sets "no fixed manner by which an express warranty must be created," courts acknowledge that "express representations need not

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[30] *See* DAVID G. OWEN, PRODUCTS LIABILITY LAW 35–37 (4th ed.2022).

[31] As it usually does, the Drug & Device Law Blog makes the point eloquently: "What's next? Lawsuits claiming that it is deceptive to put margarine next to butter? Veggie burgers next to meat? OTC drugs next to dietary supplements? Diet soda next to sugary soda? Fiction next to non-fiction? The potential for abuse and expensive discovery is obvious." Steven Boranian, *The Shelves Have Eyes*, DRUG & DEVICE LAW BLOG (Oct. 6, 2022), https://www.druganddevicelawblog.com/2022/10/the-shelves-have-eyes.html.

[32] *See In re* Dollar Gen. Corp. Motor Oil Mktg. & Sales Pracs. Litig., 2017 WL 3863866 (W.D. Mo. Aug. 3, 2017).

[33] *See* 1-800 Contacts, Inc. v. WhenU.Com, Inc., 414 F.3d 400, 411 (2d Cir. 2005) ("a drug store typically places its own store-brand generic products next to the trademarked products they emulate in order to induce a customer who has specifically sought out the trademarked product to consider the store's less-expensive alternative").

[34] *See* OWEN, *supra* note 30, at 115.

always be in words, for a description of an article may be pictorial, or presented by blueprint, technical specifications, samples, models, or even by past deliveries."[35] The Uniform Commercial Code confirms the nuance in Section 2-313 ("Express Warranties by Affirmation, Promise, Description, Sample"), noting that a "description of goods" or a "sample or model" can create an express warranty that the goods "shall conform" to the description, sample, or model.[36]

Thus, the notion that nonverbal behavior can qualify in the law as a liability-triggering "representation" is hardly unprecedented. Nor, on reflection, is it conceptually unsound. A representation is a communication of information in such a manner as to create an expectation or reliance. Viewed in this light, CFI's contention that an inference can arise from the homeopathic products' shelving neighbors seems less implausible. It might well be that a jury ultimately rejects CFI's product-placement misrepresentation theory as too attenuated or fanciful, but the invitation to declare the theory foreclosed as a matter of law would appear at least inconsistent with how the law of tortious misrepresentation and express warranty have developed over time. In the end, the debate that CFI invited was not that acetaminophen ought not to be shelved next to ibuprofen, but that shelves containing pain relievers nonverbally telegraph to customers that all products displayed there provably relieve pain (in at least some cohort of customers).[37]

### *B. Twiqbal is Not Necessarily a Push-Over*

It has become commonplace during federal pleadings attacks to recite the mercurial dimensions of *Twiqbal* plausibility, so much so that the eye of both jurist and practitioner might gloss idly past this routine. The D.C. Court of Appeals' decision here demonstrates why so breezy a discounting may be unwarranted.

"Plausibility" obligates the pleader to burnish a complaint with "enough facts" to state a claim that is "plausible on its face," one that has been "nudged" by its allegations "across the line from conceivable to plausible."[38] Detailed facts are not necessary, but nor will "an unadorned, the-defendant-unlawfully-harmed-me accusation" suffice.[39] The "plausibility" pleader's target, then, is to aver a tale that is factual (not conclusory) and suggestive (not neutral); the pleading must include those facts needed to "raise the right to relief above the speculative level,"[40] thereby allowing a court "to draw the reasonable inference that the defendant is liable for the misconduct alleged."[41]

Mindful of these testing principles, if one were to categorize *Twiqbal* challenges, three camps of indictment seem to emerge.

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[35] *See id.* at 153–57.

[36] U.C.C. § 2-313(1)(b)–(1)(c).

[37] This is, of course, not to say that homeopathic products actually fail in such a comparison, only that CFI's fact-based allegations contend that they do.

[38] Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

[39] Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

[40] *Twombly*, 550 U.S. at 555 & 557 n.5.

[41] *Iqbal*, 556 U.S. at 678.

First, a pleading may be implausible because it contains only bare conclusions, elements, labels, and formulas, devoid of any supportive factual content. Plainly, that effort squarely fails the "*plausibility*" test.[42]

Second, a pleading may be implausible because the inference reasonably drawn from the alleged facts points as equally to culpability as it does to innocence. Here, too, the effort fails the test.[43]

Third, a pleading may be implausible when, relying on its "judicial experience and common sense," a court reaches the "context-specific" assessment that unlawful conduct is not suggested by the facts alleged.[44] Here, the spectre of the type of subjective, fact/inference parsing, so decisively inappropriate during a pleadings attack, is at its most troubling. But though the risk of judicial mischief cannot be denied, the "plausibility" inquiry adds important restraints that tend to mitigate that concern—a) the regime remains "notice" pleading, a burden characterized as not onerous; b) detailed factual allegations are still not required; c) pleading every fact necessary to sustain a merits burden is also not required; d) failing to support a chosen legal theory does not doom the claim if the allegations support relief under a different, viable theory; e) weighing the pleader's likelihood of success is not proper, nor will doubting the pleader's chances before a jury warrant a dismissal; and f) choosing between several plausible, yet competing inferences remains verboten.[45]

When applied here, the *Twiqbal* "plausibility" principles led the appeals court, albeit cautiously, to rule that the CFI complaints sufficed to survive the pleadings stage. The pleaded claims were more than conclusions, labels, and formulas; they offered supportive facts with context. Although plausible that some consumers would understand "homeopathy" and appreciate its distinctiveness, the appeals court found that the pleaded facts supported as also plausible that other, reasonable consumers would be misled. Cordoned in by the restraints the "plausibility" test imposes, the court concluded that its "context-specific" assessment of the complaints' allegations had revealed a claim nudged to the requisite showing of an entitlement to relief.[46]

### *C. The Impervious Nature of "Reasonable Consumer" Pleadings*

As noted earlier, the D.C. Consumer Protection Procedures Act (like many other unfair trade practices statutes) examines unfairness and deception through the lens of the elusive "reasonable consumer." Such a standard is quintessentially context-driven, loosely bounded, immune from precise definition, summoning an intensely but fundamentally amorphous, fact-based examination. The whole notion of a "reasonable person" has been bedeviling the law for years:

> Courts seem to reach for the reasonable person when they have a sense that an inquiry demands both some sensitivity to the particular qualities

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[42] *See Twombly*, 550 U.S. at 555, 557 ("naked assertion[s]," "labels and conclusions," and "a formulaic recitation of the elements of a cause of action will not do").

[43] *See Iqbal*, 556 U.S. at 678 ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'") (quoting *Twombly*).

[44] *See id.* at 679.

[45] *See* STEVEN BAICKER-MCKEE & WILLIAM M. JANSSEN, FEDERAL CIVIL RULES HANDBOOK 490–91 (2023).

[46] *See* D.C. Sup. Ct. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . .").

> or attributes of the involved individuals as well as a more objective or fixed dimension. But if this is true, it is equally true that the test is characterized by a lack of clarity about the exact nature of the subjective and objective characteristics of the reasonable person. . . . The consequence is that while the reasonable person undoubtedly possesses a certain "common sense" appeal, it has proven extremely difficult to systematize his significance.
>
> However, looking at the reasonable person across his many appearances makes at least one thing clear—he is most often the common or ordinary man. . . . [B]oth in the context of the law of negligence and in the criminal context, the objective content of the reasonable person is closely linked to standards of ordinariness or normalcy. . . . Indeed, many of the early critiques of the reasonable person focused on the looseness of the idea of what is ordinary. They worried in particular about whether the reasonable man (as he then was) was in fact anything more than just a vehicle for the judge's own beliefs and attitudes.[47]

Relegated to so pliable a concept as the "reasonable consumer," one should expect that, in the event a pleadings attack finds itself at this point in the legal analysis, the attack is almost certain to fail.[48]

To soften the point, the appeals court observed that it has, on occasion, dismissed pleadings for failing to state a cognizable unfair trade practices claim, but the two case examples the court offered tended to defy common sense or widely shared experiences.[49] The implication of the court's choice of citations is that dismissal should be understood as the exception, not the rule. The same is likely true wherever the "reasonable consumer" serves as the vehicle for remedy entitlement.

* * *

"Matching" is embedded into our very jurisprudence. The canon of interpretation *noscitur a sociis* ("it is known by its associates") directs that "[w]hen several nouns or verbs or adjectives or adverbs—any words—are associated in a context suggesting that the words have something in common, they should be assigned a permissible meaning that makes them similar."[50] Thus framed, Walmart's and CVS Pharmacy's motion to dismiss CFI's product-shelving deception theory may have posed an uphill

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[47] Mayo Moran, *The Reasonable Person: A Conceptual Biography in Comparative Perspective*, 14 LEWIS & CLARK L. REV. 1233, 1235–36 (2010).

[48] *See generally* PROSSER AND KEETON ON THE LAW OF TORTS 175 (5th ed. 1984) ("The courts have gone to unusual pains to emphasize the abstract and hypothetical character of this mythical person. He is not to be identified with any ordinary individual, who might occasionally do unreasonable things; he is a prudent and careful person, who is always up to standard. Nor is it proper to identify him with any member of the very jury which is to apply the standard; he is rather a personification of a community ideal of reasonable behavior, determined by the jury's social judgment.").

[49] *See Center for Inquiry*, 283 A.3d at 121 n.12 (ten-digit "domestic-looking" telephone number did not create reasonable expectation that customer representative would be located in the United States, nor did practice of reporting long-distance telephone calls in full-minute increments create reasonable belief that all calls actually terminated at end of a full minute).

[50] ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS § 31 (2012).

climb from the start. Shelved together, no lesser authorities than Gene Rayburn and Antonin Scalia have encouraged us (and courts) to see the match.

# Recent Cases on "Green" Messaging in Food and Beverage Company Advertising

**RENE BEFURT, ANNE CAI, REBECCA KIRK FAIR & HELENE ROWLAND***

## I. WHY THEY MADE THE LIST

Several recent lawsuits around "green" messaging in company advertising raise the question of how we can reliably evaluate "reasonable" consumers' understanding of or reactions to sustainability or environmental messages. The allegations in these matters have pertained to a wide range of topics. Some of the messages under scrutiny include broad marketing language on product packaging, across advertising campaigns, and in other marketing materials to signal to consumers the company's and product's positive attitude towards environmental topics. Other messages are more specific and include promises such as that the product's packaging—a plastic bottle—is 100% recyclable. Unsurprisingly, lawsuits that examine and probe sustainability or environmental messages are on the rise and have garnered the attention of potential plaintiffs and defendants alike.[1] In addition, government institutions continue to scrutinize companies for aspects related to environmental, social, and governance (ESG) topics, including consumer-facing messages about environmental friendliness and sustainability. This year, the Federal Trade Commission (FTC) is in the process of updating their *Guides for Use of Environmental Marketing Claims* (commonly

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[1] *See* Tim Quinson, *A Class-Action Wave Is Coming for ESG Claims*, BLOOMBERG (Jan. 25, 2023), https://www.bloomberg.com/news/articles/2023-01-25/class-action-wave-is-coming-for-esg-claims-green-insight (increasing ESG dispute exposure).

known as the "Green Guides"), potentially incorporating additional guidelines to critically examine companies' "green" messaging.

One remarkable recent matter is *Earth Island Institute v. The Coca-Cola Company*. Plaintiff alleged that various instances of marketing language used by Coca-Cola—including in advertisements related to sustainability and combatting pollution—falsely represent Coca-Cola as "sustainable" and "taking responsibility" for waste as a means to "cultivate[] an environmentally friendly image for . . . climate-concerned consumers to continue to purchase its products and services."[2] Other cases have addressed more specific consumer-facing messages, such as *Duchimaza v. Niagara Bottling*, in which plaintiff alleged that advertising with a "100% Recyclable" claim on a plastic water bottle was misleading to consumers,[3] and *White v. Kroger*, in which plaintiff alleged that the claim "reef friendly" on sunscreen products could be misunderstood.[4] In both *Duchimaza v. Niagara Bottling* and *White v. Kroger*, the courts relied in part upon the FTC's Green Guides, which provide guidance to marketers based on the FTC's "current views about environmental claims," including "how reasonable consumers likely interpret certain claims."[5] While Niagara Bottling successfully pointed to the Green Guides to defend its use of the phrase "100% Recyclable,"[6] the Green Guides were also recently cited as evidence against Kroger's "reef friendly" claim in the court's decision to deny a motion to dismiss the litigation.[7]

These recent decisions, and other similar cases underway,[8] demonstrate the importance of assessing the understanding and behavior of a "reasonable" consumer at different points of the purchase funnel. Given the ongoing evolution of companies' ESG marketing claims, consumers' perceptions and preferences, and guidelines such as the FTC Green Guides, future matters could benefit from the development and application of frameworks to assess the perceptions and materiality of ESG claims, including approaches that incorporate empirical evidence such as well-structured survey research.

## II. DISCUSSIONS

### *A. Procedural Background and Rulings: Earth Island Institute v. The Coca-Cola Company*

In June 2021, plaintiff Earth Island Institute filed a complaint in the Superior Court of the District of Columbia, alleging that Coca-Cola engaged in false and deceptive marketing by "representing itself as a sustainable and environmentally friendly

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2 Complaint at 2, 7, 30, Earth Island Inst. v. The Coca-Cola Co., Civil Action 21-1926 (PLF) (D.D.C. June 8, 2021).

3 Complaint at 1, Duchimaza v. Niagara Bottling, LLC, 21 Civ. 6434 (PAE) (S.D.N.Y. July 28, 2021).

4 Complaint at 1, White v. Kroger Co., 21-cv-08004-RS (N.D. Cal. Oct. 12, 2021).

5 Guides for the Use of Environmental Marketing Claims, 77 Fed. Reg. 62,121, 62,124–25 (Oct. 11, 2012) (to be codified at 16 C.F.R. pt. 260).

6 Order Granting Motion to Dismiss at 7–12, Duchimaza v. Niagara Bottling, LLC, 21 Civ. 6434 (PAE) (S.D.N.Y. Aug. 5, 2022).

7 Order Denying Motion to Dismiss at 4, White v. Kroger Co., 21-cv-08004-RS (N.D. Cal. Mar. 25, 2022).

8 *See, e.g.*, Swartz v. The Coca-Cola Co., 21-cv-04643-JD (N.D. Cal. Nov. 18, 2022).

company, despite being one of the largest contributors to plastic pollution in the world."[9] More specifically, plaintiff cited to Coca-Cola advertising campaigns across media platforms—such as claims related to "sustainability" and "taking responsibility" for plastic waste—alongside failed Coca-Cola sustainability initiatives and environmental metrics. The "environmentally friendly image" of Coca-Cola presented through these claims, plaintiff alleged, falsely motivated consumers "to continue to purchase [Coca-Cola's] products and services."[10]

Coca-Cola filed a motion to dismiss in June 2022; in November of the same year, the court ultimately dismissed the case as aspirational, citing "no plausible framework to determine whether a reasonable DC consumer could be misled by a general impression," and noting that no statements appeared on actual products.[11] The court's ruling also cited to specific advertising claims, holding that "[c]ourts cannot be expected to determine whether a company is actually committed to creating a 'world without waste' or 'to doing business the right way.'"[12] The case is currently on appeal to the DC Court of Appeals.

### *B. Procedural Background and Rulings: Duchimaza v. Niagara Bottling*

Plaintiff Eladia Duchimaza filed a class action complaint against Niagara Bottling in the United States District Court for the Southern District of New York in July 2021. Duchimaza alleged that the "100% Recyclable" claim on Niagara Bottling's plastic water bottles was false and misleading, as 1) not all elements of the plastic bottle were recyclable (e.g., the bottle caps), 2) a percentage of the plastic bottles and caps sent to recycling centers do not end up recycled because they are lost or contaminated, and 3) recycling facilities in the United States do not have the capacity to recycle all recyclables consumed domestically.[13]

Citing to the Green Guides, Niagara Bottling filed a motion to dismiss in October of 2021. The Green Guides define "recyclable" as a term of art:

> A product or package should not be marketed as recyclable unless it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program for reuse or use in manufacturing or assembling another item. . . . Marketers should clearly and prominently qualify recyclable claims to the extent necessary to avoid deception about the availability of recycling programs and collection sites to consumers.[14]

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[9] Complaint at 1, Earth Island Inst. v. The Coca-Cola Co., Civil Action 21-1926 (PLF) (D.D.C. Jun. 8, 2021).

[10] *Id.* at 7.

[11] Order Granting Motion to Dismiss at 12, Earth Island Inst. v. The Coca-Cola Co., Civil Action 21-1926 (PLF) (D.D.C. Nov. 10, 2022).

[12] *Id.* at 10.

[13] Complaint at 2, Duchimaza v. Niagara Bottling, LLC, 21 Civ. 6434 (PAE) (S.D.N.Y. July 28, 2021).

[14] Guides for the Use of Environmental Marketing Claims, 77 Fed. Reg. 62,121, 62,129 (Oct. 11, 2012) (to be codified at 16 C.F.R. pt. 260). *See also* Order Granting Motion to Dismiss at 8, Duchimaza v. Niagara Bottling, LLC, 21 Civ. 6434 (PAE) (S.D.N.Y. Aug. 5, 2022).

To address Duchimaza's arguments, Niagara Bottling argued that the required prominent qualifiers regarding the availability of recycling programs do not always have to be added to a label, as the Green Guide established two exceptions to the rule. First, Niagara Bottling argued that recycling facilities were available to Duchimaza,[15] and the Green Guides indicate that marketers could use a "recyclable" claim without such qualifiers if "recycling facilities are *available* to a substantial majority of consumers or communities where the item is sold."[16] Second, Niagara Bottling argued that bottle caps and labels are "minor incidental components," which, according to the defendant's reading of the Green Guides, therefore are not required to be recyclable, even in the presence of a "recyclable" claim.[17] These arguments resonated with the court, which agreed that Niagara Bottling's "100% Recyclable" claim was not likely to mislead a "reasonable" consumer, and dismissed the case in August of 2022.

### *C. Procedural Background and Rulings: White v. Kroger*

In October 2021, plaintiff Phillip White filed a class action complaint against Kroger and Fruit of the Earth ("Kroger") in the United States District Court for the Northern District of California, alleging that Kroger's "reef friendly" claim on certain sunscreen products was misleading to the "reasonable" consumer. Specifically, plaintiff asserted that the "reef friendly" label misleads consumers into "believing that the Products only contain ingredients that are reef-safe or otherwise cannot harm reefs," while "the Products actually contain . . . chemical ingredients that are not safe for reefs because they can harm and/or kill reefs."[18]

In February 2022, Kroger filed a motion to dismiss the litigation, arguing that the "reef friendly" claim constituted "non-actionable puffery upon which no reasonable consumer could rely."[19] In March of 2022, however, the court denied the motion to dismiss. In their decision, the court cited to the Green Guides as "undermin[ing] any argument that 'reef friendly' can be dismissed as mere puffery." As of early May 2023, the litigation remains ongoing.

## III. IMPACT

These cases demonstrate the wide range of ESG claims that could potentially be subject to litigation, from specific terms on product packaging to more generalized marketing claims. In each of these cases, the courts relied on assessments of how a "reasonable" consumer would perceive a claim. As companies' ESG marketing strategies, consumer preferences and understanding of ESG claims, and guidelines such as the FTC Green Guides evolve, future cases relating to ESG claims may require identifying appropriate frameworks for analysis of consumer perceptions and purchasing behavior. Similarly, future cases may benefit from additional empirical

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[15] Memorandum of Law in Support of Defendant's Motion to Dismiss at 6–7, Duchimaza v. Niagara Bottling, LLC, 21 Civ. 6434 (PAE) (S.D.N.Y. Aug. 5, 2022).

[16] Guides for the Use of Environmental Marketing Claims, 77 Fed. Reg. at 62,129 (emphasis added).

[17] Memorandum of Law in Support of Defendant's Motion to Dismiss at 7, Duchimaza v. Niagara Bottling, LLC, 21 Civ. 6434 (PAE) (S.D.N.Y. Aug. 5, 2022); Guides for the Use of Environmental Marketing Claims, 77 Fed. Reg. at 62,129.

[18] Complaint at 8, White v. Kroger Co., 21-cv-08004-RS (N.D. Cal. Oct. 12, 2021).

[19] Order Denying Motion to Dismiss at 4, White v. Kroger Co., 21-cv-08004-RS (N.D. Cal. Mar. 25, 2022).

evidence measuring to what extent, if any, certain claims can be linked to consumers' information processing at all. As indicated by the FTC's process and goals for its periodic updates for the Green Guides to reflect "current" understanding[20] and to reflect phrases that may not have been "common when the Guides were last reviewed,"[21] environmental claims and related consumer perceptions form a changing landscape.

Based on our review of the cases above, building appropriate frameworks to evaluate a "reasonable" consumer's perceptions and behavior relating to express or implied ESG claims requires consideration of the messaging content and the particular scenario. To evaluate whether consumers are deceived, or if there is a material impact on their choices or their brand associations, the following contextual factors throughout the purchase funnel and buying process[22] may be helpful in presenting a thoughtful and thorough assessment to the court:

1. *Consumers' prior knowledge and expectations of ESG*: As ESG is an evolving field, changes in the extent of consumers' prior knowledge of or expertise in the topic may affect how they perceive and behave in response to ESG claims. For example, consumers' reactions to a marketing claim made by a company may depend on whether they have a previously held concrete belief or expectation about the implications of the claim, as opposed to a more general interpretation or even no interpretation at all.

2. *Whether/how consumers conduct research for the product category or industry*: Assessing consumers' perceptions and behavior related to ESG claims should also take into consideration the nature of how consumers buy in the product category. For instance, whether the product category is a high-involvement one for consumers, the types of information consumers seek out or consider, actual consumers' general interest in environmental and sustainability topics, and the importance of various other factors including word-of-mouth are all contextual factors that can play a role in how consumers understand and account for ESG claims.

3. *Consumers' prior associations with a particular company, brand, or product category*: Consumers' prior associations with the company, brand, or even product category more broadly including other competitors may affect their attitudes towards brands, and choosing or rejecting a brand's products. For some companies, ESG claims may be highly credible to consumers, whereas other companies may struggle in building trust with consumers regarding ESG topics.

4. *Claims implied by the advertising context*: Beyond concrete express claims, consumers may perceive implied claims when viewing a

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[20] Press Release, Fed. Trade Comm'n, FTC Seeks Public Comment on Potential Updates to its 'Green Guides' for the Use of Environmental Marketing Claims (Dec. 14, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/12/ftc-seeks-public-comment-potential-updates-its-green-guides-use-environmental-marketing-claims.

[21] Press Release, Fed. Trade Comm'n, FTC Issues Revised "Green Guides" (Oct. 1, 2012), https://www.ftc.gov/news-events/news/press-releases/2012/10/ftc-issues-revised-green-guides.

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

> company's advertising. Accordingly, the Green Guides indicate that even if a company's claims about specific attributes are substantiated through evidence, marketers should be cautious and consider "if an advertisement's context implies other deceptive claims."[23]

Various methods can be used to assess consumer understanding and behavior tailored to the context of each case, including methods of empirical evidence such as conducting rigorous survey research of relevant consumers. Depending on the context and key allegations in each case, empirical research methods such as online survey experiments can provide crucial data to answer questions such as how general ESG advertising messaging affects consumers' perceptions of particular companies, brands, or products; whether and to what extent such messaging misleads consumers relative to the facts of the real world; and whether these ESG claims are material to consumers' decision-making. Such methods and frameworks, when appropriately designed, can be applied to both future litigations about specific claims or broader advertising claims (such as in *Earth Island Institute v. The Coca-Cola Company*).

[23] Guides for the Use of Environmental Marketing Claims, 77 Fed. Reg. 62,121, 62,122 (Oct. 11, 2012) (to be codified at 16 C.F.R. pt. 260).

# Defendants Beware: Did the Sixth Circuit Just Make Prescriber Testimony Irrelevant in Failure to Warn Cases?

**ANAND AGNESHWAR & JOCELYN WIESNER***

## I. WHY IT MADE THE LIST

It is axiomatic that a plaintiff bears the burden of proof on each element of her claim. In pharmaceutical and medical device failure to warn claims, this means the plaintiff must prove that 1) the product instructions were inadequate in some regard; and 2) had the instructions contained an alternative adequate warning, the prescribing physician would have made a different treatment decision. In nearly every case, the latter element requires affirmative testimony from the prescribing physician.

In *Thacker v. Ethicon, Inc.*, however, the Sixth Circuit ignored this longstanding framework, resolving ambiguities in the prescribing doctor's testimony in favor of the plaintiff and allowing plaintiff to defeat summary judgment on the basis of the plaintiff's expert opinion that a reasonable doctor would not have made the same decision if presented with the precise warnings at issue, despite prescriber testimony to the contrary.[1] There, the plaintiff sued the manufacturers of two different vaginal mesh devices, alleging that they caused a potpourri of injuries generally attributable to either (or both) devices. Despite testimony from the prescribing physician that, even knowing what he knows today, he believes the devices were "safe and effective treatments," the Sixth Circuit overturned the lower court's grant of summary judgment. The Sixth Circuit did not do so because the plaintiff pointed to affirmative prescriber testimony that the doctor would have made a different decision had the product instructions contained alternative warnings. Rather, the Sixth Circuit found that in the absence of testimony on that exact question, a jury could conclude from circumstantial evidence (i.e., the plaintiff's expert) that he would have acted differently.

The Sixth Circuit's decision contradicts the learned intermediary doctrine, suggesting (incorrectly) that "courts have struggled to pinpoint what kinds of evidence the plaintiff can or must use to support proximate causation at the summary judgment stage."[2] Not so. Healthcare providers are considered learned intermediaries who know how to read, interpret, and, when appropriate, disregard risk information contained in

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1 47 F.4th 451 (6th Cir. 2022).

2 *Id.* at 460.

a wide variety of available sources. In other words, healthcare providers make independent medical decisions on a case-by-case basis, and it is their recommendation—not the manufacturer's—that the patient relies on.[3] Accordingly, courts routinely apply a subjective standard, requiring plaintiffs to present testimony from the prescribing physician *who treated the plaintiff* that he or she would not have prescribed the product had it contained an adequate warning. If a plaintiff cannot produce clear testimony on this point, she cannot get to trial.

By allowing the plaintiff to defeat summary judgment through expert testimony of what a "reasonable physician would do," however, the Sixth Circuit adopted an objective standard whereby deficiencies in the prescriber's testimony inure to the benefit of the plaintiff and plaintiffs can get to trial without sufficient evidence to meet their ultimate burden of proof.

## II. DISCUSSION

### *A. The Facts*

This case stems from a 2009 surgery involving two medical devices: the TVT-Secur and the Prolift. The TVT-Secur is a mesh sling introduced in the late 1990's to treat stress urinary incontinence (SUI), the involuntary leakage of urine during physical activity such as coughing, laughing, or exercise.[4] The Prolift was launched several years later to treat pelvic organ prolapse (POP), a condition where weakened muscles in the pelvis cause organs to sag or drop into the vagina.[5] Like the TVT-Secur, the Prolift uses Prolene mesh.

Plaintiff, a 60-year-old woman, was diagnosed with POP and SUI and was surgically implanted with both devices. After surgery, however, plaintiff's symptoms worsened and she attempted to have the devices removed.[6] She was subsequently diagnosed with "debilitating pelvic pain due to vaginal mesh, severe dyspareunia, urinary frequency, and urinary dysfunction," which she alleged was caused by the TVT-Secur and Prolift.[7]

The plaintiff brought suit against the manufacturer of the devices, Ethicon, Inc., and its parent company Johnson & Johnson, in the Eastern District of Kentucky, alleging strict liability failure to warn and design defect under the Kentucky Product Liability Act (Ky. Rev. Stat. § 411.300) and negligence.[8] Her case was transferred to a multidistrict litigation in West Virginia, where it lingered for several years until it was eventually remanded back to the Eastern District of Kentucky.

Following remand, defendants filed a motion for summary judgment against each of plaintiff's claims. As to the failure to warn claims, defendants argued that plaintiff could not establish proximate causation because: 1) the prescribing doctor did not rely on the Information for Use (IFU) in making treatment decisions;[9] 2) the prescribing

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3 *See* Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (2004).

4 *Id.* at 455.

5 *Id.* at 455–56.

6 *Id.* at 456.

7 *Id.*

8 *Id.* at 457.

9 Thacker v. Ethicon, Inc., 571 F. Supp. 3d 691, 697 (E.D. Ky. 2021).

doctor was independently aware of the risks;[10] and 3) even if the doctor had read the IFU, "Plaintiff cannot establish that additional warnings would have altered [the doctor's] treatment decisions."[11]

### *B. Analysis and Holding*

#### *1. District Court*

The district court agreed with defendants.

Although the district court found that there was a disputed fact as to whether the physician had relied on the IFU—he testified at deposition that he "did not review the IFU with [plaintiff] as part of her risk analysis" but that he '"probably' reviewed and read the IFUs when training"—it held that it was undisputed that he would not have made a different treatment decision even if the IFU had contained additional warnings.[12] Here, defendants presented affirmative deposition testimony that the physician would not have made a different treatment decision.[13] Plaintiff offered no contrary testimony, but rather argued that she could rely on circumstantial evidence such as her expert's opinion.[14]

The district court held that plaintiffs' expert could not overcome affirmative doctor testimony. "[W]hen the defendant does present affirmative testamentary evidence that the doctor would not have changed his course of action with the additional warning, the plaintiff must present evidence to the contrary."[15] The district court accordingly granted defendants' motion for summary judgment.

#### *2. The Sixth Circuit*

Plaintiff appealed and the Sixth Circuit reversed and remanded.[16]

Because the parties did not dispute whether the IFU contained the relevant warnings, the Sixth Circuit's analysis centered on whether the prescribing physician would have used the same medical devices had the IFU contained different warnings.[17] The doctor testified at deposition that he "felt like that was certainly the best options [sic] for her circumstances," and that "even 'with the knowledge [he] ha[d] at the time of his deposition, he still believed that the Pelvic Mesh Devices 'were safe and effective treatments for . . . SUI and POP in women' back in 2009.'"[18]

Defendants maintained that only "testimony from the treating physician" could determine whether the doctor would have acted differently.[19] Plaintiff countered that because Kentucky's "substantial factor test" permits reliance on circumstantial evidence generally, she could satisfy her burden through expert testimony that no

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[10] *Id.* at 699.

[11] *Id.*

[12] 571 F. Supp. 3d 697–99.

[13] *Id.* at 702.

[14] *Id.* at 699.

[15] *Id.* at 702.

[16] Thacker v. Ethicon, Inc., 47 F.4th 451 (6th Cir. 2022).

[17] *Id.* at 460.

[18] *Id.* at 462.

[19] *Id.* at 461.

reasonable physician would have used the devices with adequate warnings.[20] The Sixth Circuit agreed with plaintiff.

Specifically, the Sixth Circuit found that the prescribing doctor's testimony was ambiguous because he did not explain what exact new information he had learned and had not testified specifically that "he would stand by his recommendation *had he received a complete and accurate IFU*."[21] Moreover, because the doctor had also testified that certain risk information would have "affected his risk-benefit analysis," the Sixth Circuit concluded that it was left with, at most, "a handful of arguably contradictory statements."[22] Accordingly, a "jury could . . . choose to believe that" no reasonable doctor would have implanted the plaintiff with the devices had the IFU contained adequate warnings on the basis of the expert's opinion. "In sum, the plaintiff must simply provide 'some evidence from which a jury might conclude that an adequate warning would have altered the conduct that led to the injury.'"[23]

## III. THE IMPACT

In traditional product liability failure to warn cases, the plaintiff bears the burden of proving that the defendant's failure to warn the plaintiff of some risk caused the plaintiff's injury. Like nearly every other state, however, Kentucky recognizes the learned intermediary doctrine, which relieves the manufacturer of its duty to warn the patient so long as it provides an adequate warning to the prescribing physician.

The Sixth Circuit's analysis got this wrong in two respects. First, it framed the question as: "(1) did the treating physician rely on the relevant warnings (i.e., the IFUs), and (2) would the evidence allow a jury to conclude that, had the manufacturer given a proper warning, *the plaintiff* likely would have followed a different course of treatment (i.e., would not have used the medical device)."[24] Indeed, although not the focus of the opinion, the Sixth Circuit went on to suggest that a plaintiff could defeat summary judgment by showing evidence that "the *plaintiff* would not have consented to, or elected to proceed with, the treatment.[25] Under the learned intermediary doctrine, however, the question is not about what the *plaintiff* would do, but rather whether the *prescribing doctor* would have acted differently "regardless of how or if the physician warns the patient."[26]

Second, the Sixth Circuit's decision to let this case proceed in the absence of affirmative prescriber testimony that he would not have used the medical devices in the face of different warnings essentially erased plaintiff's burden of proof. Although the prescribing doctor's testimony was not a model of clarity, the plaintiff assuredly did not elicit the type of affirmative prescriber testimony that usually defeats summary judgment. Here, the prescriber testified generally that had the defendants "disclosed certain risks, that additional information would have impacted the risk-benefit

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[20] *Id.* at 462.

[21] *Id.*

[22] *Id.*

[23] *Id.* at 461 (quoting Clark v. Danek Med., Inc., 1999 WL 613316, at *6 (W.D. Ky. Mar. 29, 1999).

[24] 47 F.4th at 460 (emphasis added).

[25] *Id.* at 461 (emphasis added).

[26] Larkin v. Pfizer, Inc., 153 S.W. 3d 758, 765 (Ky. 2004).

assessment for [plaintiff's] treatment plan."[27] That is a far cry from testifying that he would not have used the devices, particularly when he also testified that "even with the knowledge he had at the time of his deposition," he "*continued to believe that the TVT-Secur and Prolift were safe and effective treatment options*" for plaintiff.[28]

The Sixth Circuit further faulted defendants for failing to present the doctor with "every warning that [plaintiff] says should have been included in the IFUs." Because he had not been asked the precise question at deposition, plaintiff was given the benefit of the doubt and could point to her expert's opinion to fill the gap—i.e., the Sixth Circuit employed an objective standard about what a theoretical reasonable physician would do in order to let the plaintiff proceed.

Defendants might be left scratching their heads. At first glance, the Sixth Circuit's decision would appear to open the flood gates, allowing plaintiffs to get past clear prescriber testimony without any constraints on the type of evidence that they can use to defeat summary judgment. Taken to its limits, this would make it nearly impossible for a defendant to win at summary judgment. For example, could a plaintiff now overcome unequivocal prescriber testimony that, even with plaintiffs' exact proposed warning, she would have made the exact same treatment decision simply by pointing to an expert's opinion or the plaintiff's own testimony? We think not.

First, this appears to be a case of a federal court getting out ahead of state courts. The Sixth Circuit suggested that there is some growing controversy over how plaintiffs can satisfy their burden of proof in the context of the learned intermediary, relying on another federal court in the Eastern District of Kentucky—*Corder v. Ethicon, Inc.*—for the proposition that prescriber testimony is not necessary.[29] The learned intermediary doctrine has been employed for decades, however, to appropriately balance a manufacturer's duty to warn with the well-established reality that doctors gather information from a variety of sources and are trained in how to make risk benefit analyses for their patients. That is why courts consistently look to the prescribing doctor's testimony to answer these critical questions. There is no reason to think the Kentucky Supreme Court won't do the same.

Second, we think this case will ultimately be limited to its facts. The plaintiff in *Thacker* successfully exploited the ambiguity in the prescriber's testimony, which allowed the court to conclude that a jury might disregard certain statements in favor of others. Indeed, the Sixth Circuit was careful to point out that the prescribing doctor's testimony was "not as strong as Ethicon suggests."[30] Had that ambiguity not existed, we aren't so sure the Sixth Circuit would have reached the same result.

In the meantime, defendants should be mindful when taking a physician's deposition and make sure they walk out of each prescriber's deposition with a clear record of how that doctor would have acted with plaintiff's alternative warnings.

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[27] 47 F.4th at 457.

[28] *Id.* (emphasis added).

[29] 473 F.Supp.3d 749 (E.D. Ken. 2020). In that case, the district court allowed the plaintiff to move forward on a failure to warn claim based on the plaintiff's (who was also a registered nurse) own testimony.

[30] 47 F.4th at 462. Likewise, we doubt the district court in *Corder* would have reached the same conclusion had the prescribing doctor provided clear testimony. In that case, *neither* plaintiff *nor* defendant deposed the prescribing physician, creating a complete vacuum of prescriber testimony. 473 F.Supp.3d at 578–59.

# Significant Digital Health and Cybersecurity Regulatory Developments, 2022

**STEPHANIE PHILBIN, STEVEN TJOE & LAUREN FARRUGGIA***

Throughout 2022, the U.S. Food and Drug Administration (FDA or the agency) continued to refine its frameworks for oversight of the digital health and broader device industry with important regulatory updates impacting device software and cybersecurity. The Food and Drug Omnibus Reform Act of 2022 (FDORA), included as part of the Consolidated Appropriations Act of 2023, also meaningfully impacted FDA's authority with respect to device cybersecurity.

## I. CLINICAL DECISION SUPPORT

On September 28, 2022, FDA published three final guidance documents impacting the digital health industry: Clinical Decision Support Software (the CDS Guidance);[1] Policy for Device Software Functions and Mobile Medical Applications;[2] and Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices.[3]

Of the three final guidances, the CDS Guidance is perhaps the most impactful. FDA clarified key concepts for determining whether clinical decision support (CDS) software is a medical device and meaningfully modified the agency's September 2019 draft guidance of the same name.[4] Specifically, the CDS Guidance provided FDA's interpretation of the four criteria established by the 21st Century Cures Act for determining whether a decision support software function is excluded from the definition of a device (i.e., is considered Non-Device CDS).[5] Most significantly:

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[1] U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 28, 2022), https://www.fda.gov/media/109618/download [hereinafter CDS GUIDANCE].

[2] U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 28, 2022), https://www.fda.gov/media/80958/download.

[3] U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE DATA SYSTEMS, MEDICAL IMAGE STORAGE DEVICES, AND MEDICAL IMAGE COMMUNICATIONS DEVICES, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 28, 2022), https://www.fda.gov/media/88572/download.

[4] Clinical Decision Support Software, Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 84 Fed. Reg. 51,167 (Sept. 27, 2019).

[5] A software function must meet all of the following four criteria to be considered Non-Device CDS:

> (1) Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device (IVD) or a pattern or signal from a signal acquisition system (Criterion 1);

(1) FDA elaborated on its interpretation of what it considers to be "medical images, signals, and patterns" under Criterion 1. From the agency's perspective:

> (a) "Medical images" include not only images generated by use of "medical imaging systems (e.g., computed tomography (CT), x-ray, ultrasound, and magnetic resonance imaging (MRI)) to view any part(s) of the body or images acquired for a medical purpose (e.g., pathology, dermatology)," but also images that were not "originally acquired for a medical purpose but are being processed or analyzed for a medical purpose."
>
> (b) "Signals" include those that typically require use of either an *in vitro* diagnostic device (IVD) or a "signal acquisition system that measures a parameter from within, attached to, or external to the body for a medical purpose."
>
> (c) "Patterns" mean "multiple, sequential, or repeated measurements of a signal or from a signal acquisition system."[6]

(2) The agency clarified that "medical information" under Criterion 2 is intended to be the type of information that normally is, and generally can be, communicated between health care providers (HCPs) in a clinical conversation or between HCPs and patients in the context of a clinical decision, meaning that the relevance of the information to the clinical decision being made is well understood and accepted.[7] Notably, FDA introduced the concept of "sampling frequency" as a consideration when determining whether information is considered "medical information" under Criterion 2 or a signal/pattern under Criterion 1.[8] FDA explained that a "single, discrete test or measurement result that is clinically meaningful" is medical information under Criterion 2, while "a more continuous sampling of the same information" is a pattern/signal under Criterion 1.[9]

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> (2) Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (Criterion 2);
>
> (3) Intended for the purpose of supporting or providing recommendations to a health care professional (HCP) about prevention, diagnosis, or treatment of a disease or condition (Criterion 3); and
>
> (4) Intended for the purpose of enabling such HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (Criterion 4).

CDS GUIDANCE, *supra* note 1, at 6.

6 *Id.* at 8.

7 *Id.* at 9.

8 *Id.*

9 *Id.* at 10.

> (3) FDA significantly expanded its interpretation of Criterion 3 by introducing the concepts of software automation bias and time-critical decision-making in determining whether a software function is intended for the purpose of supporting or providing recommendations to an HCP.[10]
>
> (4) The agency provided an updated and more granular explanation of its expectations for certain disclosures to enable HCPs to independently review the basis of a software's recommendations consistent with Criterion 4 by introducing specific software and labeling recommendations related to: identification of the product's intended use, the intended HCP user, the intended patient population, the required input medical information, and a plain language description of the underlying algorithm development and validation that forms the basis for the CDS implementation.[11]

FDA also provided numerous, specific examples of Non-Device CDS and software functions that are a device, including some examples that have potentially far-reaching implications. Industry response to the CDS Guidance has largely been critical. As 2023 progresses, industry will eagerly anticipate additional clarification from the agency.

## II. PRE-CERT PILOT PROGRAM

On September 28, 2022, FDA announced that its Pre-Cert Pilot Program was completed and released its report entitled, "The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings" (the Pre-Cert Report). FDA launched the Pre-Cert Pilot Program in 2017 to encourage the development of innovative technologies and explore methods of ensuring regulatory oversight of medical device software.[12] Ultimately, the Pre-Cert Report revealed that, throughout the Pre-Cert Pilot Program, the agency "encountered challenges with implementing the proposed approach under [its] current statutory authorities."[13] Further, FDA acknowledged that limiting participation to nine pilot participants, and only permitting formal implementation of approaches via the *de novo* classification process, did not result in many devices becoming available for consideration under the Pre-Cert Pilot Program.[14] The agency emphasized the need for new legislative authority targeted at device software to supplement the agency's existing regulatory pathways, although that legislative authority remains to be seen.[15] Nevertheless, FDA assured industry that the Center for Devices and Radiological Health's (CDRH) Digital Health Center for Excellence will continue to explore the tools available under its current authority to improve its oversight of medical device software.[16]

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[10] *Id.* at 11.

[11] *Id.*

[12] U.S. FOOD & DRUG ADMIN., THE SOFTWARE PRECERTIFICATION (PRE-CERT) PILOT PROGRAM: TAILORED TOTAL PRODUCT LIFECYCLE APPROACHES AND KEY FINDINGS 5 (Sept. 2022), https://www.fda.gov/media/161815/download.

[13] *Id.* at 3.

[14] *Id.* at 4.

[15] *Id.* at 14.

[16] *Id.* at 5.

## III. CYBERSECURITY

In December 2022, President Biden signed into law FDORA, which amends the Federal Food, Drug, and Cosmetic Act (FDCA) to ensure the protection of device cybersecurity.[17] The new FDCA provisions contemplate a category of devices called "cyber devices," which include software validated, installed, or authorized by a sponsor as the device itself or as part of a device, that has the ability to connect to the internet, and that contains technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.[18]

FDORA requires applicants submitting premarket submissions ninety days after the date of enactment of FDORA for devices meeting the definition of "cyber device" to include in their application a plan to monitor, identify, and address postmarket cybersecurity vulnerabilities and exploits as well as a software bill of materials, including commercial, open-source, and off-the-shelf software components; to design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device and related systems to address certain vulnerabilities; and to comply with any other applicable regulations that the agency may promulgate.[19]

FDORA also authorizes the agency to identify devices or categories of devices that are exempt from cybersecurity requirements, and adds noncompliance with these cybersecurity provisions to the prohibited acts enumerated under 21 U.S.C. § 331.[20] Finally, FDORA requires FDA to update its 2014 final guidance entitled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (Final Premarket Cybersecurity Guidance) within two years of enactment.[21]

Prior to FDORA's passage, the agency itself took steps to prioritize device cybersecurity. On April 8, 2022, FDA published its draft guidance entitled, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Draft Guidance for Industry and Food and Drug Administration Staff" (the Cybersecurity Draft Guidance).[22] The Cybersecurity Draft Guidance reflects the agency's latest attempt at replacing its Final Premarket Cybersecurity Guidance in response to a rapidly evolving technological landscape and emerging threats.

The Cybersecurity Draft Guidance reaffirms FDA's position that cybersecurity is a fundamental part of device safety. The agency introduces the Secure Product Development Framework (SPDF) as one option for manufacturers to ensure compliance with the Quality System Regulation.[23] The SPDF is intended to reduce the

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[17] Pub. L. No. 117-328 (2022) (FDORA).

[18] FDORA § 3305(a).

[19] *Id.*

[20] FDORA § 3305(b).

[21] FDORA § 3305(e); U.S. FOOD & DRUG ADMIN., CONTENT OF PREMARKET SUBMISSIONS FOR MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Oct. 2, 2014), https://www.fda.gov/media/86174/download.

[22] U.S. FOOD & DRUG ADMIN., CYBERSECURITY IN MEDICAL DEVICES: QUALITY SYSTEM CONSIDERATIONS AND CONTENT OF PREMARKET SUBMISSIONS DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Apr. 8, 2022), https://www.fda.gov/media/119933/download.

[23] *Id.* at 9.

number and severity of vulnerabilities and reduce the likelihood that a device will be exploited and includes recommended processes such as security risk management (including threat modeling and assessment of third-party software components), security architecture, and cybersecurity testing.[24]

FDA also outlines in the Cybersecurity Draft Guidance a framework for ensuring cybersecurity transparency. The agency suggests certain labeling recommendations for devices with cybersecurity risks, including the inclusion of any risks transferred to the user and consideration of such risks as tasks to be assessed during usability testing.[25] FDA also recommends that manufacturers develop vulnerability management plans and to submit such plans as part of the manufacturer's premarket submissions, including identification of responsible personnel; sources, methods, and frequency for monitoring for and identifying vulnerabilities; periodic security testing; identifying a timeline to develop and release patches; update processes; patching capability; a description of coordinated vulnerability disclosure process; and a description of how the manufacturer intends to communicate updates to customers.[26]

In addition, on October 7, 2022, FDA released a new video, "Tips for Clinicians - Keeping Your Patients' Connected Medical Devices Safe" to help clinicians discuss cybersecurity of connected medical devices with patients.[27] On November 15, 2022, the agency updated the "Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook" in collaboration with MITRE, which is intended to educate health care organizations to prepare for cybersecurity incidents before they occur.[28]

It is not yet clear how FDA will revise the Cybersecurity Draft Guidance in light of the new FDCA sections establishing requirements for cyber devices and FDORA's requirement for FDA to update its Final Premarket Cybersecurity Guidance. However, the Cybersecurity Draft Guidance is on the agency's A-List of prioritized guidance documents that CDRH intends to publish in fiscal year 2023, so industry should expect to have an answer relatively soon.

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[24] *Id.* at 13–28.

[25] *Id.* at 29.

[26] *Id.* at 31.

[27] *Cybersecurity*, U.S. FOOD & DRUG ADMIN. (content current as of May 1, 2023), https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity.

[28] MITRE, MEDICAL DEVICE CYBERSECURITY REGIONAL INCIDENT PREPAREDNESS AND RESPONSE PLAYBOOK, VERSION 2.0 (Nov. 2022), https://www.mitre.org/sites/default/files/2022-11/pr-2022-3034-medical-device-cybersecurity-regional-preparedness-response-playbook.pdf.

# 2022 Significant Settlements

VANESSA K. FULTON*

## I. INTRODUCTION

This chapter summarizes a selection of significant settlements (including non-litigated resolutions such as criminal plea bargains or agency consent orders) in 2022 between members of the food and drug industry and government agencies, such as the U.S. Food and Drug Administration (FDA) and the U.S. Department of Justice (DOJ). The enforcement authority of FDA and DOJ includes both civil penalties and criminal prosecution.

Consistent with last year's significant settlements chapter, a majority of these settlements arise from enforcement action brought by DOJ under the False Claims Act (FCA), which imposes liability on persons and companies who defraud governmental programs and contracts. However, this year, we also include several non-litigated resolutions (typically consent decrees) of enforcement actions brought by DOJ and FDA involving violations of the Federal Food, Drug, and Cosmetic Act (FDCA). These non-litigated resolutions primarily focus on issues related to manufacturing conditions, including failure to follow good manufacturing practice regulations.

Settlements under the FCA between DOJ and members of the food and drug industry focused on enforcement against entities that engaged in fraud related to healthcare services provided to patients.[1] This included, for example, fraud involving the payment of kickbacks to referring physicians, whether in cash or in kind, and the provision of medically unnecessary services improperly billed to federal healthcare programs.

Of note, as anticipated in last year's significant settlements chapter, in 2022 we saw the first two significant settlements involving healthcare-related FCA allegations arising out of COVID-19 relief programs. The first settlement resolved government allegations that Physician Partners of America LLC, a practice management company and its related health care entities, ordered unnecessary testing and billed for unnecessary appointments to increase revenue during the COVID-19 pandemic. The government also alleged that, while engaging in this illegal activity, the practice management company obtained a loan under the federal loan program created under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), and as a result falsely certified in its loan application that it was not engaged in illegal activity. The second settlement related to COVID-19 involved allegations that MorseLife Health

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[1] In 2022, roughly 77% of the federal government's recoveries under FCA judgments and settlements came from health care and life sciences companies, totaling approximately $1.7 billion. *False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022*, U.S. DEP'T OF JUST. (Feb. 7, 2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022.

System Inc., a corporation that oversees health care facilities including nursing homes and assisted living facilities, facilitated vaccinations for hundreds of individuals ineligible to receive vaccinations at a time when COVID-19 vaccines were in limited supply and intended only for long-term care facility residents and staff.

# I. FEDERAL FOOD, DRUG, AND COSMETIC ACT

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

## *A. Food*

### *1. Abbott Laboratories*[2]

Abbott Laboratories (Abbott) agreed to be bound by a proposed consent decree to resolve allegations that it violated the FDCA and good manufacturing practice (GMP) requirements by manufacturing powdered infant formula under conditions and using practices that failed to comply with regulations designed to ensure the quality and safety of infant formula, which led to the presence of *Cronobacter sakazakii* bacteria in environmental samples taken from Abbott's manufacturing facility.

Under the proposed consent decree, Abbott agreed to bring its manufacturing facility into compliance with the FDCA and GMP requirements and retain outside experts to assist Abbott in developing compliance plans to reduce and control the risk of bacterial contamination and periodically evaluate Abbott's facility for compliance with FDCA regulations and the consent decree.

## *B. Drugs*

### *1. Dr. Lindsey Clark*[3]

California doctor Lindsey Clark and her medical practice pled guilty to violating the FDCA by receiving and delivering misbranded drugs and misbranded adulterated devices. Clark specialized in procedures that use injectable drugs and devices for cosmetic purposes, such as Botox (injectable botulinum toxin) and hyaluronic acid fillers such as Juvederm.

The government alleged that Clark obtained injectable botulinum toxin and hyaluronic acid fillers that were not the subject of FDA licenses or approvals from sellers outside the United States and then used these unapproved drugs and devices on patients, representing that these products were FDA-approved products such as Botox and Juvederm. The government alleged that Clark purchased these products for $270,951 and received more than $1,069,880 in revenue from services rendered in connection with these products.

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[2] *Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula*, U.S. DEP'T OF JUST. (May 16, 2022), https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott.

[3] *Doctor Pleads Guilty to Using Misbranded and Adulterated Products Sold as Botox and Juvederm*, U.S. DEP'T OF JUST. (Nov. 28, 2022), https://www.justice.gov/opa/pr/doctor-pleads-guilty-using-misbranded-and-adulterated-products-sold-botox-and-juvederm.

### 2. *Morton Grove Pharmaceuticals*[4]

Morton Grove Pharmaceuticals, a manufacturer of over-the-counter (OTC) drugs such as cough syrups and nasal sprays, agreed to be bound by a consent decree to settle allegations that it violated the FDCA by manufacturing and distributing adulterated drugs. Specifically, the government alleged that Morton Grove Pharmaceuticals failed to have adequate procedures in place to prevent cross contamination of equipment, failed to reject drug lots using a contaminated ingredient, and failed to fully investigate the root cause of such contamination. The government also alleged that many of the violations were repeat violations that FDA had previously identified during five different inspections of the manufacturer's facility.

Under the consent decree, Morton Grove Pharmaceuticals is enjoined from violating the FDCA and is required, among other things, to cease manufacturing, processing, labeling, holding, or distributing adulterated drugs and destroy all drugs in the facility other than those that are medically necessary.

### 3. *Edge Pharm Inc.*[5]

Compounding pharmacy Edge Pharm Inc. agreed to be bound by a consent decree settling allegations that it violated the FDCA by manufacturing and distributing drugs under unsanitary conditions and failing to follow good manufacturing practice requirements. The government alleged that Edge Pharm manufactured injectable drugs intended to be sterile under non-sterile conditions and that FDA had previously inspected the Edge Pharm facility and identified several violations of the FDCA, including record-keeping violations, labeling inadequacies, improper airflow, structural disrepair, and mold in cleanroom suites.

Under the consent decree, Edge Pharm agreed to cease manufacturing and distributing drugs until it takes specific remedial measures to demonstrate compliance with federal law.

## II. FALSE CLAIMS ACT AND ANTI-KICKBACK STATUTE

Below is a review of some of the key FCA settlements between the food and drug industry and the government in 2022.

### *A. Drugs*

#### 1. *Mallinckrodt ARD LLC*[6]

Mallinckrodt ARD LLC agreed to pay $260 million to resolve allegations that it violated the False Claims Act by knowingly underpaying Medicaid rebates due for its

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[4] *District Court Enjoins Illinois Pharmaceutical Manufacturer from Making and Selling Adulterated Drugs*, U.S. DEP'T OF JUST. (Aug. 19, 2022), https://www.justice.gov/opa/pr/district-court-enjoins-illinois-pharmaceutical-manufacturer-making-and-selling-adulterated.

[5] *District Court Enjoins Vermont Pharmacy from Distributing Drugs Not Made in Compliance with FDCA*, U.S. DEP'T OF JUST. (June 13, 2022), https://www.justice.gov/opa/pr/district-court-enjoins-vermont-pharmacy-distributing-drugs-not-made-compliance-fdca.

[6] *Mallinckrodt Agrees to Pay $260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks*, U.S. DEP'T OF JUST. (Mar. 7, 2022), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-260-million-settle-lawsuits-alleging-underpayments-medicaid-drug.

drug and violated the Anti-Kickback Statute by using a foundation as a conduit to pay illegal co-pay subsidies.

Regarding the alleged violations of the False Claims Act, the government alleged that Mallinckrodt knowingly underpaid rebates for its drug, Acthar, from 2013 to 2020, by paying rebates for Acthar as if Acthar was a "new drug" first marketed in 2013, rather than a drug that had been approved since 1952. Treating Acthar as a "new drug" first marketed in 2013 significantly lowered Medicaid rebate payments for Acthar. As part of the settlement agreement, Mallinckrodt admitted that Acthar was not a new drug as of 2013 but rather was approved by FDA and marketed prior to 1990.

Regarding the alleged violations of the Anti-Kickback Statute, the government alleged that Mallinckrodt knowingly used a foundation to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as "free" to doctors and patients while at the same time increasing its price.

Under the settlement, Mallinckrodt agreed to pay approximately $234.7 million to resolve the Medicaid rebate allegations and approximately $26.3 million to resolve the kickback allegations. Also as part of the settlement, Mallinckrodt entered a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires Mallinckrordt to, among other things: 1) comply with unique drug price transparency provisions and monitoring provisions focused on Medicaid rebate and patient assistance program activities; 2) establish a risk assessment program, 3) implement executive recoupment provisions, and 4) obtain compliance-related certifications from company executives and board members.

#### *2. Biogen Inc.*[7]

Biogen Inc. agreed to pay approximately $900 million to resolve a lawsuit filed under the qui tam provisions of the False Claims Act by a former Biogen employee that alleged that Biogen violated the False Claims Act by causing submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce them to prescribe Biogen's multiple sclerosis drugs Avonex, Tysabria, and Tecfidera.

Specifically, the government alleged that Biogen offered health care professionals that attended Biogen's speaker programs renumeration in the form of speaker honoraria, speaker training fees, and consulting fees and meals in an effort to induce them to prescribe Biogen's multiple sclerosis drugs.

Biogen agreed to pay approximately $843.8 million to the United States and $56.2 million to the states. The former employee that brought the qui tam action against Biogen will receive approximately 29.6% of the federal proceeds from the settlement.

### *B. Medical Devices*

#### *1. Eargo Inc.*[8]

Eargo Inc., a company that sells and dispenses hearing aid devices directly to customers, agreed to pay $34.37 million to resolve allegations that it violated the False

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[7] *Biogen Inc. Agrees to Pay $900 Million to Settle Allegations Related to Improper Physician Payments*, U.S. DEP'T OF JUST. (Sept. 26, 2022), https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments.

[8] *Hearing Aid Company Eargo Inc. Agrees to Pay $34.37 Million to Settle Common Law and False Claims Act Allegations for Unsupported Diagnosis Codes*, U.S. DEP'T OF JUST. (Apr. 29, 2022),

Claims Act by submitting or causing to be submitted claims for reimbursement for hearing aid devices to the Federal Employees Health Benefits Program (FEHBP) that contained unsupported hearing loss diagnosis codes.

The government alleged that Eargo included unsupported hearing loss-related diagnosis codes on claims for reimbursement for its hearing aid devices that Eargo submitted to the FEHBP and on invoices that Eargo provided to FEHBP beneficiaries to obtain reimbursement for its hearing aid devices from the FEHBP. Further, the government alleged that Eargo continued to include these unsupported hearing loss-related diagnosis codes on claims and superbills even after completing an internal review of its billing and coding practices.

#### *2. Philips RS North America, LLC*[9]

Medical device manufacturer Philips RS North America, LLC, formerly Respironics, Inc., agreed to pay $24.75 million to resolve False Claims Act allegations that the company caused suppliers of medical equipment to submit false claims to Medicare and Medicaid by providing illegal inducements. Specifically, the government alleged that Respironics gave the suppliers physician prescribing data free of charge (to assist the suppliers in marketing to physicians) to induce the suppliers to purchase Respironics' ventilators, oxygen concentrators, CPAP and BiPAP machines, and other respiratory-related medical equipment. The government alleged that the suppliers would then submit claims for the medical equipment it purchased from Respironics to Medicare and Medicaid.

In addition to the civil settlement, Respironics entered into a five-year CIA with HHS-OIG that requires Respironics to implement and maintain a compliance program that includes review of referral sources and monitoring Respironics' sales force. The CIA also requires that Respironics retain an independent monitor to assess the new compliance program.

The settlement also resolved claims brought under the qui tam provisions of the False Claims Act by a former employee. As part of the settlement, the former employee will receive $4.3 million of the settlement amount.

### *C. Healthcare Services*

#### *1. Gold Coast Health Plan*[10]

Gold Coast Health Plan, a health system in California, and three of its providers agreed to pay a total of $70.7 million through three separate settlements to resolve claims that they violated the False Claims Act and the California False Claims Act by submitting or causing to be submitted false claims to California's Medicaid program

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https://www.justice.gov/opa/pr/hearing-aid-company-eargo-inc-agrees-pay-3437-million-settle-common-law-and-false-claims-act.

[9] *Philips Subsidiary to Pay Over $24 Million for Alleged False Claims Caused by Respironics for Respiratory-Related Medical Equipment*, U.S. DEP'T OF JUST. (Sept. 1, 2022), https://www.justice.gov/opa/pr/philips-subsidiary-pay-over-24-million-alleged-false-claims-caused-respironics-respiratory.

[10] *California County Organized Health System and Three Health Care Providers Agree to Pay $70.7 Million for Alleged False Claims to California's Medicaid Program*, U.S. DEP'T OF JUST. (Aug. 18, 2022), https://www.justice.gov/opa/pr/california-county-organized-health-system-and-three-health-care-providers-agree-pay-707.

under the Medicaid Adult Expansion under the Patient Protection and Affordable Care Act.

Specifically, the United States and California alleged that Gold Coast Health Plan and its providers submitted claims for payments that were not for "allowed medical expenses," were for amounts that did not reflect fair market value, and were duplicative and unnecessary services.

Under the three settlements, Gold Coast Health Plan will pay $17.2 million to the United States, and the providers will pay $51.05 million to the United States and $2.45 million to the State of California. Gold Coast Health Plan and one of the providers also agreed to enter into five-year CIAs that require implementation of a centralized risk assessment program as part of a compliance program and to hire an independent review organization to complete annual reviews.

The settlement also resolved claims brought under the qui tam provisions of the False Claims Act by two former employees.

### *2. Providence Health & Services Washington*[11]

The largest health care fraud settlement in the Eastern District of Washington, Providence Health & Services Washington (Providence), a health care and hospital system, agreed to pay $22.7 million to resolve allegations that it billed federal health care programs for deficient and medically unnecessary neurosurgeries.

Specifically, the government alleged that Providence paid neurosurgeons based on a productivity metric that resulted in a significant financial incentive to perform more surgical procedures of greater complexity. The government alleged that, in response to this productivity metric, two neurosurgeons at Providence conducted medically unnecessary neurosurgery procedures.

As part of the settlement, Providence admitted that medical personnel at Providence expressed concern that the two neurosurgeons were, among other things, endangering patient safety, creating an excessive level of complications and negative outcomes through their unnecessary surgeries, performing surgery on candidates who were not appropriate for surgery, submitting medical documentation with falsified and exaggerated diagnoses, performing more complex surgeries than were medically appropriate, and failing to properly document their procedures and outcomes.

Providence also agreed to enter into a CIA that requires, among other things, that Providence implement and maintain a number of quality-of-care and patient safety obligations and retain outside experts annually to review claims and clinical quality systems.

### *3. Physician Partners of America LLC*[12]

Physician Partners of America LLC (PPOA), a practice management company, several health care entities managed by PPOA, and PPOA's former chief medical officer agreed to pay $24.5 million to resolve allegations that they billed federal health

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[11] *Providence Health & Services Agrees to Pay $22.7 Million to Resolve Liability From Medically Unnecessary Neurosurgery Procedures at Providence St. Mary's Medical Center*, U.S. ATTY'S OFFICE, E.D. WASH. (Apr. 12, 2022), https://www.justice.gov/usao-edwa/pr/providence-health-services-agrees-pay-227-million-resolve-liability-medically.

[12] *Physician Partners of America to Pay $24.5 Million to Settle Allegations of Unnecessary Testing, Improper Remuneration to Physicians and a False Statement in Connection with COVID-19 Relief Funds*, U.S. DEP'T OF JUST. (Apr. 12, 2022), https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper.

care programs for unnecessary urine, psychological, and genetic testing and scheduled unnecessary telehealth appointments for the sole purpose of increasing revenue during the COVID-19 pandemic.

The government alleged that PPOA instructed its physician-employees to order multiple urine tests without confirming that the tests were necessary and to order psychological and genetic testing before confirming whether the physicians actually intended to use the results of the testing. The government also alleged that, at the start of the COVID-19 pandemic, PPOA directed its employees to schedule unnecessary telehealth appointments with its patients every fourteen days, instead of every month as had been PPOA's practice before the COVID-19 pandemic, to compensate for lost revenue. The government alleged that PPOA instructed its employees to bill the additional telehealth visits using inaccurate procedure codes.

The government also alleged that, at the time PPOA was engaged in this conduct, it obtained a loan under the Paycheck Protection Program (PPP), a federal loan program created under the CARES Act, and as a result falsely certified in its PPP loan application that it was not engaged in illegal activity.

The settlement also resolved claims brought under the qui tam provisions of the False Claims Act by several former employees.

### *4. Metric Lab Services, LLC*[13]

Three clinical laboratories and two owners and operators agreed to pay $5.7 million to resolve allegations that the laboratories and the owners submitted false claims to federal health care programs by using third-party marketers to encouraging physicians to fraudulently submit genetic testing as medically necessary.

Specifically, the government alleged that the laboratories used third-party marketers to solicit genetic testing samples from Medicare beneficiaries. The government alleged that the third-party marketers would encourage physicians to submit genetic testing for Medicare beneficiaries through one of the three laboratories, despite the fact that the genetic testing was medically unnecessary. The laboratories would then process the tests, receive reimbursements from Medicare, and pay a portion of the reimbursement to the third-party marketers. The government further alleged that the laboratories attempted to conceal the fraudulent activity by entering into sham agreements with the marketers to provide various consulting and marketing services at an hourly rate, when in reality the laboratories paid the marketers a percentage of revenue in return for soliciting unnecessary genetic testing. For example, the government alleged that the marketers would submit "invoices" to the laboratories for hourly services, but the amounts on the invoice matched the agreed-upon amount that the marketers would receive in exchange for each genetic test.

### *5. MorseLife Health System Inc.*[14]

MorseLife Health System Inc. (MorseLife), a corporation that oversees health care facilities including a nursing home and an assisted living facility, agreed to pay $1.75

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[13] *Metric Lab Services, Metric Management Services LLC, Spectrum Diagnostic Labs LLC, and Owners Agree to Pay $5.7 Million to Settle Allegations of False Claims for Unnecessary Genetic Testing*, U.S. DEP'T OF JUST. (July 22, 2022), https://www.justice.gov/opa/pr/metric-lab-services-metric-management-services-llc-spectrum-diagnostic-labs-llc-and-owners.

[14] *MorseLife Nursing Home Health System Agrees to Pay $1.75 Million to Settle False Claims Act Allegations for Facilitating COVID-19 Vaccinations of Ineligible Donors and Prospective Donors*, U.S.

million to resolve allegations that it violated the False Claims Act by distributing COVID-19 vaccinations to over 500 ineligible individuals.

Specifically, the government alleged that MorseLife facilitated COVID-19 vaccinations for hundreds of individuals ineligible to receive vaccines under the Centers for Disease Control and Prevention's Pharmacy Partnership for Long-Term Care Program, a program to vaccinate long-term care facility residents and staff when doses of the COVID-19 vaccine were in limited supply. The government alleged that MorseLife facilitated vaccination for hundreds of ineligible persons (including board members, donors, and friends of board members and donors) by characterizing them as "staff" and "volunteers."

## III. CONCLUSION

These settlements illustrate the government's commitment to combatting fraud in the food and drug space, including health care services. In 2022 we saw the first two significant settlements involving the COVID-19 Fraud Enforcement Task Force and anticipate that the government will continue to prioritize health care fraud related to COVID-19. We also expect that the government will continue to focus on enforcement actions against manufacturers of food and drug products that violate the FDCA, including violations of GMP requirements.

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DEP'T OF JUST. (June 30, 2022), https://www.justice.gov/opa/pr/morselife-nursing-home-health-system-agrees-pay-175-million-settle-false-claims-act.

# Food and Drug Cases to Watch in 2023*

We asked our Top Cases chapter authors for their picks on which current litigations, regulatory actions, and other developments have the potential to change the food and drug landscape in the balance of 2023. 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.

## LOPER BRIGHT ENTERPRISES V. RAIMONDO[1]

Whether federal courts should defer to an agency's construction of an act of Congress will be revisited by the U.S. Supreme Court during its October Term 2023. In 1984, a unanimous 6–0 Court adopted the two-step "Chevron deference"—which prescribed that a federal agency's construction of a statute it administers is not to be upset by a court unless either: 1) Congress already directly addressed the question at issue, or 2) the agency's construction is not a permissible one.[2] The first Chevron "step" checks for legislative silence or ambiguity; the second "step" tests for reasonableness. The Court had reasoned that in empowering an agency to administer its law, the legislature may have delegated both policy formulation and "the making of rules to fill any gap left, implicitly or explicitly, by Congress."

The petitioner (a commercial fishing firm) challenged rulemaking by a federal agency charged with administering a law intended to protect against overfishing. That law requires fishing vessels to make room for federal observers, among other requirements. Notwithstanding that New England herring fishing was not one of the three settings where Congress had expressly authorized imposition of observer costs, the agency invoked its "necessary-and-appropriate" authority to impose those costs on New England herring fishing vessels. A divided 2–1 panel of the U.S. Court of Appeals for the D.C. Circuit ruled that Congress had provided "no wholly unambiguous answer" on the matter and that the agency's fee impositions were not an impermissible construction of Congress' statute. The Supreme Court granted certiorari on two issues: should Chevron deference be overruled or, alternatively, should Congress' silence on the use of an authority granted by its statute inapplicably elsewhere foreclose judicial deference to an agency's construction of that law?

## SHEARS V. ETHICON, INC.[3]

In April 2023, the Fourth Circuit Court of Appeals certified to the Supreme Court of Appeals of West Virginia the following question:

> Whether Section 411 of the West Virginia Pattern Jury Instructions for Civil Cases, entitled "Design Defect—Necessity of an Alternative,

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

1 No. 22-451 (Sup. Ct.), appeal from 45 F.4th 359 (D.C. Cir. 2022).

2 *See* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843–44 (1984) (Marshall, Rehnquist & O'Connor, JJ., not participating).

3 No. 22-1399 (4th Cir. 2023), appeal from No. 1:20-cv-00264-IMK (N.D. W. Va.).

> Feasible Design," correctly specifies the plaintiff's burden of proof for a strict liability design defect claim pursued under West Virginia law.
>
> More specifically, whether a plaintiff alleging a West Virginia strict liability design defect claim is required to prove the existence of an alternative, feasible product design—existing at the time of the subject product's manufacture—in order to establish that the product was not reasonably safe for its intended use. And if so, whether the alternative, feasible product design must eliminate the risk of the harm suffered by the plaintiff, or whether a reduction of that risk is sufficient.

The appeal to the Fourth Circuit followed the award of summary judgment to the defendant on the design defect theory in a pelvic mesh product liability case because the plaintiff couldn't meet the current West Virginia standard for proof of alternative design, by contrast with which the actual product could be ruled deceptive. The question certified by the Fourth Circuit describes West Virginia's "Elimination Mandate," under which a plaintiff alleging a design defect "must prove that there was an alternative, feasible design that eliminated the risk that injured" the plaintiff. The district court held, in granting summary judgment, that plaintiff had not proven the existence of an alternative design meeting these two criteria of 1) feasibility and 2) elimination, as opposed to mere reduction, of the possibility of the type of injury complained of.

## MELINTA THERAPEUTICS, LLC V. FOOD AND DRUG ADMINISTRATION[4]

In this matter arising out of a Hatch-Waxman case, Melinta sued FDA to suspend approval of an Abbreviated New Drug Application (ANDA) filed by a generic entrant with respect to Melinta's drug Minocin, which treats bacterial infections. The district court granted a temporary restraining order and preliminary injunction for Melinta because, it held, the generic manufacturer's notice was insufficient, due to FedEx's COVID-19 contactless delivery policy. Melinta claimed that it did not have actual notice until March 31, 2021, rather than December 8, 2020, when the notice was delivered.

Co-defendant Nexus Pharmaceuticals has appealed the case to the D.C. Circuit Court of Appeals. We will be watching this case for its implications for sufficient notice of the filing of an ANDA.

## NISSAN CHEMICAL CORPORATION V. FOOD AND DRUG ADMINISTRATION[5]

*Nissan Chemical Corp. v. FDA* is an Administrative Procedures Act challenge by Merck (and related entities) regarding FDA's determination of the regulatory review period for patent term restoration for the animal drug BRAVECTO. The case was under voluntary remand to FDA for much of last year but was recently reinvigorated. The government answered the recently amended complaint and filed the

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[4] No. 22-5288 (D.C. Cir.), appeal from No. 1:22-cv-02190 (D.D.C.).

[5] No. 1:22-cv-01598 (D.D.C.).

administrative record at the end of last month, and summary judgment filings are underway.

## AMA SYSTEMS, LLC V. FOOD AND DRUG ADMINISTRATION[6]

Plaintiff filed this complaint against FDA for failure to respond to a Freedom of Information Act (FOIA) request within twenty-four months. FDA answered the Complaint in April 2023. FDA's defense appears to be, in part, that the complained-of delay happened in the midst of COVID. This case is worth watching for a potential indication of how responsive the agency is required to be to FOIA requests.

## ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS V. FOOD AND DRUG ADMINISTRATION[7]

This is an APA case brought by Public Citizen and NRDC, among others, alleging that FDA's determination to allow the continued use of medically important antibiotics for disease prevention in healthy livestock and poultry was arbitrary and capricious, citing concerns about the contribution to the creation of antibiotic-resistant bacteria that can be transferred to humans. NRDC asserts that "the ability of disease-causing bacteria to withstand the drugs designed to kill them is one of the greatest threats to public health today."[8]

Plaintiffs in this case claim that "many" of the antibiotics used in these animals are not used to treat sick animals, but rather prevent diseases caused by the unsanitary and stressful conditions in which they are often kept. As they put it, "The FDA has shirked its duty to ensure that the use of drugs in food-producing animals is safe for human health,"[9] although their case alleges not that the antibiotics are directly harmful to humans through ingestion, but rather that they contribute more generally to a human health hazard by creating an environment where bacteria are more resistant and antibiotics less effective. The case is worth watching for the viability of this unconventional theory.

FDA must file its answer by May 24, 2023.

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6 No. 8:23-cv-00489 (D. Md.).

7 No. 8:23-cv-00176 (D. Md.).

8 *Alliance of Nurses for Healthy Environments et al. v. FDA et al. (Antibiotic Resistance)*, NRDC (Jan. 24, 2023), https://www.nrdc.org/court-battles/alliance-nurses-healthy-environments-et-v-fda-et-antibiotic-resistance.

9 *Id.*