Top Food and Drug Cases, 2017, & Cases to Watch, 2018

Edited by August T. Horvath

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Contents

Introduction

AUGUST T. HORVATH*

The slim volume in your hands is the distillation, by a selection of seasoned practitioners from leading law firms, universities, and public interest organizations, of the top legal and enforcement matters that we collectively reckoned to be among the most influential of 2017 and early 2018. But there is much more here than summaries of ten cases. The authors have situated each case in its legal or regulatory context, citing and discussing other recent and not-so-recent matters that contribute to the state of play. In addition, we have chapters discussing significant litigation and enforcement settlements and significant regulatory and enforcement actions of the past year. The authors also teamed up to nominate and discuss the currently ongoing cases that were expected to yield significant decisions and results in the months following our time of press.

Food and drug law might seem a narrow topic, but to my mind, the most impressive thing about this book is its breadth. It covers food, drugs, dietary supplements, medical devices, and tobacco products, and when appropriate, our team has not hesitated to discuss cases outside of the food and drug area that are important developments in areas of law that strongly impact practice the FDA product arena. Conversely, many of the legal issues described in this book have much more general applicability. *Bristol Myers Squibb v. Superior Court of California* deals with jurisdictional issues important to anyone litigating a class action, for example, and *Eike v. Allergan* has broad applicability in consumer deception cases. Core issues in FDA law continue to be aired in the courts; two significant examples in this volume are *Sandoz v. Amgen*'s interpretation of the Biologics Price Competition and Innovation Act and *T.H. v. Novartis*' entry in the controversy over who, if anyone, is legally responsible for failure to warn for a generic drug when the original brand maker is no longer in a position to update the labeling.

As a first-time editor of this volume, I extend an especially heartfelt thanks to our team of authors, many of whom have contributed to past editions, and are such seasoned pros at producing this book that such little coaching as was necessary flowed mainly from them to me! They are to be commended not only for making our editorial task painless, but for producing such insightful, thoroughly researched summaries of the "top ten" influential cases affecting FDA-regulated products over the past twelve months.

But don't take my word for it. Read on!

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Sandoz v. Amgen: Biosimilar Act Disclosure Obligations Not Enforceable by Injunction—Anywhere

LYNN C. TYLER*

WHY THESE TWO CASES MADE THE LIST

The Supreme Court's first encounter with the Biologics Price Competition and Innovation Act (BPCIA) came last year in *Sandoz, Inc. v. Amgen, Inc.*[1] The BPCIA was enacted in 2009 as part of the Patient Protection and Affordable Care Act, a/k/a ObamaCare, and created a regulatory pathway for the approval of "biosimilars," biologic medicines that are highly similar to previously approved biologics. It has been estimated that biosimilars will save consumers, including the federal government, billions of dollars over the next ten years. The BPCIA also includes an elaborate (but ambiguous) set of provisions governing litigation of patent disputes related to biologics and two of them were the subject of the Supreme Court's decision and a decision by the Federal Circuit on remand.

DISCUSSION

Statutory Background

Some background on the BPCIA is helpful to understand the issues in the cases. The BPCIA's litigation provisions are known as the "patent dance" because they set forth several steps in which owners of an original biologics license application (BLA), called "reference product sponsors" (sponsor) in the BPCIA, and biosimilar applicants (applicants) can engage before commencing any patent infringement litigation.[2] The dance begins when the applicant submits an application to FDA for approval of a biosimilar drug. The statute states that "[w]hen a subsection (k) applicant submits an application" to FDA, the applicant "shall" give a copy of the application to one in-house lawyer for the sponsor and to outside counsel for the sponsor, subject to certain confidentiality restrictions. Later, the statute states that the copy of the application "shall" be provided to the sponsor "[n]ot later than 20 days after the Secretary [through the FDA] notifies the subsection (k) applicant that the application has been accepted for review." In addition, at that point the applicant "shall" also provide "such other information that describes the process or processes used to manufacture the biological product that is the subject of the application."

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1 137 S. Ct. 1664 (2017).

2 *See* 42 U.S.C. § 262(l) (2017).

The next step is that, within 60 days after the receipt of the application and manufacturing process information, the sponsor must provide the applicant with a list of patents which the sponsor believes "could reasonably be asserted" and identify any that are available for license. Sixty days after receiving the sponsor's list of patents, the applicant must provide the sponsor with (1) its own list of patents that it believes could be asserted, and either (2) a detailed statement, on a claim by claim basis, of the factual and legal basis why each patent on the sponsor's and applicant's (if any) list(s) is invalid, unenforceable, or would not be infringed, or (3) a statement that the applicant does not intend to market the product before the patent expires. These lists are referred to as "Paragraph 3" lists based on their position in the statute. The applicant must also provide a response to the sponsor's indication of patents that are available for license. The final step in this phase is that, within 60 days of receiving the applicant's detailed statement, the sponsor must provide its own detailed statement, again on a claim by claim basis, of the factual and legal basis why each patent will be infringed and a response to the applicant's statement on validity and enforceability.

After providing a relatively brief period for the parties to agree on patents to be litigated, if the parties cannot agree, the statute goes on to prescribe another set of steps in the pre-litigation dance. The first of these is that the applicant notifies the sponsor of the number of patents the applicant will include on a list of patents to be litigated. Five days later, the parties simultaneously exchange lists (referred to as "Paragraph 5 lists") of patents that each believes "should be the subject of an action for patent infringement." The number of patents on the sponsor's list cannot exceed the number on the applicant's list, unless the applicant's list does not include any patents, in which case the sponsor can list one patent.

Whether the parties agreed on a list of patents to be litigated or exchanged lists, within thirty days of completing the applicable process the sponsor must file an infringement suit. If the parties agreed on patents to be included, the sponsor's suit must include those patents. If the parties did not agree, the sponsor's suit must include all the patents on the Paragraph 5 lists.

Another section of the statute provides that the applicant must give the sponsor 180 days advance notice of its intention to begin commercial marketing of the biosimilar. Between its receipt of the notice and the expiration of the 180 days, the sponsor can seek a preliminary injunction against sales of the applicant's biosimilar based on any patent that (1) was included on a Paragraph 3 list but (2) was not included on either an agreed list of patents for litigation or a Paragraph 5 list (or, under another section of the statute, based on a patent that issued or was licensed after the sponsor created its Paragraph 3 list).

Factual and Procedural Background

The underlying case arose out of Sandoz's application for approval of a biosimilar to Amgen's NEUPOGEN® (filgrastim), a granulocyte colony stimulating factor (G-CSF) protein. In July, 2014, Sandoz became the first company to have FDA accept an application for a biosimilar. FDA's acceptance of Sandoz's application should have cued the music for the patent dance to begin, but instead Sandoz left Amgen on the sidelines. According to Amgen's Complaint, Sandoz "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of FDA's notification of acceptance." Amgen further alleged that, in a subsequent letter, Sandoz wrote that

Amgen's "next step under the BPCIA can only be starting a declaratory judgment action as specified in that statute."

Amgen alleged a variety of harms from Sandoz's conduct and sought several remedies. Amgen's first claim was for an alleged violation of California's unfair competition statute. Amgen alleged that the violation deprived it of information it would receive under the BPCIA's provisions and the right to seek a preliminary injunction. Amgen also alleged several economic injuries, including the cost of monitoring and responding to Sandoz's actions, and lost profits and increased costs if Sandoz was allowed to market its competing biosimilar.

Amgen's second claim was for conversion. Amgen alleged that its BLA for NEUPOGEN® is property and Sandoz was converting that property by basing the biosimilar application on the BLA without Amgen's permission and without complying with the BPCIA litigation provisions. Amgen alleged that the conversion diminished the value of the BLA and that it would also suffer lost sales and market share. Amgen sought to recover the costs of monitoring and responding to Sandoz's actions. Amgen alleged Sandoz's actions were oppressive and malicious and sought punitive damages.

Amgen's third and final claim was for infringement of U.S. Patent No. 6,162,427, titled "Combination of G-CSF With a Chemotherapeutic Agent for Stem Cell Mobilization." Amgen sought an injunction restoring the benefits it would have received under the BPCIA litigation provisions and against the manufacturing of Sandoz's biosimilar.

Supreme Court's Decision

The Supreme Court's decision involved two of the steps in the patent dance, (1) turning over the application and manufacturing information and (2) providing the notice of commercial marketing. First, the Court addressed "whether the requirement that an applicant provide its application and manufacturing information to the manufacturer of the biologic is enforceable by injunction" and concluded that "an injunction is not available under federal law."[3] The Court remanded to the Federal Circuit to decide whether an injunction is available under state law. Second, the Court considered "whether the applicant must give notice [of commercial marketing] to the manufacturer after, rather than before, obtaining a license from FDA for its biosimilar" and held that "an applicant may provide notice before obtaining a license."[4]

With respect to the availability of an injunction to enforce the provision for turning over the application and manufacturing information, the Court wrote that a specific provision of 42 U.S.C. § 262, § 262(l)(9)(C), provides a remedy for an applicant's failure to turn over its application and manufacturing information. That subsection authorizes the sponsor, but not the applicant, to bring an immediate declaratory judgment action for artificial infringement as defined in 35 U.S.C. § 271(e)(2)(C)(ii). The Court held, "The remedy provided by § 262(l)(9)(C) excludes all other federal remedies, including injunctive relief,"[5] reasoning that where "a statute expressly provides a remedy, courts must be especially reluctant to provide

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[3] 137 S. Ct. at 1669.

[4] *Id.*

[5] *Id*. at 1675.

additional remedies."[6] Because Congress expressly provided the declaratory judgment remedy, and did not expressly provide an injunctive remedy, the Court inferred that Congress did not intend to authorize an injunction, at least as a matter of federal law, to enforce the disclosure requirement.

On the second issue, the Court held that the language of the BPCIA allowed the biosimilar applicant to give the notice of commercial marketing before its biosimilar was approved, i.e., licensed, by FDA. The statute provides that the applicant must give "notice" at least 180 days "before the date of the first commercial marketing" and the "commercial marketing," in turn, must be "of the biological product licensed under subsection (k)."[7] The Court reasoned that because "of the biological product licensed under subsection (k)" modifies "commercial marketing" rather than "notice," the time of commercial marketing is when the biosimilar must be licensed. The Court found that the BPCIA's use of the word "licensed" merely reflects the fact that, on the date of the first commercial marketing, the product must be licensed. Accordingly, the applicant may provide notice either before or after receiving FDA approval.[8]

Federal Circuit's Decision

As noted above, the Supreme Court remanded the case to the Federal Circuit to decide in the first instance if Amgen could obtain an injunction to enforce the disclosure requirement based on one of its state law claims. The Federal Circuit held that "Sandoz did not forfeit its preemption defense and the BPCIA preempts state law remedies for an applicant's failure to comply with § 262(l)(2)(A)." After first deciding it would apply its own law to decide the question, [9] the court affirmed the district court's dismissal of Amgen's state law claims.[10]

On the merits of the preemption issue, the Federal Circuit noted that there are three types: express, field, and conflict. Because the BPCIA does not expressly preempt state law remedies, the court turned to field and conflict preemption. Under field preemption, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively."[11] Conflict preemption exists "where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[12] The court concluded that both field and conflict preemption barred Amgen's state law claims.

As to field preemption, the court began by noting that patents are "inherently federal in character" because a patent "originates from, is governed by, and terminates according to federal law."[13] Picking up on the Supreme Court's comment

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6 *Id*. (quoting Karahalios v. Federal Employees, 489 U. S. 527, 533, 109 S. Ct. 1282, 103 L. Ed. 2d 539 (1989)).

7 *Id*. at 1677 (quoting § 262(l)(8)(A)).

8 *Id*. (citing § 262(a)(1)(A)).

9 *Id*. at 1325.

10 Amgen, Inc. v. Sandoz Inc., 877 F.3d, 1315, 1320 (Fed. Cir. 2017).

11 *Id.* (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)).

12 *Id.*

13 *Id*. (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347 (2001)).

that the BPCIA is a "carefully crafted and detailed enforcement scheme" and its holding that § 262(l)(9)(C) excludes all other federal remedies,[14] the Federal Circuit concluded that the BPCIA's "comprehensive, carefully calibrated 'scheme of federal regulation . . . [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'"[15]

Turning to conflict preemption, the court observed that Amgen's attempt to enjoin Sandoz under state law to comply with the BPCIA's disclosure requirements would impose a penalty unavailable under federal law. This result would present a "conflict in the method of enforcement" between the BPCIA and state law and thereby create "an obstacle to the regulatory system Congress chose."[16] The Federal Circuit (again taking a cue from the Supreme Court) concluded that where "Congress made a deliberate choice not to impose" certain penalties for noncompliance with federal law, state laws imposing those penalties "would interfere with the careful balance struck by Congress."[17] To avoid this conflict, the court found that Amgen's state law claims were barred by conflict preemption as well.

IMPACT

At least one lesson from these cases is that things are not always as they seem. Starting from a statute that states a biosimilar applicant "shall provide" its application and manufacturing information to the innovator, the law is now that providing the application and manufacturing information is optional and the innovator cannot obtain an injunction to require the information to be provided. The entire "carefully calibrated" Congressional scheme for patent litigation involving biosimilars can be bypassed from the very beginning at the option of the biosimilar applicant.

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[14] 137 S. Ct. at 1375.

[15] *Id*. at 1328 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

[16] *Id*. at (quoting Arizona v. United States, 567 U.S. 387, 405-06 (2012)).

[17] *Id*.

Bristol-Myers Squibb Co. v. Superior Court of California

MARK E. HADDAD* AND NAOMI A. IGRA**

WHY IT MADE THE LIST

Bristol-Myers Squibb (*BMS*)[1] made the list because it reshaped the landscape for mass tort litigation. Many tort reformers considered that landscape distorted by the effects of "litigation tourism"—the practice of non-resident plaintiffs filing mass actions against non-resident defendants in a few jurisdictions that plaintiffs considered favorable for their cases. *BMS* restricted that practice. It reiterated that a state court may not assert specific jurisdiction over a non-resident plaintiff's claims against a non-resident defendant, unless the defendant's in-state conduct is connected to those claims.

The decision had an immediate impact. In many mass actions, the claims of non-resident plaintiffs were promptly dismissed. Those cases included actions against pharmaceutical manufacturers facing long battles in reputedly plaintiff-friendly jurisdictions, including Missouri, California, and Illinois.

Still, the full impact of *BMS* remains to be seen. In particular, the decision did not address whether federal courts should apply *BMS* in class actions and refuse to adjudicate the claims of non-resident class members against non-resident defendants. District courts have already begun to disagree about the answer to that critical question. The application of *BMS* in class action litigation will be an issue to watch in 2018 and beyond.

DISCUSSION

Background

Bristol-Myers Squibb (BMS) is the manufacturer of the anti-coagulant, Plavix. BMS is incorporated in Delaware and maintains substantial operations in New York and New Jersey. Between 2006 and 2012, BMS sold nearly 190 million Plavix pills in California. Those sales generated more than $900 million for BMS, representing roughly one percent of the company's nationwide revenue. BMS also operates laboratory facilities in California, employs California sales representatives, and maintains an office in Sacramento focused on state-government advocacy. But none of the work to develop, manufacture, or create a marketing strategy for Plavix took place in California.

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[1] Bristol-Myers Squibb Co. v. Superior Court of California, 137 S. Ct. 1773 (2017).

In March 2012, a group of 678 plaintiffs named across eight nearly-identical complaints filed suit against BMS in California state court, asserting false advertising and product liability claims related to Plavix. Eighty-six of the plaintiffs were California residents; the other 592 were residents of 33 other states. None of the non-resident plaintiffs alleged that they obtained Plavix from a California physician or that they were injured or treated in California.

BMS moved to quash service of summons as to the non-residents. The California Superior Court denied the motion, finding that California courts could exercise general jurisdiction because BMS engaged in what it considered "extensive activities" in California.[2] BMS sought review from the California Court of Appeal but to no avail.

The same day the California Court of Appeal denied BMS's writ of mandate, the U.S. Court decided *Daimler AG v. Bauman*.[3] In that case, the Court reiterated that general jurisdiction over a non-resident defendant exists only where a corporation is essentially at home. The Court explained that a corporation will generally be "at home" where it is incorporated or has a principal place of business.[4]

In light of *Daimler*, the California Supreme Court granted review and transferred the matter back to the Court of Appeal. The Court of Appeal issued a new decision, holding that BMS's forum activities did not suffice for general jurisdiction under *Daimler* but were sufficient to establish specific jurisdiction.

In a 4-3 decision, the California Supreme Court affirmed. It concluded that California courts had specific jurisdiction over BMS as to the non-residents' claims according to a "sliding scale" approach. Under that approach, "the more wide ranging the defendant's forum contacts, the more readily is shown a connection between the forum contacts and the claim."[5]

The majority found a sufficient connection because the resident and non-resident plaintiffs all asserted claims based on the same allegations about the same product, which BMS promoted through the same nationwide marketing program, and distributed through a California-based distributor. Applying the sliding scale, the majority concluded that was enough to establish specific jurisdiction.[6]

A vigorous dissent admonished the majority for undermining "the essential distinction between specific and general distinction."[7] In the dissenters' view the non-residents' claims arose from marketing and sales of Plavix in other states so there was no connection between their claims and any of BMS's activities in the forum. They argued that the majority's loose application of the sliding scale would undo *Daimler* for many corporate defendants and subject them to unconstitutional assertions of authority by California state courts.

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2 *Id.* at 1778.

3 571 U.S. 117 (2014).

4 *See id*.

5 Bristol-Myers Squibb Co. v. Superior Court, 1 Cal. 5th 783, 806 (2016) (quotation and citation omitted).

6 *See id.* at 804-805.

7 *Id.* at 817.

The U.S. Supreme Court Majority Opinion[8]

The U.S. Supreme Court agreed with the California dissenters and reversed the decision below. In an 8-1 opinion, the majority rejected the sliding-scale approach as "a loose and spurious form of general jurisdiction."[9] The Court reiterated that "a defendant's general connections with the forum are not enough," to establish specific jurisdiction "regardless of the extent of a defendant's unconnected activities in the State."[10] Specific jurisdiction requires "'an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State.'"[11] In other words, it requires "a connection between the forum and the specific claims at issue."[12]

Non-resident plaintiffs could not establish the requisite connection. "The mere fact that *other* plaintiffs were prescribed, obtained, and ingested Plavix in California—and allegedly sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the nonresidents' claims."[13]

BMS's contacts with a California distributor also did not satisfy the Court's requirement. As the Court made clear, a "'defendant's relationship with a third party, standing alone, is an insufficient basis for jurisdiction.'"[14] Because there was no allegation that the two defendants had engaged in "relevant acts" in California together, or that BMS was derivatively liable for the distributor's conduct, the "bare fact" that BMS had contracted with a California-based distributor was insufficient to establish specific jurisdiction.[15]

The Court acknowledged that its decision was based on considerations beyond the inconvenience of out-of-state litigation. There was also "the more abstract matter of submitting to the coercive power of a State that may have little legitimate interest in the claims in question."[16] A federal system demands that state courts respect the sovereignty of other States. For that reason, the Court held that federalism concerns "may be decisive" in the personal jurisdiction analysis.[17]

The Court concluded by emphasizing that plaintiffs from different states could still bring a consolidated action in a forum with general jurisdiction. It also expressly held open the question of whether its decision would apply with equal force to mass actions brought in federal courts; it said nothing about nationwide class actions.

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[8] The authors of this article were counsel to the Pharmaceutical Research and Manufacturers of America as *amicus curiae* in support of BMS.

[9] *BMS*, 137 S. Ct. at 1776.

[10] *Id*.

[11] *Id*. at 1780 (*quoting* Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. 915, 919 (2011)).

[12] *Id*.

[13] *BMS*, 137 S. Ct. at 1781 (emphasis in original).

[14] *Id.* at 1783 (citation omitted).

[15] *Id*.

[16] *Id.* at 1780.

[17] *Id.* at 1781.

In the Court's view, its decision did not represent a shift in its jurisprudence. Instead, a "straightforward application" of the Court's "settled principles" required reversal of the decision below.[18]

Justice Sotomayor's Dissent

Justice Sotomayor dissented. In her view, the majority departed from the Court's precedents to the detriment of individuals injured by the conduct of corporate defendants. All of the plaintiffs' claims related to the nationwide marketing and distribution of Plavix; that meant the claims were connected to BMS's activities in California. The burden of litigating the case would be minimal for BMS so it would not offend "traditional notions of fair play and substantial justice" to call BMS into California state court.[19] The Court's failure to measure the scope of the forum's jurisdiction according to the "yardstick" of fairness struck Justice Sotomayor as an unwarranted deviation from the Court's precedents and the purpose of the Due Process Clause.

Justice Sotomayor also expressed concern about the practical consequences of the majority's holding. She predicted that *BMS* would make it "profoundly difficult for plaintiffs who are injured in different States by a defendant's nationwide course of conduct to sue that defendant in a single, consolidated action."[20] The decision "hand[ed] one more tool to corporate defendants determined to prevent the aggregation of individual claims, and forces injured plaintiffs to bear the burden of bringing suit in what will often be far flung jurisdictions."[21] In her view, that could not be a result that due process requires.

IMPACT OF THE CASE

BMS was a victory for defendants in general and particularly those in the pharmaceutical industry. Several federal district courts quickly concluded that *BMS* limited their jurisdiction, and courts in reputedly plaintiff-friendly jurisdictions dismissed the claims of non-resident plaintiffs in multiple mass actions against drug manufacturers.

Whether *BMS* will have a similarly profound impact on nationwide class actions remains to be seen. Defendants across the country have argued that *BMS* prevents courts from exercising specific jurisdiction as to the claims of non-resident class members against a non-resident defendant. So far, the courts that have confronted the issue have reached conflicting conclusions.

Some read *BMS* as articulating Constitutional limits on jurisdiction that must apply in every case, including class actions. For example, a federal court in Illinois applied *BMS* to a consumer class action in *McDonnel v. Nature's Way Prods.*[22] There, the class representative alleged that the non-resident defendant misrepresented a product that she bought in Illinois. Applying *BMS*, the court found that it could assert specific jurisdiction only as to the claims of the named plaintiff

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[18] *Id.* at 1783.

[19] *See id* at 1785-89 (quotations and citations omitted).

[20] *Id.* at 1789.

[21] *Id*.

[22] 2017 U.S. Dist. LEXIS 177892 (N.D. Ill. Oct. 26, 2017).

and other Illinois purchasers; it could not adjudicate the claims of non-residents because those claims were unconnected to the defendant's activities in Illinois.[23]

Other courts have reached the opposite result in factually similar circumstances. In *Fitzhenry-Russel v. Dr. Pepper Snapple Grp.*,[24] a federal court in California considered the implications of *BMS* in a consumer class action alleging misrepresentations about a product that the class representative bought in California. But there, the court found that it only needed specific jurisdiction over the defendant as to the named plaintiffs' claims even if those plaintiffs represented a nationwide class. In its view, class actions are distinguishable from mass tort actions because unnamed class members are not considered parties for all purposes. Absent clear instruction from the Supreme Court, the district court refused to extend the reasoning in *BMS* to class actions.[25]

At the time of writing, no circuit court had reached the issue of whether *BMS* limits the jurisdiction of federal courts as to nationwide class claims against non-resident defendants. The issue will be one to watch for years to come.

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[23] *Id.* at **10-11.

[24] 2017 U.S. Dist. LEXIS 155654 (N.D. Cal. Sept. 22, 2017).

[25] *Id.* at **14-16.

T.H. v. Novartis Pharmaceuticals Corp.

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WHY IT MADE THE LIST

T.H. v. Novartis Pharmaceuticals Corp.[1] represents a significant departure from established product liability and innovator liability law. The case tackles two high-stakes theories of liability for brand-name manufacturers of pharmaceutical products: (1) whether they can be liable for injuries caused by a generic manufacturer's drug; and (2) whether that liability extends after the brand-name manufacturer transfers rights to the product and no longer makes or sells it. Nearly every court that has addressed these theories has rejected them. In *T.H.*, the California Supreme Court charted a different course. It held that a brand-name manufacturer can be liable for failure to update a label even when the plaintiffs used a generic version of the product, years after the brand-name manufacturer last held rights to it.

The Facts

Plaintiffs, fraternal twins, sued Novartis in California state court for negligence and negligent misrepresentation for alleged failure to warn of the risks of Brethine (generic name terbutaline), an asthma medicine that works by relaxing smooth muscle tissue. Novartis initially owned the rights to market Brethine in its oral form. In December 2001, however, Novartis transferred the New Drug Application (NDA) for Brethine to NeoSan Pharmaceuticals Inc., a wholly owned subsidiary of AAIPharma.[2]

Plaintiffs' mother, J.H., was hospitalized for premature labor in September 2007—nearly six years after Novartis divested Brethine—and was prescribed the generic version, terbutaline.[3] Terbutaline was not FDA-approved for such a use, and her prescription was thus off-label.[4]

Plaintiffs alleged that the terbutaline passed to them *in utero*, causing them to suffer neurological damage, including autism.[5] They claimed that pre-2001 studies questioned the efficacy of terbutaline to prevent preterm labor and demonstrated the risks of the drug to fetal brain development. They further alleged that Novartis knew or should have known this information and updated the label warning accordingly.

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1 407 P.3d 18, S233898 (Cal. Dec. 22, 2017).

2 *See id.*, slip op. at 9.

3 *Id.*, slip op. at 9-10.

4 *See id.*, slip op. at 7.

5 *Id.*, slip op. at 10.

Instead, they contended, Novartis falsely represented that terbutaline was safe and effective for pregnant women.

Novartis moved to dismiss on two grounds: First, that it did not owe Plaintiffs a duty of care because it did not manufacture the generic terbutaline ingested by Plaintiffs' mother; and second, that it was not the NDA holder when Plaintiffs' mother took terbutaline and thus had no ability or legal duty to update the product labeling.

The Holding and Analysis

Question 1: Did Novartis owe a duty to the users of generic terbutaline?

The California Supreme Court started its analysis with what it perceived as the central issue: Does a brand-name drug manufacturer have a duty to warn to users of generic drugs manufactured and marketed by other companies? The answer from the court was a resounding "yes."

Before diving into the court's analysis, some background on applicable federal regulations is necessary. A brand-name manufacturer is responsible for drafting, updating, and maintaining the warnings in a prescription drug label. In most circumstances, it must obtain FDA approval before changing the product labeling. However, an exception allows a brand-name manufacturer to change a label—prior to FDA approval—to add or strengthen warning information under certain circumstances[6] (i.e., a Changes Being Effected or CBE label change). A generic manufacturer, by contrast, must ensure only that its labeling is identical to that of the brand-name drug.[7] In *PLIVA, Inc. v. Mensing*, the U.S. Supreme Court ruled on this dichotomy between brand-name and generic manufacturers in a case brought against a generic.[8] Because generic manufacturers have a duty of "sameness" and cannot independently update product labeling, the Court held federal law preempts state tort claims based on generics' failure to warn.

In the wake of *Mensing*, plaintiffs' attorneys have brought cases against brand-name manufacturers for injuries allegedly caused by generic products. They argue that a brand-name manufacturer has a duty to warn users of both brand-name and generic products because it is reasonably foreseeable that the generic product labeling will be identical to that of the branded. Courts have almost universally rejected this argument, however, holding that only the seller or manufacturer of a product is liable for product liability claims.[9]

The result, in theory, should be no different under California product liability law.[10] But California courts have charted a different course. In *Conte v. Wyeth, Inc.*,[11] the California Court of Appeal rejected the widely accepted rule in

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6 *See* 21 C.F.R. 314.70(c).

7 *See* 21 U.S.C. § 355(j)(v).

8 564 U.S. 604 (2011).

9 *See, e.g.*, Strayhorn v. Wyeth Pharmaceuticals, Inc., 737 F.3d 378, 404-06 (6th Cir. 2013).

10 *See* O'Neil v. Crane Co., 53 Cal. 4th 335, 365-66 (2012) (manufacturer of valve cannot be liable for injuries caused by asbestos used to insulate valve because imposing liability on company for a product it did not manufacture or sell would "exceed the boundaries established over decades of product liability law").

11 168 Cal. App. 4th 89 (2008).

pharmaceutical product liability cases. In *Conte*, the plaintiff alleged that she developed tardive dyskinesia after taking the generic version of Reglan and alleged negligent misrepresentation by the brand-name manufacturer.

The court found that negligent misrepresentation claims turn, not on whether the defendant manufactured the product, but on whether the harm is foreseeable. According to the court, it is "eminently foreseeable" that a physician might prescribe a generic product in reliance on the branded labeling.[12] While *Conte* has not gained traction elsewhere, it formed the basis of the California Supreme Court's reasoning in *T.H.*

As in *Conte*, the court in *T.H.* held that a brand-name manufacturer's duty and potential liability hinges on the foreseeability of harm. Because generic manufacturers are bound by the requirement of "sameness," a brand-name manufacturer exercises "complete control" over the product label. It "knows to a legal certainty [] that any deficiencies in the label for its drug will be perpetuated in the label for its generic bioequivalent."[13] Thus, it is foreseeable that a doctor may rely on branded product labeling even when prescribing a generic product, and a brand-name manufacturer accordingly owes a duty of care to users of both the branded and generic product.

Policy concerns drove much of the court's analysis. The brand-name manufacturer is the only one in a position to change the product labeling, yet, the court reasoned, a brand-name manufacturer's incentive to do so "declines once the patent expires and generic manufacturers enter the market." With liability for generic products at stake, a brand-name manufacture will continue to update labeling with risk information, thus safeguarding patients.[14] At the same time, the court rejected concerns that it was effectively making brand-name manufacturers insurers for the entire market. It deemed its holding to apply in only "narrow circumstance" because generics can still be liable for manufacturing defects, for failing to meet the "sameness" requirement, or for promoting off-label.[15]

Question 2: Did Novartis continue to owe a duty of care after it transferred the NDA?

The court next turned to the thornier issue: the fact that Novartis had not held marketing rights to the product for six years before the alleged injury occurred. The court recognized that only the current NDA holder has the authority to update a product label.[16] Nor was there any doubt that Novartis had not held the NDA for years before plaintiffs' mother was prescribed terbutaline. Facing similar facts, other courts have held that the predecessor manufacturer is not liable, either because it does not owe a duty of care to the plaintiff or because its negligence is too remote from the plaintiff's injury to constitute proximate cause.[17]

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[12] *Id.* at 105.

[13] *See* T.H. v. Novartis, S233898 (Cal. Dec, 22, 2017), slip op. at 18.

[14] *See id.*, slip op. at 22.

[15] *Id.*, slip op. at 24.

[16] *See id.*, slip op. at 40.

[17] *See, e.g.*, In re Minnesota Breast Implant Litig., 36 F Supp. 2d 863 (D. Minn. 1998); Christian v. Minnesota Min. & Mfg. Co., 126 F. Supp. 2d 951 (D. Md. 2001); Lyman v. Pfizer, Inc., 2012 WL 2970627 (D. Vt. 2012).

But the California court once again framed this issue as one of foreseeability. Plaintiffs alleged that the terbutaline label was deficient in 2001 when Novartis transferred the label. The court reasoned that it was "reasonably foreseeable" that the new NDA holder, AAIPharma, would not update the label. According to the court, it was "at least plausible" that AAIPharma would not independently review the medical literature to determine if a label change was needed, but would instead rely on its predecessor for adequate labeling.[18] Further, Novartis could have predicted that AAIPharma would be "reluctant to add warnings about the risk to fetal brain development" in order to protect its market share of off-label prescriptions for premature labor.[19] And, the court found, any negligence by AAIPharma with respect to labeling updates was "reasonably foreseeable" and did not excuse Novartis from liability.

IMPACT

The California court's decision may embolden other courts looking to protect consumers of generic products. Indeed, the Supreme Court of Massachusetts issued one such opinion in March, holding that a brand-name manufacturer may be liable for reckless failure to warn because it would be unfair to leave generic drug users without legal recourse.[20]

There are holes in the court's rationale that other courts may not be so keen to ignore, however. For example, the court overstated Novartis' ability to change the label before it transferred the NDA. While the CBE process allowed Novartis to make unilateral labeling changes, it is far from clear that it could have used a CBE label change to add information about an *off-label* indication without prior approval from FDA.[21] In fact, FDA regulations specifically caution against any labeling that suggests a product can be used off label.[22]

Other courts may take particular issue with the application of predecessor liability in *T.H*, which thus far has met universal rejection. As noted in the concurring and dissenting opinion, after a divestiture, a brand-name manufacturer has no ability to change the label.[23] "Predecessor manufacturers have a right to presume successors will perform their duty and follow the law."[24] The majority's embrace of predecessor liability indefinitely extends a branded manufacturer's duty to warn.

While proximate cause perhaps could serve as a backstop to this indefinite liability, the court paid it no heed. It played up the weight of the evidence linking terbutaline to fetal health, leaving it to the dissenting judge to note that it was not until 2001—the same year in which Novartis transferred the NDA—that a long-term study first demonstrated a potential link between terbutaline and human

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[18] T.H. v. Novartis, S233898 (Cal. Dec, 22, 2017), slip op. at 43.

[19] *Id.* at *42.

[20] *See* Rafferty v. Merck & Co., Inc., 2018 WL 1354064 (Mass. Mar. 16, 2018).

[21] *See* 21 C.F.R. § 201.57(c)(6)(i) ("[a] specific warning relating to a use not provided for under the 'Indications and Usage' section *may be required by FDA*") (emphasis added).

[22] *See* 21 C.F.R. § 201.57(c)(2)(v) ("Indications or uses must not be implied or suggested in other sections of the labeling if not included in [the Indications] section.").

[23] *See* T.H. v. Novartis, S233898 (Cal. Dec, 22, 2017), slip op. dissenting opinion at 8.

[24] *Id.*, slip op. dissenting opinion at 5.

development.[25] Studies suggesting a link with autism did not appear until after Novartis transferred the NDA. The opinion provides no guidance as to when a failure to warn would be too attenuated or remote to be the proximate cause of an injury.

* * *

While *T.H. v. Novartis* may not change the shape of product liability law across the country, it certainly represents an expansion of liability in California. Proximate cause is traditionally considered a question of fact that is hard to address at the motion to dismiss stage. Thus, under the court's holding, a brand-name manufacturer is potentially exposed to perpetual liability for its products and the generic equivalents, whether it continues to manufacture the product or not.

Other courts considering these issues should not follow *T.H.*'s lead. Not only does this decision overturn a fundamental tenet of tort law, but it also expands innovator liability well beyond what a brand-name manufacturer can reasonably be expected to control. That expansion—particularly if followed elsewhere—could have consequences as companies consider whether to market innovative and much needed drugs.

[25] *See id.*, slip op. dissenting opinion at 6.

Eike v. Allergan, Inc.

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

Did you ever need just one "AA" battery? You can buy that size batteries in packages of four, or eight, or ten, or sixteen, or twenty, or twenty-four, or forty-eight, or eighty, or even a whopping box of one hundred and forty-four (presumably, for folks who own remote-control everything).

But what if you just needed one? The best a leading manufacturer seems able to do for you is a pack of two "AA" batteries. Concededly, that's better. But still, you just needed one.

And it's not just batteries. Why are *Cuties* mandarin oranges always sold in a netted sack in groups of twenty? What if you don't want twenty? Why do those little plastic creamer cups that restaurants serve you with your coffee never seem to have the just-right amount of milk for your taste? Why do printer ink cartridges sell for $20 when they contain about a thimble's volume of ink? Why should airplane tickets that cost $160 for a weekend flight soar to $698 if you fly on a Tuesday? Can't someone fix all of this?

Charlene Eike thought she'd try. A resident of Illinois, she bought and used prescription eye drops sold by two manufacturers (Allergan and Alcon). She filed a federal class action complaint in Illinois alleging that the dropper tips on those eye drop bottles were too large, causing a portion of the eye medicine to run down her cheek or drain into her nasal cavity. She contended that the manufacturers knew both that their drops were larger than necessary and that portions of every drop would be wasted. She reasoned that these too-large plastic dropper tips constituted an unlawful, unfair, and unethical practice because they caused her (and her fellow class members) to "use more medication than they should, run out of medicine before they should, and have to buy additional bottles at great expense, providing increased, but unfair, profits for" the manufacturers.[1] Because of this waste, Ms. Eike concluded that she and her class were unfairly paying more than they would have had the eye medicine bottles been manufactured with smaller dropper tips. As a remedy, she sought, on behalf of her class, financial compensation for the economic value of the wasted portion of each eye drop, along with an award of punitive damages.

The Illinois federal district court granted Ms. Eike's motion to certify a class of fellow eye drop purchasers. The United States Court of Appeals for the Seventh Circuit vacated that order (a mere 27 days after hearing oral argument), and did so in nine short paragraphs.

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[1] Eike v. Allergan, Inc., No. 3:12-civ-01141-DRH-DGW (S.D. Ill. Nov. 1, 2012) (Complaint) at ¶ 8.

The Seventh Circuit's opinion in *Eike v. Allergan, Inc.*[2] ranks as one of the top food and drug law cases of 2017 for several reasons. First, it rebuffed an audacious contention that consumers, who are otherwise uninjured, can sue medicine manufacturers for failing to supply medicine in a manner those consumers consider most optimally economical. Second, it rejected that theory in a unanimous, withering opinion from Judge Richard Posner[3] that not just overturned the trial judge's class certification order, but did so with the unusual further direction to the district judge to dismiss the lawsuit with prejudice. Third, its reasoning for turning away the class was grounded not in the underlying merits of the claim, but for an absence of the class's Article III standing (the court ruling that the class's claimed injury was irredeemably vacuous). Fourth, its logic was weighed by a sister Circuit just a few months later; in that appeal, a divided 2-1 panel of the Third Circuit ruled the opposite way, finding the *Eike* reasoning unpersuasive.

Consequently, there is now a spirited Circuit clash on the issue of the standing of patients to posit a claim of economic injury grounded on a contention that a prescription medicine—otherwise safe, effective, not misrepresented, and not collusively priced—is priced and delivered to consumers in a way they consider not to be ideal. The ramifications of that theory are difficult to fully digest.

DISCUSSION

The complaint in *Eike* was crisp. It charged six leading ophthalmic pharmaceutical manufacturers with engaging separately in "an unfair and unscrupulous scheme" to compel patients to pay for medicine that "goes to waste."[4] This "scheme," *Eike* contended, violated consumer protection laws in Illinois (because it amounted to an unfair and/or deceptive act or practice) and similar laws in Missouri (because it constituted a deception, fraud, false pretense or promise, misrepresentation, unfair practice, or a concealment, suppression, or omission of a material fact). Citing various medical literature, the complaint averred that the tolerable fluid volume in typical human eyes is quite small, and the insertion of over-large drops of medicine is soon expelled. Accordingly, the complaint continued, smaller eye drop sizes are "at least as bioavailable" as larger drops and, thus, should be preferred over larger drops.[5] The eye drop bottles sold by the defendants generate drops that were noted to be two, three, or more times larger than the optimal, smaller drop size. Thus, the complaint alleged, if the defendants' eye drop bottles had been reconfigured so as to dispense smaller-sized drops, the medication in each bottle would last the patients a longer time (because there would be more doses in each bottle) and would therefore save the patients

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2 850 F.3d 315 (7th Cir. 2017).

3 The colossally prolific Judge Richard Posner retired from the Seventh Circuit effective September 2, 2017. To say the *Eike* opinion was one of his last is true but unilluminating. In the span of less than six months that separated the release of the *Eike* decision and his retirement, Judge Posner wrote 43 more opinions for his court, 10 dissents, and 2 concurrences.

4 Eike v. Allergan, Inc., No. 3:12-civ-01141-DRH-DGW (S.D. Ill. Nov. 1, 2012) (Complaint) at ¶ 38.

5 *See id.* at ¶¶ 45-60. The complaint defines "bioavailability" as "the extent and rate at which a drug accesses the desired site of action." *Id.* at ¶ 50.

money.[6] Because the defendants had failed to bottle their medicines in this way, the complaint insisted that compensatory and punitive damages were appropriate.

The Seventh Circuit was unimpressed. The court began by canvassing a number of (seemingly) undisputed litigation facts:

1. The complaint's ideal eye drop size (16 microliters) is a really, really small volume—about one-tenth of one-percent of a tablespoon.
2. The complaint raised no antitrust accusation, nor collusion of any type (tacit or express).
3. The complaint pressed no allegation of misrepresentation.
4. The complaint made no claim that any members of the putative class personally experienced any untoward side effects from the larger eye drop tip size (beyond their financial claim).
5. The complaint never contended that larger-drops were unsafe or ineffective within the meaning of the federal drug laws.
6. To the contrary, the bottles that produce these larger-drops had been approved by FDA as safe and effective for the treatment of glaucoma.
7. Nowhere, among the relief sought, did the complaint ever demand that the current, larger-drop sized bottles be withdrawn.
8. Rather, the complaint sought only to have the defendants also start manufacturing bottles that produce smaller eye drops.[7]

This canvas left the court troubled at a number of points. Preliminarily, because the only injury the class posited was a "pocketbook" one, the accusation of defendants' profit-over-patient motivations hinged on the assumption "that profits would decline if the defendants switched to selling the smaller, cheaper-to-produce eye drops."[8] But that assumption, reasoned the court, was "far from certain."[9] Next, the court catalogued some of the manufacturers' justifications for larger-sized eye drops: the small portion of each drop that contains the active pharmaceutical ingredient; the small portion of the ingredient that crosses the eye's cornea into the eye itself; the varying size of human eyes; and the drop-administration challenges posed by the medicine's cohort of "elderly patients, patients with unsteady hands, and patients who already have serious eye problems" where "the smaller the drop the likelier they are to miss."[10] Finally, the court mused that the complaint, at its core, seemed more akin to a pitch that FDA should be regulatorily mandating smaller dropper bottle tip sizes, but that pitch, admonished the court, was reserved for administrative audiences, not judicial ones.

In the end, Judge Posner's pithy eloquence closed out the Seventh Circuit's opinion: "You cannot sue a company and argue only—'it could do better by us'—which is all they are arguing."[11] Such an argument, Judge Posner concluded, failed for want of Article III standing:

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[6] *See id.* at ¶¶ 72-78. The complaint also defended the feasibility of generating smaller-sized drops. *See id.* at ¶¶ 78-88.

[7] *Eike*, 850 F.3d at 316-18.

[8] *Id.* at 317.

[9] *Id.*

[10] *Id.*

[11] *Id.* at 318.

> One cannot bring a suit in federal court without pleading that one has been injured in some way (physically, financially—whatever) by the defendant. That's what's required for standing. The fact that a seller does not sell the product that you want, or at the price you'd like to pay, is not an actionable injury; it is just a regret or disappointment—which is all we have here, the class having failed to allege "an invasion of a legally protected interest."[12]

Lacking constitutional standing to sue, Ms. Eike and her putative class not only could not press their federal claim in a class action, they lacked the ability to press a federal claim at all. Accordingly, ruling that the federal courts lacked constitutionally adequate jurisdiction to proceed any further in the matter, the Seventh Circuit directed the dismissal with prejudice.

The *Eike* appeal had been argued on February 7, 2017. Two weeks earlier, a similar too-large-eye-drop claim was heard by the Third Circuit. The putative class members there, in *Cottrell v. Alcon Laboratories*,[13] pressed claims under the consumer protection laws of the States of California, Florida, Illinois, New Jersey, North Carolina, and Texas. The parallels are fascinating; the two cases are procedural mirror images of one another. In *Eike*, the patient class had obtained class certification, and the defendant manufacturers were the parties seeking relief on appeal. Those manufacturers, as appellants, won; the Seventh Circuit ended the lawsuit for lack of constitutional standing. In *Cottrell*, the patient class had lost on a motion to dismiss, and they were the ones seeking relief on appeal. The patients, as appellants in their case, also won; the Third Circuit reversed the dismissal, found constitutional standing, and remanded for further proceedings. The Third Circuit case was orally argued before *Eike*, but its opinion was handed down after *Eike*. Only in unanimity was there missing mirror-symmetry: the Seventh Circuit's decision was 3-0, the Third Circuit's ruling was split, 2-1.

The allegations in *Cottrell* were (in the language of the court) "materially identical" to those in *Eike*,[14] with a few enhancements. The *Cottrell* patients had added that the defendants' true motivations for the larger-sized bottle tips were unintentionally revealed: their complaint quoted a consultant (working for one of the defendants) who had evidently been told that the company was "unwilling to reduce drop sizes because if they did, the company 'would sell less product and make less money.'"[15] As had the *Eike* class, the patients in *Cottrell* contended that the defendants' knowing decisions to manufacture eye drop bottles with larger tip sizes, in contravention of various medical literature advocating otherwise, constituted unfair or unconscionable trade practices in violation of their States' consumer protection laws. The *Cottrell* class then offered a calculation of how much their patients would have saved had their eye drop bottles lasted longer by dispensing the same medicine at a slower rate.

At the trial level, the defendant manufacturers in *Cottrell* argued that the putative prescription eye medicine patients' class should be dismissed for several reasons, including lack of standing, preemption, and failure to state a claim upon which relief could be granted. The district judge relied only on the first of these grounds, dismissing

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

[13] 874 F.3d 154 (3d Cir. 2017), *reh'g denied*, 709 F. Appx. 156 (3d Cir. 2017).

[14] *Id.* at 165.

[15] *Id.*

the complaint for lack of standing. Standing, then, was the only issue squarely addressed on appeal (just as in *Eike*).

At the Third Circuit, the parties had the benefit of Judge Posner's unanimous opinion in *Eike* that had rejected constitutional standing for this sort of claimed injury. The 2-1 Third Circuit majority found that standing existed, reasoning that the patient class had pleaded an economic injury (spending money on medication "that was impossible for them to use"), had sought remuneration from the entities they contended caused that harm, and had alleged that their harm flowed from a violation of various States' unfair trade practice laws which constituted an invasion of their legally protected interests.[16] These claims, ruled the court, also possessed the requisite concreteness (actual, tangible, monetary harm) and the necessary imminence (non-conjectural and non-speculative, linked to cost-savings from using the same volume of medicine at a less-wasteful, slower rate) to qualify for Article III standing. Where Judge Posner had erred in his logic, ruled the 2-1 Third Circuit majority, was in premising plaintiff standing on a prior showing that the plaintiff claim was meritorious. Whether the plaintiff class could win or not on the merits was a separate legal inquiry than whether they possessed standing to try, reasoned the *Cottrell* majority. Instead, all the claimants needed was a plausible allegation of standing.

A sharp dissent framed the class's position as imposing liability on defendants because they "*could have* manufactured a more efficient product, which in turn *could have* lowered plaintiffs' overall treatment costs."[17] This contention, the dissent insisted, "ignores both clear precedent . . . and the complexities of pricing in the pharmaceutical industry."[18] To the dissent's eye, the class's theory contravened settled precedent that standing cannot exist by "rely[ing] on a chain of contingencies and speculation."[19] The dissent concluded that courts "cannot do precisely what the plaintiffs here ask of us: isolate and change one variable [dose size] while assuming that no downstream changes would also occur [to, say, price]."[20] If the manufacturers priced their eye drops on a dose basis, rather than a unit (or volume) basis, the price of the medicine bottle with the reconfigured tip could very well increase. Thus, the class's claimed injury was "overly speculative and untenable" because it asked the court "to assume certain facts about *other actors'* behavior—exactly the sort of assumption that cannot be proven at trial."[21]

A subsequent petition for rehearing and rehearing en banc was denied, but not without another animated dissent, this time written by the Third Circuit's chief judge. Allowing the class to legally speculate about a hypothetical pharmaceutical marketplace was unwise, that dissent announced, because "everyday business decisions may be subject to litigation by creative plaintiffs capable of theorizing a way that those business decisions could have been made to serve plaintiffs more efficiently."[22]

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[16] *Id.* at 165.

[17] *Id.* at 171 (Roth, J., dissenting).

[18] *Id.*

[19] *Id.* at 172-73.

[20] *Id.* at 173.

[21] *Id.* at 174.

[22] Cottrell v. Alcon Laboratories, 709 F. Appx. 156, 160 (3d Cir. 2017) (Smith, C.J., dissenting sur denial of rehearing).

In late March 2018, the defendant manufacturers petitioned for a writ of certiorari, with no decision from the U.S. Supreme Court as of the date this text went to press.[23]

IMPACT

Should the law allow a commercial remedy to consumers who claim that a product-maker could have made that product in a way that would cost them less?

In thinking critically through whether that sort of contention poses a creditable theory of injury, consider what was *not* alleged by these classes: (a) that the product claimants purchased was unsafe or ineffective in the manner it was sold; (b) that the product caused them a physical (noneconomic) injury of any sort; (c) that the product was sold with deceptive labeling of some sort; (d) that the product otherwise violated the federal pharmaceutical laws; or (e) that the manner in which the product is sold should be stopped. These patient classes evidently did not want smaller eye drop bottle tips for everyone (apparently acknowledging, at least implicitly, that some meaningful cohort of product users benefit from larger drops—the elderly, those with unsteady hands, those with impaired eyesight). Instead, they proposed that civil liability could be used to coerce manufacturers into bottling eye drops in an *additional* way that would, they argued, save them money. (And that they should receive both compensatory and punitive damages for their troubles.)

Although, traditionally, these sorts of expansive civil liability theories might be assailed for failing to state a claim upon which relief could be granted, here the manufacturers took a more primary, threshold strategy. Constitutional standing is anchored in Article III's command that federal judicial power extends only over "cases" and "controversies"; the standing doctrine is thus employed to foreclose a litigant's invocation of judicial processes to "usurp the power of the political branches" and, thereby, to "confine[] the federal courts to a properly judicial role."[24] The core minimum for constitutional standing obligates claimants to show (1) that they have suffered an injury in fact, (2) that is fairly traceable to the defendant's conduct, and (3) that is likely to be redressed by a victory in court.[25]

It is on the first standing element—injury in fact—that the unanimous Seventh Circuit and the dissenting Third Circuit judges believed the *Eike* and *Cottrell* classes foundered. Putting to the side the boldness of the contention that a product's packaging could ever qualify as an "unfair trade practice" because it delivers more product than some consumers wish to have delivered to them, it is difficult to see how the classes' claims hold together—even theoretically—without one key assumption: that the eye drop bottle price would remain the same. There is no savings to the patient class if the manufacturers, *forced* to sell prescription eye drops in bottles with smaller tips, raise the price of those bottles. As the *Cottrell* dissent makes plain, pricing a pharmaceutical product on the basis of doses-delivered, rather than volume-contained, is neither unexpected nor irrational. It is also the historic province of seller prerogative. It belabors the obvious to note that, in a free market economy, the price for goods is typically set by the supplier of those goods. Consequently, a bottle of eye drops that

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[23] Alcon Laboratories, Inc. v. Cottrell, No. 17-1337 (U.S.) (petition filed Mar. 22, 2018).

[24] Spokeo, Inc. v. Robins, _ U.S. _, 136 S. Ct. 1540, 1547 (2016).

[25] *Id.*

formerly contained 25 doses but now contains 50 might well be expected to double in price to meet the doubled dose-delivery volume. But the logic need not even reach so far to indict constitutional standing: so long as the *Eike* and *Cottrell* injury theories hinged on the defendants' autonomous pricing of their eye-drop bottles, those theories were incontestably dependent on unprovable assumptions of other actors' behavior (something Article III standing would traditionally not tolerate). It is, then, quite impossible for these eye drop classes to find a constitutionally concrete and nonspeculative rooting for their injury theories unless they also propose to pitch to a factfinder that any subsequent defendant price increase for the reconfigured bottles is also some sort of actionable unfair trade practice. For a free market economy, such a pitch is unmistakably, and ominously, across the Rubicon.

FDA, as gatekeeper for the Nation's pharmaceutical marketplace, might one day consider eye drop bottle tip size as a topic for supplementary regulation. That is the agency's prerogative.

But the question of judicial intervention is a materially different matter entirely. If civil liability is triggered by what consumers (and only some of them) think to be a sub-optimal product feature, then a far-reaching new category of judicial intrusion opens against product makers. The consequences—intended and unintended—are incompatible with our commercial marketplace paradigm. It would be only a modest journey forward to force Duracell to launch single-battery "AA" packages (at exactly one-half the price of its two-battery packs), *Cuties* mandarin oranges to be sold individually (at exactly one-twentieth the price of the netted sack of twenty), and printer ink to be sold at a price that more rationally tracks actual manufacturer hard costs. Consumers may welcome these outcomes, but permitting them fundamentally rewrites tort law and the principle of free-market participant independence.

In re Fosamax Products Liability Litigation

JAMES M. BECK*

WHY IT MADE THE LIST

Since 2008, parties to pharmaceutical product liability cases have struggled with the "clear evidence" implied preemption standard articulated by the U.S. Supreme Court in *Wyeth v. Levine*.[1] In cases of allegedly inadequate warnings about FDA-approved prescription drugs, *Levine* rejected the contention that FDA approval did not, by itself, preempt state-law warning-based claims. Preemption could occur, *Levine* held, if "clear evidence" showed that "the FDA would not have approved" the label that the plaintiff claim state law required, so that simultaneous compliance with state and federal law would be "impossible."[2]

Following *Levine*, courts varied in the rigor that they applied the "would not have approved" standard set by the Supreme Court. However, in those situations where FDA had actually rejected the warning being advocated by the plaintiff, they held that the warning claim was preempted.[3] Another area of general agreement was that preemption generally, and the question of what FDA "would have" done in particular, was a question of law for courts to determine.[4]

The Third Circuit departed from both of these points of post-*Levine* consensus in In re Fosamax (Alendronate Sodium) Products Liability Litigation,[5] and imposed a standard for impossibility preemption that is literally almost impossible to meet. For this result, and because of the likelihood of further review by the Supreme Court, *Fosamax* makes this year's list.

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1 555 U.S. 555 (2009) (*Levine*).

2 *Id*. at 571

3 Cerveny v. Aventis, Inc., 855 F.3d 1091, 1101-03 (10th Cir. 2017); Rheinfrank v. Abbott Laboratories, 680 F. Appx. 369, 386 (6th Cir. 2017). Chambers v. Boehringer Ingelheim Pharmaceuticals, Inc., 2018 WL 849081, at *4-5 (M.D. Ga. Jan. 2, 2018); Amos v. Biogen Idec, Inc., 249 F. Supp.3d 690, 699-700 (W.D.N.Y. 2017); Willis v. Abbott Laboratories, 2017 WL 5988215, at *4 (W.D. Ky. Dec. 1, 2017); Swanson v. Abbott Laboratories, 2017 WL 5903362, at *7-8 (S.D. Ohio Nov. 28, 2017); Christison v. Biogen Idec, Inc., 199 F. Supp.3d 1315, 1347-48 (D. Utah 2016); In re Depakote, 87 F. Supp.3d 916, 921-23 (S.D. Ill. 2015); Cleary v. Biogen Inc., 2017 WL 4126240, at *5-6 (Mass. Super. Sept. 13, 2017); Gentile v. Biogen Idec, Inc., 2016 WL 4128159, at *8 (Mass. Super. July 25, 2016); In re Byetta Cases, 2015 WL 7184655, at *14-15(Cal. Super. Nov. 13, 2015).

4 Guilbeau v. Pfizer, Inc., 880 F.3d 304, 318 (7th Cir. 2018); Cerveny, 855 F.3d at 1096; Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1343 (10th Cir. 2015); In re Pharm. Industry Average Wholesale Price Litigation, 582 F.3d 156, 173 (1st Cir. 2009); Lofton v. McNeil Consumer & Specialty Pharmaceuticals, 672 F.3d 372, 375 (5th Cir. 2012); Risperdal & Invega Product Liability Cases, 2017 WL 4100102, at *7 (Cal. Super. March 16, 2017), reconsideration denied, 2017 WL 4479317, at *2 (Cal. Super. July 24, 2017).

5 852 F.3d 268 (3d Cir. 2017).

DISCUSSION

Fosamax is an FDA approved prescription drug made by defendant Merck Sharp & Dohme Corp. (Merck). It is FDA approved for prevention and treatment of osteoporosis in postmenopausal women.[6] Fosamax is one of a class of drugs, called bisphosphonates, whose chemical properties allow them to retard the resorption of calcium in post-menopausal women's bones, thereby maintaining bone strength and mass. Retarding calcium loss unfortunately has some drawbacks, or so it is alleged, that over the long term, it can lead to "microcracks" that increase the otherwise very low risk of "atypical" femoral fractures (AFF).[7] That risk is what the Fosamax litigation is about.

This risk of AFF from long-term Fosamax use has also been the subject of FDA review, which gives rise to Merck's preemption defense. The initial labeling for Fosamax, following FDA approval "in the 1990s"[8] did not mention AFF. In March 2008, Merck submitted a safety update addressing AFF and, based on some recent medical articles, suggested there might be an association between long-term bisphosphonate use and AFF. FDA saw the information as a "developing safety signal," and wanted more information.

FDA did not act before Merck filed an NDA supplement, seeking FDA approval to add AFF-related language to the label that did not confirm causation. Substantial dialogue with FDA ensued, with FDA looking toward classwide labeling for all bisphosphonates. Ultimately, in May 2009, FDA formally approved changes to the Adverse Reactions section but rejected the rest of Merck's NDA supplement. Almost a year later, FDA publicly stated that research had "not shown a clear connection" between bisphosphonates and AFF. FDA demanded more study. By October 2010, causation was "still not clear," but the association was strong enough for FDA to "consider[] label revisions." FDA-ordered label changes in October 2010 conceded causation was still "not clear," but informed physicians that AFF "have been reported" in long-term bisphosphonate patients, identifying symptoms to watch for and recommending "[i]nterrupt[ing] treatment" where those symptoms appeared.

In the resultant litigation, Merck contended that FDA's actions preempted claims that stronger warnings against AFF should have been given earlier. The District Court handling the Fosamax multi-district litigation (MDL) ultimately agreed, entering summary judgment on implied preemption grounds first in a bellwether case,[9] and ultimately extending its preemption ruling to the rest of the MDL.[10] The ground for finding preemption was that FDA's actions constituted "clear evidence" under *Levine* that FDA would have rejected the label changes demanded by plaintiffs at the time that plaintiffs contended they should have been made:

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[6] In re Fosamax (Alendronate Sodium) Products Liability Litigation, 852 F.3d 268, 271 (3d Cir. 2017) (Fosamax).

[7] See Donnelly *et al.*, "Atypical Femoral Fractures: Epidemiology, Etiology, & Patient Management," 6(3) Current Opinion in Support of Palliative Care, 348 (Sept. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556525/; *Fosamax*, 852 F.3d at 272.

[8] *Fosamax*, 852 F.3d at 271.

[9] In re Fosamax (Alendronate Sodium Products Liability Litigation, 951 F. Supp. 2d 695, 703-04 (D.N.J. 2013).

[10] In re Fosamax (Alendronate Sodium): Products Liability Litigation, 2014 WL 1266994, at *15-17 (D.N.J. Mar. 26, 2014).

> [P]reemption is warranted because there is clear evidence that the FDA would not have approved a change to the Precautions section of the Fosamax label prior to [plaintiff's] fracture. . . . In May 2009, approximately one month after [plaintiff's] fracture, the FDA sent Defendant a letter approving the change to the Adverse Reactions section of the label but denying the change to the Precautions section of the label. The FDA's rejection constitutes clear evidence that the FDA would not have approved a label change to the Precautions section of the label prior to [plaintiff's] injury.[11]

The Third Circuit vacated and remanded. First, the court addressed the "cryptic and open-ended" nature of the "clear evidence" preemption inquiry under *Levine*.[12] That standard, predicating preemption on "clear evidence that the FDA would not have approved a change" to a drug's label,[13] was, according to the Third Circuit "an anomaly in our preemption jurisprudence: the number of cases applying the clear evidence standard continues to grow, yet the clear evidence standard remains undefined."[14]

The Third Circuit addressed this perceived "anomaly" in two ways. First, it equated *Levine*'s reference to "clear evidence" with an actual heightened standard of proof. Under *Fosamax*, for preemption to exist "[t]he manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases, but by 'clear evidence,'" which the court translated to mean "clear and convincing evidence."[15] This imposition of a different, more stringent, burden of proof on preemption—that the defendant must prove it is "highly probable" that FDA would have rejected the change[16]—is incompatible with U.S. Supreme Court precedent, which had rejected heightened standards of proof in the implied preemption context, also in a product liability case.[17]

Second, the Third Circuit ignored a mountain of precedent, including many of its own prior decisions, which had held preemption to be a question of law for courts to decide.[18] Instead, in another unique post-*Levine* ruling, *Fosamax* held that the

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[11] *Fosamax*, 951 F. Supp.2d 02 (citation omitted).

[12] 853 F.3d at 282.

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

[14] 853 F.3d at 284.

[15] *Id.* at 285.

[16] *Id.* at 286.

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

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

"counterfactual" preemption question whether FDA would have rejected the plaintiff's proposed label change is one for the jury—even where, as in *Fosamax*, the historical facts establishing that FDA did in fact reject that same label changed are undisputed.[19] Thus, a manufacturer can no longer establish the preemption defense pretrial, absent a "'smoking gun' rejection letter from the FDA."[20]

The *Fosamax* court's rationale was: (1) the question involves the likelihood of a future event; (2) the decision maker must weigh conflicting evidence and draw inferences; and (3) predicting FDA's actions requires assessment of the motives and thought processes of FDA officials.[21] *Fosamax* considered each of these inquires "typically understood to be fact questions committed to the jury rather than the court."[22] That led to the ultimate conclusion in *Fosamax* that "[a] state-law failure-to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change."[23]

Thus, even though FDA had in fact rejected the same warning that the plaintiffs sought in the subsequent litigation, the Third Circuit reversed because a jury could speculate about why FDA did what it did:

> Once the FDA rejected [defendant's] proposal, the ball was back in [its] court to submit a revised, corrected proposal. A reasonable juror could therefore conclude that it was [defendant's] failure to re-submit a revised [warning change] without stress-fracture language, rather than the FDA's supposedly intransigent stance on the science, that prevented the FDA from approving a label change.[24]

To affirm summary judgment on preemption, *Fosamax* requires that a court must find "that no reasonable juror could conclude that it is anything less than highly probable that the FDA would have rejected Plaintiff's proposed . . . warning had [defendant] proposed it to the FDA" at a causally relevant time."[25] In the Third Circuit, impossibility preemption under *Levine* "clear evidence" standard thus became effectively impossible.

IMPACT

Predictably, plaintiffs in preemption cases across the country immediately latched onto *Fosamax* and argued that other courts should adopt it. So far, *Fosamax* has not found wide acceptance.[26] Among courts in the Third Circuit, the conflict between

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Philadelphia Housing Authority, 908 F.2d 1184, 1188 (3d Cir. 1990); Pokorny v. Ford Motor Co., 902 F.2d 1116, 1119 (3d Cir. 1990).

[19] 852 F.3d at 297.

[20] *Id.* at 294.

[21] *Id.* at 289-91.

[22] *Id.* at 291.

[23] *Id.* at 293

[24] *Id.* at 299.

[25] *Id.* at 296.

[26] To date, *Fosamax* has been rejected or distinguished in the following decisions: Cerveny v. Aventis, Inc., 855 F.3d 1091, 1099, 1103 (10th Cir. 2017) (court "reticent" to follow *Fosamax*; imposing "bright line" preemption test instead); In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation, ___ F. Supp.3d ___, 2018 WL 1471684, at *6 (D. Md. March 26,

Fosamax and prior precedent adds another layer of confusion to preemption cases generally, because the Third Circuit's rule, when dissonant precedents must be harmonized, is that the "earlier" precedent "is controlling."[27] Thus, whether or not preemption is a question of fact or a question of law, and who is to decide those issues, is now profoundly unsettled in the Third Circuit.

Assuming the *Fosamax* holding that predicting what FDA would have done on a set of facts that did not, in fact, occur is something to be decided by a jury, what evidence is going to be available to make those decisions? Unlike almost every other factual question, the issue of what FDA—a federal agency—would have done is not amenable to the usual rules of discovery. Federal agencies, by and large, are immune from civil discovery.[28] Thus, the means of proving the "counterfactual" situation postulated in *Fosamax* are quite limited. Post-*Fosamax*, issues concerning what FDA might have done with different possible warning proposals are not likely to be decided based on actual evidence, but rather on the basis of each side's paid FDA expert witnesses, usually former FDA employees, most of whom will not have worked for the agency for many years and thus are not familiar with FDA's current thinking on any particular issue.

Further, the ability of any "expert" witness, FDA or otherwise, to testify about legal issues, such as how FDA should have interpreted and applied its regulations to a given set of facts, is likewise limited. "Each courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards."[29] Between the restrictions imposed by FDA on factual discovery and the restrictions of the rules of evidence on expert testimony on questions of law, the likelihood that juries will make informed decisions on the issues *Fosamax* would force them to decide is relatively small.

Fosamax has, not surprisingly, been appealed to the U.S. Supreme Court.[30] The petition for certiorari remains pending. In a development suggesting that the Supreme Court is giving the *Fosamax* petition serious consideration, on December 4, 2017, the Court invited the Solicitor General to file an *amicus curiae* brief stating the federal government's—and thus FDA's—view on whether the issues raised warrant

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2018) ("preemption is not an issue for the jury"); Allbright v. Teva Pharmaceuticals USA, Inc., ___ F. Supp.3d ___, 2017 WL 5971720, at *5 (S.D. Fla. Dec. 1, 2017) (*Fosamax* inapplicable to generic cases); Sikkelee v. AVCO Corp., 268 F. Supp.3d 660, 704-05 (M.D. Pa. 2017) (*Fosamax* is "readily distinguished" and not "trans-substantive"); Utts v. Bristol-Myers Squibb Co., 251 F. Supp.3d 644, 672 (S.D.N.Y. 2017) (Fosamax limited to "clear evidence" cases); Amos v. Biogen Idec, Inc., 249 F. Supp. 3d 690, 700, 2017 WL 1316968 (W.D.N.Y. 2017) (distinguishing *Fosamax* on facts); In re Xarelto (Rivaroxaban) Products Liability Litigation, MDL 2592, slip op. (E.D. La May 1, 2017) (preemption is "a question of law, not for the jury. I'm not even sure they [a jury] know what preemption is") (Fallon, J.); In re Risperdal® & Invega® Product Liability Cases, 2017 WL 4479317, at *2 (Cal. Super. July 24, 2017) ("Fosamax is not controlling and is wrongly decided").

[27] United States v. Joseph, 730 F.3d 336, 341 (3d Cir. 2013). *Accord, e.g.*, Pardini v. Allegheny Intermediate Unit, 524 F.3d 419, 426 (3d Cir. 2008) (Third Circuit "has long held that if its cases conflict, the earlier is the controlling authority and the latter is ineffective").

[28] See United States ex rel. Touhy v. Ragen, 340 U.S. 462, 468 (1951) (federal agencies generally have the authority to preclude their personnel from being subjected to discovery in third-party litigation); Giza v. HHS, 628 F.2d 748, 751-52 (1st Cir. 1980) (FDA properly precluded discovery by valid regulation).

[29] Burkhart v. Washington Metropolitan Area Transit Authority, 112 F.3d 1207, 1213 (D.C. Cir. 1997).

[30] See Merck Sharp & Dohme Corp. v. Albrecht, No. 17-290 (U.S. filed Aug. 22, 2017).

grant of the petition.[31] Should the Supreme Court elect to hear the *Fosamax* appeal, the eventual decision would certainly rank among the most important drug/medical device preemption decisions of this decade.

[31] *Id.*, docket entry, https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/17-290.html. The government's brief has not yet been filed.

United States ex rel. Campie v. Gilead Sciences, Inc.

ANNE K. WALSH[*] AND ANDREW J. HULL[**]

WHY THIS CASE MADE THE LIST

The Supreme Court's 2016 decision in *Universal Health Services. v. United States* ex rel. *Escobar*[1] renewed the focus on the strict materiality standard contained in the False Claims Act (FCA), and has been applied by numerous courts to find that materiality does not exist if the government failed to take regulatory action on the conduct underlying an FCA claim. Although several circuit courts have cited *Escobar* to affirm dismissals of cases against life sciences companies, the Ninth Circuit's decision in *United States* ex rel. *Campie v. Gilead Sciences., Inc.*[2] deviated from its sister circuits. This uneasy circuit split is why *Gilead* made the list, and the U.S. Supreme Court ultimately may settle the issue.[3]

DISCUSSION

Facts

In the mid-2000s, Gilead Sciences, Inc. (Gilead) sought and received approval for three new drug applications (NDAs): Emtriva, Truvada, and Atripla. Each of these anti-HIV drugs contained the active ingredient emtricitabine, commonly referred to as FTC. Before approval, Gilead told FDA that it would source FTC from certain suppliers located in Canada, Germany, South Korea, and the United States.

Jeff and Sherilyn Campie, who were married and, at the time, former and current Gilead employees, respectively, filed a *qui tam* complaint[4] alleging that Gilead obfuscated the actual place of manufacture of the active ingredient for the three drugs. Specifically, the relators claimed that Gilead actually contracted with an unregistered Chinese company, Synthetics China, to manufacture FTC, and that

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[1] 136 S. Ct. 1989 (2016). For an in-depth analysis of the *Escobar* decision, see Mark E. Haddad & Naomi A. Igra, *Universal Health Services v. Escobar*, in FOOD & DRUG LAW INSTITUTE, TOP FOOD AND DRUG CASES, 2016 & CASES TO WATCH, 2017, at 67 (Gregory J. Wartman ed., 2017).

[2] 862 F.3d 890 (9th Cir. 2017).

[3] Petition for Certiorari, Gilead Scis., Inc. v. United States *ex rel*. Campie, No. 17-936 (Dec. 26, 2017).

[4] United States *ex rel*. Campie v. Gilead Scis., Inc., No. C-11-0941 (N.D. Cal.) (date of original complaint under seal).

Gilead stopped using Synthetics China as a supplier in October 2011 after a number of contamination issues resulted in recalls of the drug product. Relators also alleged that Gilead falsified or covered up data in statements to FDA.

According to the relators, had FDA been aware of these issues, the agency never would have approved Gilead to use FTC supplied by the Synthetics China facility. Because Gilead sold drugs containing unapproved FTC, and because the drugs were reimbursed by federal healthcare programs, relators contended that Gilead's actions resulted in Gilead submitting, or causing to be submitted, false claims to the federal government in violation of the FCA.

District Court Dismissals

The United States declined to intervene in the case, and relators proceeded with litigation on their own. The District Court dismissed the first amended complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim under the FCA.

Relators filed a second amended complaint, which contained an implied false certification theory. Under this theory, relators claimed Gilead was liable because the company had impliedly certified that it had complied with a statute or regulation, and that compliance was a condition to payment by federal healthcare programs. Relators also alleged a factually false certification theory—that Gilead misrepresented the goods or services provided to the government because the drugs at issue were "nonconforming." The court did not address the FCA materiality requirement specifically, but determined that relators had failed to state a plausible claim and dismissed the case with prejudice in June 2015.[5]

Ninth Circuit Reversal

In July 2017, the Ninth Circuit reversed. The court rejected the lower court's finding that relators had not adequately pled the FCA elements, and specifically addressed the materiality standard in *Escobar*, which had been issued in the interim.

The Ninth Circuit acknowledged that the "materiality standard is demanding," that materiality "cannot be found where noncompliance is minor or insubstantial," and that it is not "sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."[6] The Ninth Circuit also stated that it is "undisputed that at all times relevant, the drugs at issue were FDA-approved, and that the government continues to make direct payments and provide reimbursements for the sale of the three drugs."[7] As such, relators faced "an uphill battle" in sufficiently alleging materiality.[8]

The Ninth Circuit was unconvinced, however, by Gilead's argument that the government's inaction (i.e., continued reimbursement) with full knowledge of the alleged violations demonstrated that those violations were not material to the government's payment decision. The court distinguished the government's continued payments upon Gilead's change to an approved supplier as not as significant as if the

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[5] Order Granting Defendant's Motion to Dismiss, United States *ex rel*. Campie v. Gilead Scis., Inc., No. C-11-0941, 2015 U.S. Dist. LEXIS 77261 (N.D. Cal. June 12, 2015).

[6] *Gilead*, 862 F.3d at 905 (quoting *Escobar*, 136 S. Ct. at 2003).

[7] *Id.*

[8] *Id.*

government had "continued to pay despite continued noncompliance."[9] The Ninth Circuit noted that the parties disputed "exactly what the government knew and when": "Although it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us."[10]

The court also expressed skepticism over the First Circuit's analysis in *D'Agostino v. ev3, Inc.*,[11] in which that court concluded that FDA's failure to withdraw approval of a medical device upon learning that approval was fraudulently obtained crippled any attempt to state a claim that the fraud on FDA was material to the government's payment decision. The Ninth Circuit stressed that "mere FDA approval cannot preclude [FCA] liability" where false claims "procured certain approvals in the first instance."[12]

Thus, the Ninth Circuit reversed and remanded the case to the district court, concluding that the "issues raised by the parties here are matters of proof, not legal grounds to dismiss relators' complaint."[13] The court noted that the lower court had not addressed whether relators' complaint met the heightened pleading standards under Federal Rule of Civil Procedure 9(b), but declined to address that question, thus leaving open the door that the case could separately be dismissed on that ground—a basis that other courts have used to throw out similar cases.[14]

IMPACT OF THE DECISION

Circuit Split

The *Gilead* decision created a split among the circuit courts regarding the application of *Escobar*'s materiality standard. As discussed below, the First, Second, and Third Circuits, at least, have found that no materiality exists when FDA (or the Centers for Medicare and Medicaid Services (CMS)) failed to take action despite knowledge of the alleged regulatory violation. Whether an FCA complaint can survive the pleading stage now depends on the circuit in which the complaint is filed.

The First Circuit's decision in *D'Agostino* was the first significant post-*Escobar* case to address the effect of *Escobar* on routine claims by relators that a drug or device manufacturer obtained product approval by FDA through fraudulent statements (i.e., a "fraud-on-FDA" theory). The First Circuit affirmed the dismissal of a *qui tam* complaint alleging that a device manufacturer's fraudulent representations to obtain FDA's approval caused the submission of false claims. The First Circuit emphasized that the government's decision to continue reimbursement of procedures using these devices despite knowledge of the alleged fraud, along with the fact that FDA had not withdrawn approval of the device, "preclude[d]" the relator "from resting his claims on a contention that the FDA's approval was

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[9] *Id.* at 906.

[10] *Id.* at 906-07.

[11] 845 F.3d 1 (1st Cir. 2016).

[12] *Gilead*, 862 F.3d at 905.

[13] *Id.* at 907.

[14] *See, e.g.*, United States *ex rel*. Higgins v. Boston Sci. Corp., No. 11-cv-2453, 2017 WL 3732099 (D. Minn. Aug. 29, 2017).

fraudulently obtained."[15] In the court's words: "To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so."[16]

In another decision from the same circuit issued after *Gilead*, *United States* ex rel. *Nargol v. DePuy Orthopaedics, Inc.*,[17] the First Circuit reconfirmed its position in *D'Agostino* and criticized the Ninth Circuit's reasoning in *Gilead*. *DePuy* was another fraud-on-FDA case in which relators argued FDA would not have approved the medical devices absent the alleged misrepresentations. The First Circuit agreed that relators had failed to adequately state a claim because FDA did not take the device off the market even after learning of the alleged misrepresentations. The court highlighted that the *Gilead* decision did not offer a solution to the observation in *D'Agostino* that "six jurors should not be able to overrule the FDA," or to the "problems of proving that FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted at doing anything."[18]

The Third Circuit similarly found no materiality in *United States* ex rel. *Petratos v. Genentech Inc.*[19] The relator claimed that a manufacturer's alleged concealment from FDA of an approved drug's health risks resulted in the submission of false claims that did not meet the Medicare statute's "reasonable and necessary" requirement.[20] The Third Circuit held that because the complaint "essentially concede[d] that CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance," relator could not meet *Escobar*'s materiality threshold.[21] The court also explained that FDA's continued approval of the drug after learning of the alleged misinformation more than seven years prior, combined with FDA's approval of three new indications for the drug during that time, the lack of any FDA enforcement action, and DOJ's inaction and declination to intervene, all supported the lack of materiality.

An unpublished decision by the Second Circuit, *Coyne v. Amgen, Inc.*,[22] reiterated that a relator must plausibly claim that alleged misrepresentations—in this case, a manufacturer's misrepresentations on a drug's packaging and marketing materials about increased quality of life—"caused the government to make the reimbursement decision."[23] The Second Circuit affirmed dismissal because, despite learning that the manufacturer eventually changed its labeling with FDA, CMS "did not alter its reimbursement practices . . . or exercise any independent discretion from the presumption of FDA approval."[24]

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15 *D'Agostino*, 845 F.3d at 8.

16 *Id.*

17 865 F.3d 29 (1st Cir. 2017).

18 *Id.* at 36.

19 855 F.3d 481 (3d Cir. 2017).

20 *See* 42 U.S.C. § 1395y(a)(1)(A).

21 *Genentech*, 855 F.3d at 490.

22 No. 17-1522-cv, 2017 WL 6459267 (2d Cir. Dec.18, 2017).

23 *Id.* at *6.

24 *Id.* at *7.

Petition for Certiorari

Seizing on this split, and the uncertainty regarding *Escobar's* materiality standard, Gilead filed a petition for certiorari with the Supreme Court at the end of 2017.[25] The company presented the following question: "Whether an FCA allegation fails when the Government continued to approve and pay for products after learning of alleged regulatory infractions and the pleadings offer no basis for overcoming the strong inference of immateriality that arises from the Government's response."[26]

A number of groups have submitted briefs in support of Gilead, including the U.S. Chamber of Commerce, America Health Care Association, Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and the Washington Legal Foundation.

Relators filed their brief in opposition in early March 2018, arguing that there is no circuit split and that the Ninth Circuit's decision was correct.[27] The Supreme Court should make a determination on whether to grant Gilead's petition in the coming months. The circuit split and differing interpretations of the Court's decision in *Escobar* make this case, in Gilead's words, an "excellent vehicle" for providing clarity and certainty among the federal courts.[28]

Uncertainty in a Post-Escobar World

The clear trend among the circuits is that FDA inaction—i.e., allowing products to stay on the market, even in the face of a government investigation—is a materiality hurdle that relators cannot overcome at the pleading stage.[29] The Supreme Court should adopt that approach. To rule otherwise would conflict with the Court's concern in *Escobar* that the FCA not be turned into a "vehicle for punishing garden-variety breaches of contract or regulatory violations."[30] And it would subvert the role of the FCA as a tool for protecting the federal government from fraudulent claims for money by using it in place of agency regulatory enforcement to ensure compliance. As the First Circuit noted in the *D'Agostino* decision: "The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings."[31]

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[25] Petition for Certiorari, Gilead Scis., Inc. v. United States ex rel. Campie, No. 17-936 (Dec. 26, 2017).

[26] *Id.* at i.

[27] Brief in Opposition, Gilead Scis., Inc. v. United States *ex rel*. Campie, No. 17-936 (Mar. 5, 2018).

[28] Petition for Certiorari at 28, Gilead Scis., Inc. v. United States *ex rel*. Campie, No. 17-936 (Dec. 26, 2017).

[29] *See* United States *ex rel*. Ruckh v. Salus Rehabilitation, LLC, No. 8:11-cv-1303, 2018 WL 375720 (M.D. Fla. Jan. 11, 2018) (dismissing a $350 million judgment awarded by jury because there was no evidence that the non-compliance was material to the government's payment decision).

[30] Universal Health Servs. v. United States *ex rel*. Escobar, 136 S. Ct. 1989, 2003 (2016).

[31] D'Agostino v. ev3, Inc., 845 F.3d 1, 8 (1st Cir. 2016).

LabMD, Inc. v. FTC

GINGER PIGOTT* AND RICHARD TABURA**

WHY IT MADE THE LIST

Normally, neither an opinion from the Federal Trade Commission (FTC) nor a subsequent stay order from the Eleventh Circuit putting the FTC's opinion on hold would "make the list" of this publication.[1] It was expected that the Eleventh Circuit would have a final decision in this matter by the end of 2017; nonetheless, while a surprising delay has changed the focus, it is the importance of the FTC's role in policing cybersecurity and the pending Eleventh Circuit decision from the appeal of this FTC opinion that pushes it and the pending decision onto the must-review and must-watch list of this publication.

These important preliminary decisions are worth discussion because they highlight a current battle between industry and the FTC. The Eleventh Circuit's ruling will provide additional important guidance and may significantly impact the FTC's ability to police cybersecurity practices in industries which use sensitive consumer information. Presently, the FTC has no explicit statutory or regulatory authority to combat data security breaches. If the Eleventh Circuit agrees with the FTC, the agency will be able to continue determining what an "unfair" act and a "reasonable" security measure are on an *ad hoc* basis, leaving businesses that handle sensitive consumer information with some uncertainty as to how to implement a data security policy and potentially exposed to monetary penalties with almost no notice. Technology is constantly evolving and hackers are becoming more sophisticated; what may have been considered a "reasonable" security measure a few years ago may no longer be adequate. The medical device and drug industries inherently involve sensitive consumer information, and therefore this decision will have many implications for these industries.

FRAMEWORK FOR DISCUSSION

Below we first provide you with a basic understanding of the authority the FTC has relied on to police the cybersecurity practices of businesses handling sensitive consumer information such as LabMD, Inc. We then turn to the complicated procedural history of this dispute between LabMD and the FTC, which has spanned several years. Then we discuss the oral arguments before the Eleventh Circuit Court

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[1] LabMD, Inc. v. FTC, TBD (11th Cir ___) [*See In re* LabMD, Inc., Docket No. 9357, Op. of the Comm'n and Final Order (FTC July 29, 2016), https://www.ftc.gov/system/files/documents/cases/160729 labmd-opinion.pdf].

of Appeals heard on June 21, 2017, and an assessment of how the Court might rule. Lastly, we discuss what impact the Eleventh Circuit's decision will have in the area of data security in the food and drug industries.

DISCUSSION

FTC's Authority: Section 5 of the Federal Trade Commission Act

At this time, despite various legislation efforts in Congress, there remains no specific statute or regulation authorizing the FTC to police data breaches.[2] Instead, the FTC has relied on a broad interpretation of Section 5 of the Federal Trade Commission Act (Section 5), which prohibits "unfair or deceptive acts or practices in or affecting commerce." Relying on Section 5, the FTC has indicated through its enforcement actions that private businesses must implement "reasonable" security measures and that the failure to do so can be an "unfair act or practice" under Section 5.[3]

The FTC has stated that the following considerations are touchstones in determining whether a business is implementing "reasonable" security measures: whether the data security measures are reasonable and appropriate in light of the sensitivity and volume of consumer information it holds; the size and complexity of its business; and the cost of available tools to improve security and reduce vulnerabilities.[4] The FTC has also stated that while there is no single solution for "reasonable" data security practices, such a program should follow these basic principles:

(1) companies should know what consumer information they have and what employees or third parties have access to it;

(2) companies should limit the information they collect and retain based on their legitimate business needs so that needless storage of data does not create unnecessary risks of unauthorized access to the data;

(3) businesses should protect the information they maintain by assessing risks and implementing protectives in certain key areas—physical security, electronic security, employee training, and oversight of service providers;

(4) companies should properly dispose of information they no longer need; and

(5) companies should have a plan in place to respond to security incidents, should they occur.[5]

Furthermore, in determining whether a company's failure to protect against a data breach has violated Section 5, the FTC applies its "unfairness test." The unfairness test applies the following factors in the context of data breaches: *(1) whether the breach was likely to cause substantial injury to consumers;* (2) whether the breach was not reasonably avoidable by consumers themselves; and (3) whether the breach

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[2] Jaclyn K. Haughom, *Who Are the Real Cyberbullies: Hackers or the FTC? The Fairness of the FTC's Authority in the Data Security Context*, 66 CATH. U. L. REV. 881, 904 (2017).

[3] *LawMD v. FTC: Tackling "Unfair" Data Security Practices in the Eleventh Circuit*, Center for Democracy & Technology (June 20, 2017), https://cdt.org/insight/labmd-v-ftc-tackling-unfair-data-security-practices-in-the-eleventh-circuit/.

[4] Fed. Trade Comm'n, Commission Statement Marking the FTC's 50th Data Security Settlement 1 (Jan. 31, 2014), http://ftc.gov/system/files/documents/cases/140131gmrstatement.pdf.

[5] *Id.*

was not outweighed by countervailing benefits to consumers or to competition.[6] As discussed in more detail below, the first factor is the primary issue in the *LabMD v. FTC* matter.

Since 2002, the FTC has policed data security breaches by filing administrative actions against companies and typically obtaining a consent decree. If after investigation the commission has determined that a company's data security practices are "unreasonable," the FTC files an administrative action against the company, with the company ultimately agreeing to a consent decree.[7]

Procedural History

LabMD, Inc. was a small Atlanta-based laboratory that performed cancer-detection testing services for doctors.[8] These services included the collection of sensitive personal information such as test results, Social Security numbers, and insurance data.[9] In 2008, an internet-security company named Tiversa informed LabMD that it had obtained sensitive patient information from LabMD.[10] The FTC eventually learned about the breach[11] and began an investigation of LabMD's data-security practices.[12] In July 2013, the FTC gave notice of its intent to file an administrative action against LabMD.[13]

In August 2013, the FTC filed its administrative complaint, alleging that LabMD violated Section 5 of the FTCA by failing to prevent unauthorized access to its patient information. The FTC's complaint alleged that in two separate incidents, LabMD collectively exposed the personal information of approximately 10,000 consumers. The FTC asserted that the breach was an "unfair act or practice" within the meaning of Section 5.[14] Rather than reaching a consent decree like most companies do in response to such administrative actions, LabMD challenged the FTC.[15] LabMD's motion to dismiss the administrative complaint argued that Section 5 did not apply to the specific context of data security breaches. The FTC denied LabMD's motion to dismiss, asserting that Congress purposely delegated broad

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6 15 U.S.C. § 45(n).

7 *See* Houghman, *supra* note 1, at 888.

8 LabMD no longer does business, but its counsel argued that it is a going concern in order to support its argument that the matter is not moot.

9 *Supra* note 2.

10 LabMD, Inc. v. F.T.C., 776 F.3d 1275, 1277 (2015).

11 Tiversa's forensic analysts obtained sensitive information from LabMD. Tiversa tried to leverage this information in an effort to obtain LabMD's business. After LabMD refused Tiversa's business, Tiversa informed the FTC that LabMD had data breaches which involved customers' personal information. LabMD, Inc. v. FTC, No. 16-16270-D, Order Granting Stay (11th Cir. Nov. 10, 2016), http://f.datasrvr.com/fr1/016/73315/2016_1111.pdf.

12 *Supra* note 9. LabMD's CEO publicly criticized the FTC's actions by publishing a book called "The Devil Inside the Beltway." In the book, LabMD's CEO attempts to expose corruption in the FTC. Shortly after an online trailer was posted about the book, the FTC filed its administrative proceeding against LabMD.

13 *Id.*

14 *Id.*

15 Jimmy H. Koo, *Still Waiting on 'LabMD' Ruling on FTC Data Security Power*, Bloomberg Law (Dec. 13, 2017), https://www.bna.com/waiting-labmd-ruling-b73014473153/.

authority to the FTC to deem what is an "unfair practice."[16] In November 2015, an Administrative Law Judge (ALJ) dismissed the FTC's complaint.[17]

The FTC appealed the decision and one year later the agency unanimously overruled its own ALJ.[18] In so doing, the FTC found that the ALJ applied the wrong legal standard for unfairness and that LabMD's security practices were "unreasonable, lacking even basic precautions to protect the sensitive consumer information maintained on its computer system" in violation of Section 5 of the FTCA.[19] The FTC's final order identified the following lapses in security: it did not maintain an automated intrusion detection system; it lacked file integrity monitoring software and penetration testing; it failed to monitor traffic coming across its firewalls; and it failed to provide its employees with data security training.[20] The FTC cited to well-known and accepted standards such as regulations provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that LabMD could have looked to for guidance in implementing its own data security policy.[21] As a result of LabMD's security practices (or lack thereof), sensitive medical information of 9,300 consumers were exposed. The FTC found that the exposure of these consumers' sensitive medical information outweighed any countervailing benefits to LabMD's lax security practice and was therefore an "unfair" practice.[22]

The FTC's Final Order required LabMD to implement several data security measures. First, the FTC ordered that LabMD "establish, implement, and maintain a comprehensive information security program that is reasonably designed to protect the security and confidentiality of consumers' personal information." Second, LabMD was ordered to "obtain initial and then biennial assessments and reports regarding its implementation of the information security program." Third, LabMD is to notify individuals whose personal information had been exposed. Lastly, LabMD was ordered to comply with standard orders issued by the FTC which include record-keeping and compliance reporting requirements.[23]

LabMD immediately appealed the FTC's Final Order to the Commission, asking for a stay of the Final Order pending review of an appeal to the Eleventh Circuit Court of Appeals to vacate the FTC's Final Order.[24] In its request for a stay of the FTC's final order, LabMD argued that it was likely to succeed on the merits because the Final Order violated due process, was unsupported by substantial evidence, and was otherwise contrary to law. LabMD also argued that the FTC's order would require LabMD to incur substantial compliance costs which LabMD had no ability to pay as a result of the FTC's investigation. Further, LabMD argued that there was no

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16 *Supra* note 2.

17 *See In re* LabMd, Inc., Docket No. 9357, ALJ's Initial Decision (F.T.C. Nov. 13, 2015), https://www.ftc.gov/system/files/documents/cases/151113labmd_decision.pdf.

18 *See In re* LabMD, Inc., Docket No. 9357, Op. of the Comm'n and Final Order (F.T.C. July 29, 2016), https://www.ftc.gov/system/files/documents/cases/160729labmd-opinion.pdf.

19 *Id.*

20 *Id.*

21 *Id.*

22 *Id.*

23 *Id.*

24 *See In re* LabMD, Inc., Docket No. 9357, LabMD's Application for Stay of Final Order Pending Review by a United States Court of Appeals (FTC August 30, 2016).

risk of harm to any consumers and it was in the interest of the public to ensure the Commission's order was constitutional.[25] The FTC was not persuaded that LabMD would prevail for similar reasons addressed in its Final Order. Therefore, the FTC denied LabMD's request for a stay on the Final Order.[26]

LabMD then turned to the Eleventh Circuit Court of Appeals for a stay from the FTC's Final Order.[27] LabMD made similar arguments to the Eleventh Circuit that it made to the FTC in LabMD's Application for Stay of the Final Order. The Eleventh Circuit noted that this case would turn on whether the FTC's interpretation of Section 5 of the FTCA is reasonable.[28] In particular, it focused on whether LabMD's practices "caused or is likely to cause substantial injury to consumers."[29] LabMD argued that the FTC failed to assess whether it "caused or is likely to cause substantial injury to consumers" because it could not identify any tangible harm such as identity theft or physical harm.[30] The Eleventh Circuit indicated that it was not clear that a reasonable interpretation of Section 5 of the FTCA included intangible harms like those found by the FTC in LabMD's case.[31] The Eleventh Circuit also did not think it was clear that the FTC reasonably interpreted the "likely to cause" prong of the unfairness test. The FTC interpreted "likely to cause" to mean "significant risk." LabMD interpreted "likely" to mean "a high probability of occurring." The Court looked to the plain meaning of "likely" and did not believe that the FTC's interpretation was a reasonable one.[32] The Court agreed with the other arguments made by LabMD in support of its argument for a stay on the FTC's Final Order. Ultimately, the Eleventh Circuit Court of Appeals agreed to the stay, suggesting the court might be sympathetic to LabMD's plight.[33]

The Appeal: Oral Argument

The Eleventh Circuit Court of Appeals heard oral arguments in the *LabMD, Inc. v. FTC* matter on June 21, 2017.[34]

The Court focused the parties' arguments on the following issues (1) whether *any* unauthorized access giving rise to *any* potential privacy harm constituted a "substantial injury" under Section 5's unfairness test and (2) whether LabMD had sufficient notice that its data security practices ran afoul of the FTC's rules.[35]

As to the first issue, LabMD argued that the legislative history of Section 5 was clear that the FTC should interpret "substantial injury" to be limited to tangible harm

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[25] *Id.*

[26] *See In re* LabMD, Inc., Docket No. 9357, Commission Order Denying LabMD's Application For Stay of Final Order Pending Review (FTC September 30, 2016).

[27] *Supra* note 10.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Supra* note 2.

[34] Oral Argument Recording, http://www.ca11.uscourts.gov/oral-argument-recordings?title=&field_oar_case_name_value=labmd&field_oral_argument_date_value%5Bvalue%5D%5Byear%5D=&field_oral_argument_date_value%5Bvalue%5D%5Bmonth%5D=&=Search.

[35] *Id.*

such as a financial loss as opposed to an intangible harm where the consumer is not even aware of the harm. The Court seemed to latch onto this argument as the FTC was forced to admit that no consumer affected by LabMD's breach had filed a lawsuit, and as far as the FTC knew, no consumer was even aware that their personal information had been compromised. The Court characterized the injury involved in this action as a "tree fell and nobody heard it."[36]

But the FTC argued that LabMD's characterization of the injury at issue was unfair, and suggested that the unauthorized disclosure of healthcare information, in and of itself, was a "substantial injury." Further, the FTC argued that the legislative history and enactment of Section 5 took into account a long history of FTC enforcement actions, and that this history supported the FTC's position that Congress intended the FTC to have the discretion to initiate enforcement actions. The FTC further argued that the legislative history of Section 5 did not state that the "substantial injury" was limited to tangible harms.[37]

The Court then questioned the FTC at length regarding the Court's concern that the FTC's order did not provide LabMD with any notice of what it was doing wrong. LabMD suggested it was unaware of any insufficient data security practices at the time of the data breach. In response, the FTC argued that at the time of LabMD's data breach in 2005-2008, all businesses knew they had a duty to have "reasonable" data security practices. The FTC drew comparisons to ordinary tort law which requires all businesses to act reasonably. On rebuttal, LabMD pointed out that where businesses are held to the reasonableness standard in tort law there are industry standards to inform what is reasonable. But here, a small company like LabMD did not have industry standards informing what was "reasonable" data security practices in 2005-2008. The Court responded that the "reasonable" data security practices standard was "about as nebulous as you can get."[38]

The Court did express concern that they were limited to reviewing whether the underlying final decision by the FTC contained "substantial evidence." Further, the FTC relied on *Chevron* Deference, an administrative law principle that requires courts to defer to interpretations of statutes made by those government agencies charged with enforcing them.[39] LabMD countered that since the FTC misinterpreted the plain meaning of Section 5 in the first place, the Court could engage in a more thorough review of the FTC's final order.

On one hand, the Court's language in its order granting the stay on the FTC's order seemed to doubt the FTC's interpretation of Section 5 of the FTCA, suggesting it may side with LabMD. In addition, the Court appeared to side more with LabMD throughout oral argument.

The Court took the matter under submission. However, the FTC's ability to rely on *Chevron* Deference could upend LabMD's arguments. To date, the Eleventh Circuit has not issued a ruling on the appeal.

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[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984)

IMPACT AND CONCLUSION

The Eleventh Circuit's ruling on the *LabMD v. FTC* matter will likely have far-reaching effects in the area of data security. This may be particularly true in the healthcare industry, which is susceptible to data breaches involving sensitive patient information. The number of data breaches has risen and may continue to rise, especially as healthcare providers move towards interconnected facilities, hospital equipment, and medical devices. In fact, there are nearly 400 cases, each involving breaches of protected health information affecting 500 or more individuals, currently being investigated by the U.S. Department of Health and Human Services.[40]

If the Court affirms the FTC's final order, the FTC can be expected to continue filing administrative complaints under Section 5 for data breaches against companies unless and until federal data security legislation is passed. If the Court overrules the FTC's final order, there may be more companies challenging the FTC instead of reaching consent decrees. Regardless of how the matter is decided, companies should look to industry norms for data security practices. Times have changed since the data breach giving rise to this case. While there may not have been industry standards a decade ago, many know from personal experience at their own offices that data security measures have increased substantially in just the past few years. As work, commerce, and healthcare continue to become increasingly interconnected through the internet, basic security measures should be put in place to prevent data breaches.

[40] Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information, U.S. Department of Health and Human Services Office for Civil Rights, https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.

Federal Trade Commission v. Quincy Bioscience Holding Company Inc.

MEGAN OLSEN*

WHY IT MADE THE LIST

Efficacy claims for dietary supplements, such as those claims that state or suggest that a dietary supplement will have an effect on health (e.g., "X ingredient supports a healthy brain" or "Y product can support heart health") must be supported by competent and reliable scientific evidence; however, there is often disagreement among regulators and regulated companies as to what is considered appropriate competent and reliable scientific evidence to support a claim. The Federal Trade Commission (FTC) is the principal regulatory agency overseeing dietary supplement efficacy claims made in advertising.[1] Since the FTC released guidance in 2001, articulating that competent and reliable scientific evidence was necessary to support these types of claims, companies have grappled with what this standard requires. This latest litigation continues to shape the FTC's ability to impose specific substantiation requirements through the competent and reliable scientific evidence standard and the burden the FTC must meet to demonstrate violations of substantiation requirements.

DISCUSSION

Background

FTC v. Quincy Bioscience Holding Co.[2] could affect two issues important to dietary supplement companies – the substantiation standard for dietary supplement efficacy claims and the burden the FTC must meet to bring a complaint against dietary supplement companies for alleged false and deceptive advertising.

Substantiation Standard

The FTC has long held that, before disseminating an advertisement, advertisers must have a reasonable basis to support all express and implied claims made in the ad.

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1 The Food and Drug Administration (FDA) and state attorneys general also play an important role in regulating dietary supplement efficacy claims. FDA and FTC operate under an agreement, through which the FTC possesses primary enforcement responsibility for claims made in advertising, while FDA has primary enforcement responsibility for claims made on a product label or material accompanying the label. *See* Memorandum of Understanding between the FTC and FDA, MOU 225-71-8003 (Apr. 1971), https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm.

2 Case No. 1:17-cv-00124-LLS (S.D.N.Y. Sept. 28, 2017).

In 2001, the FTC released guidance for dietary supplements that articulated what is generally considered a reasonable basis for dietary supplement efficacy claims.[3] Specifically, the FTC indicated that companies should have "competent and reliable scientific evidence" (CRSE) to support claims, which the FTC defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[4]

The FTC's guidance goes on to state that the standard is "a flexible one that depends on many factors" and that the "FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science."[5] Unless an advertisement refers to a specific level of support (e.g., "a clinical study conducted by [name of university] shows"; "clinically proven"; "numerous clinical studies demonstrate"), there is no fixed formula for the number or type of studies, sample size, study duration, or other parameter requirements. FTC, however, has long considered well-controlled human clinical studies to be the most reliable form of evidence, with randomized, double-blind, placebo controlled clinical trials (RCTs) serving as the gold standard of substantiation.

Despite the FTC's statements that the CRSE standard is a flexible standard, the FTC, since developing this guidance, has sought to impose specific standards on certain types of dietary supplement claims. These have included requiring companies, through consent orders settling FTC advertising enforcement investigations, to possess two RCTs for a variety of claims, such as weight-loss claims, immunity strengthening claims, and certain disease claims.[6] When such standards have been litigated, however, some courts have rejected FTC's efforts to create more rigid substantiation standards than the 2001 guidance suggests is necessary, particularly where claims are about general health and nutrition, as opposed to claims that a product will have an effect on a disease.[7]

Pleading Standard

Also at issue in *FTC v. Quincy* is the standard that the FTC's complaint must meet to survive a motion to dismiss.

To survive a motion to dismiss under Federal Rules of Civil Procedure Rule 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to state

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[3] Federal Trade Commission, *Dietary Supplements: An Advertising Guide* (April 2001), https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf.

[4] *Id.* at p. 9.

[5] *Id.* at pp. 3 and 8.

[6] *See e.g.,* FTC v. Iovate Health Sciences USA, Inc.*,* Case No. 10-CV-587 (W.D.N.Y July 29, 2010) (Stipulated Final Judgment); Nestle HealthCare Nutrition Inc., FTC File No. 092-3087, Agreement Containing consent Order (July 14, 2010).

[7] *See e.g.,* U.S. v. Bayer, Case No. 23:07-cv-00001-JLL-JAD (D. NJ Sept. 24, 2015) (Opinion) (finding that "placebo-controlled, double-blind testing is not a legal requirement for consumer products" and that "something less may do"); POM Wonderful, LLC v. FTC, Case No. 13-1060 (DC Cir. 2015) (making clear that studies that do not meet the RCT standard may still have value in substantiating health-related, dietary supplement efficacy claims).

a claim to relief that is plausible on its face."[8] The standard developed first under *Bell Atlantic Corp. v. Twombly* and further developed under *Ashcroft v. Iqbal* goes on to articulate that (1) a complaint must do more than plead facts that are merely consistent with a defendant's liability; (2) "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions"; and (3) a complaint must make a "showing, rather than a blanket assertion, of entitlement to relief" supported by sufficient "factual allegation[s]."[9]

Facts of Quincy

The FTC, in conjunction with the New York Attorney General's office, brought a complaint alleging that the defendant, Quincy Bioscience Holding Company, Inc.,[10] had violated federal and state deceptive advertising laws for cognitive health claims made about Prevagen—a dietary supplement product that the defendant manufactured.

According to the FTC's complaint,[11] claims at issue included cognitive health claims, such as the following type of claims:

- Prevagen improves memory;
- Prevagen improves memory within 90 days;
- Prevagen reduces memory problems associated with aging;
- Prevagen provides other cognitive benefits; and
- That all of these benefits are clinically proven.

To support these claims, Quincy provided a randomized, double-blind, placebo-controlled study known as the Madison Memory study. During the study, a variety of cognitive skills were assessed. The court noted that "[n]o statistically significant results were observed for the study population as a whole"; however, certain subgroups within the trial showed statistically significant improvements over participants who received placebo on some of the cognitive tasks that were measured by the study. The defendant indicated that the subgroups in which statistically significant results were demonstrated were those subgroups within the study that are most relevant to the healthy, adult population at which sales of the supplement are targeted.

The FTC alleged that the researchers arrived at their results by conducting "more than 30 post hoc analyses" and that this subgroup analysis "greatly increases the probability that the statistically significant improvements shown are by chance alone." Thus, according to the FTC, "the few positive findings on isolated tasks for small subgroups of the study population do not provide reliable evidence of a treatment effect."[12]

The FTC also alleged that the claims were based on a theory that the main ingredient in the Prevagen product—apoaequorin—enters the human brain to supplement proteins that are lost during the natural aging processes. The FTC's complaint alleges, however, that the defendants did not possess studies demonstrating that this orally-

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

[9] Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 n. 3 (2007).

[10] Other defendants included subsidiaries of Quincy Biosciences and individual officers of these companies.

[11] Quincy Bioscience Holding Co., Case No. 1:17-cv-00124-LLS (Complaint for Permanent Injunction and Other Equitable Relief Jan. 9, 2017).

[12] *Id.*

administered ingredient crosses the human blood-brain barrier and, in fact, certain studies showed that the ingredient is rapidly digested, causing it to act like any other dietary protein.

Based on these allegations, the FTC argued that the defendant's cognitive health claims were false and misleading or "not substantiated at the time . . . [they] were made" in violation of Sections 5(a) and 12 of the Federal Trade Commission Act (FTC Act).[13]

According to the defendants, the FTC's complaint failed because (1) it did not meet the *Twombly/Iqbal* standard and (2) the FTC sought to impose liability based on a new and different substantiation standard than the competent and reliable scientific evidence standard. Specifically, the defendant argued that the FTC's complaint failed to meet this standard because "it relies entirely on conclusory allegations that materials referenced in and attached to the Complaint contradict, and also because Plaintiffs fail to allege that Quincy violated the FTC's own standard for false or misleading advertising."[14]

District Court Decision

On September 28, 2017, U.S. District Court for the Southern District of New York Judge Louis L. Stanton dismissed all the claims in the lawsuit without prejudice.[15]

To establish a violation of the FTC Act, the FTC is required to show three elements: (1) identify a representation, omission, or practice, that (2) is likely to mislead consumers acting reasonably under the circumstances; and (3) the representation, omission, or practice is material. The district court's decision analyzed the second element of this test and whether the FTC's complaint alleged facts from which it can be reasonably inferred that the representations at issue are false or unsubstantiated.

The court found that the Madison Memory study followed well-accepted procedures, confining the FTC's challenge of Quincy's substantiation to the analysis that Quincy conducted on the study subgroups. This is where, according to the district court, the FTC's complaint failed because it did nothing more than point to possible sources of error and did not allege that any actual errors occurred.

The court criticized the FTC's complaint on a number of grounds, including that (1) the challenge never proceeded beyond the theoretical; (2) the FTC criticized what they alleged were "post hoc exploratory analysis" by arguing that these types of analyses increase the risk of false positives and the probability of results altered by chance alone, but the FTC complaint did not explain the nature of such risks nor show that the risks affected the subgroup performance or created false positives; and (3) the FTC failed to provide any reason that the alleged risks are so large that they prevent any use of subgroup analysis.

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[13] The complaint also alleges that Quincy's actions violated Sections 349 and 350 of New York General Business Law and Section 63(12) of the New York Executive Law; however, as the New York allegations were dismissed for non-substantive reasons, this article only focuses on the court's treatment of the alleged violations under the FTC Act. Once the district court dismissed the FTC's complaint brought under federal law, the court found that there was no basis to exercise supplemental jurisdiction over the state law claims. Thus, the court declined to rule on the merit of the New York state law claims, finding that this decision would be better decided by New York state courts.

[14] Quincy Bioscience Holding Co., Inc., Case No. 1:17-cv-00124-LLS (Memorandum of Law in Support of Defendants' Motion to Dismiss Apr. 6, 2017).

[15] Quincy Bioscience Holding Co., Inc., Case No. 1:17-cv-00124-LLS (Opinion and Order Sept. 28, 2017).

Based on these deficiencies, the court found that the complaint failed to show that Quincy's reliance on subgroup data to support its memory and cognitive health claims "is likely to mislead consumers acting reasonably under the circumstances," as is required for the FTC to state a proper claim. The court went on to note that the FTC's lack of clarity in its complaint as to why Quincy's substantiation does not support its claims and the FTC's reliance on theoretical possibilities "stops short of the line between possibility and plausibility of 'entitlement to relief.'"[16] In other words, the court found that "the complaint does not allege facts from which it can be reasonably inferred that the representations at issue are false or unsubstantiated."[17]

IMPACT

The *Quincy* decision has an important impact on the standards that the FTC, and potentially other regulators, must meet when bringing a complaint regarding dietary supplement claim substantiation, as well as the level of substantiation that companies are required to provide for dietary supplement claims.

In arriving at this ruling, the court accepted that subgroup analysis (or "post hoc" analysis, as described by the FTC and the court) could be an acceptable method to substantiate the types of claims at issue in the FTC's complaint. Beyond specifics of scientific analysis, however, such as whether "post hoc" or subgroup analysis, in particular, is acceptable, the court's decision continues to demonstrate that courts are wary of allowing the FTC to apply rigid substantiation standards for dietary supplement substantiation, in light of the FTC's own statements that the CRSE standard is meant to be flexible and allow for different types of scientific evidence to support these claims. This action also continues to represent courts' unwillingness to accept, on its face, FTC blanket statements that certain types of substantiation are not appropriate to support health-related efficacy claims.

The FTC has appealed the district court ruling to the U.S. Court of Appeals for the Second Circuit. The appeal will continue to shape the FTC's substantiation doctrine, particularly around how flexible the CRSE standard is in practice. If the district court's decision is upheld on appeal, it could mean that the FTC and state regulators with statutes similar to the FTC Act will face additional scrutiny when bringing complaints alleging that an advertiser's claims are false or unsubstantiated. Private plaintiffs have often faced such scrutiny over their pleadings and cases are regularly dismissed based on findings of implausibility, but regulators have not faced the same scrutiny over allegations they put forth. Should the district court's decision be upheld, this action could temper FTC enforcement actions against companies for using substantiation that the FTC considers as novel or where experts disagree as to how the scientific research should be interpreted.

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[16] *Id.* at 12 *quoting Iqbal*, 556 U.S. at 678.

[17] *Id.* at 10.

Nicopure Labs, LLC v. Food and Drug Administration et al.

STACY L. EHRLICH* **AND JAMES WILLIAM WOODLEE****

WHY IT MADE THE LIST

Nicopure Labs, LLC v. Food and Drug Administration et al.[1] is the latest decision in a string of industry challenges to aspects of the U.S. Food and Drug Administration's (FDA's) implementation of the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA). In this case, the plaintiffs objected to FDA's so-called "Deeming Rule" as applied to electronic nicotine delivery system (ENDS) products, including e-cigarettes and e-liquids. The ENDS product category is a relatively new entrant to the tobacco product marketplace, and it includes innovative products viewed as lower-risk alternatives to combustible tobacco products such as cigarettes.

Indeed, exactly one week after the district court's decision in the *Nicopure* case, the then-recently-installed FDA Commissioner, Dr. Scott Gottlieb, announced a new comprehensive plan for tobacco and nicotine regulation intended to "strike an appropriate balance between regulation and encouraging development of innovative tobacco products that could reduce the public health harms caused by cigarette smoking."[2] Dr. Gottlieb stated that "we must recognize the potential for innovation to lead to less harmful products, which, under FDA's oversight, could be part of a solution" to the death and disease caused by combustible cigarettes.[3] The public health question at the core of the *Nicopure* case is whether the Deeming Rule strikes an appropriate balance in regulating ENDS products in the same manner (or, arguably, in a more stringent manner) as the more harmful category of cigarettes.

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1 266 F. Supp. 3d 360 (D.D.C. 2017).

2 FDA's Plan for Tobacco and Nicotine Regulation (July 28, 2017), https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm.

3 Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, July 28, 2017, Remarks by Scott Gottlieb, M.D., https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm.

DISCUSSION

Background

Upon its effective date, the TCA immediately subjected to FDA's authorities under Chapter IX of the Federal Food, Drug, and Cosmetic Act (FDCA or Act) cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and components, parts, and accessories of such products.[4] The TCA further provided that for other categories of "tobacco products"—defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)[5]—FDA may issue regulations "deeming" them to be subject to its tobacco product authorities.[6] On May 10, 2016, FDA issued a final rule deeming all products meeting the statutory definition of "tobacco product" (except accessories of such products) to be subject to Chapter IX of the Act (Deeming Rule).[7]

Nicopure, a manufacturer of ENDS products and e-liquids, brought a challenge in the United States District Court for the District of Columbia on the basis that the Deeming Rule exceeded the agency's statutory authority, violated the Administrative Procedure Act (APA), violated the First and the Fifth Amendments to the U.S. Constitution, and was not supported by the requisite cost-benefit analysis. In a separate action, the Right to be Smoke Free Coalition (RSF), along with several other industry trade associations, challenged the Deeming Rule on similar grounds. The district court consolidated the two cases and both sides filed for summary judgment.

In its summary judgment brief, Nicopure claimed that FDA's action to regulate ENDS products "will crush the vaping industry." This assertion stemmed in large part from the FDCA's requirement that a company obtain prior FDA authorization to market "new tobacco products," defined to include any product not commercially marketed in the United States "as of" February 15, 2007, or modified in any physical respect since that date. As FDA has conceded, virtually all ENDS products so qualify. Under policies announced and refined since the issuance of the Deeming Rule, FDA has permitted the continued marketing of ENDS products that qualify as "new tobacco products" that were on the U.S. market on the Deeming Rule's effective date of August 8, 2016. However, these policies would eventually require the submission of expensive and uncertain marketing applications for such products, removal from the market of any product not covered by a timely filed application, and removal from the market of any product covered by a timely filed application for which FDA's review concludes without issuance of a marketing authorization. In her opinion, U.S. District Court Judge Amy Berman Jackson stated that she "wishes to reassure the many worried vapers who followed these proceedings closely that this case is not about banning the

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4 21 U.S.C. § 387a(b).

5 21 U.S.C. § 321(rr).

6 21 U.S.C. § 387a(b).

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

manufacture or sale of the devices."[8] Yet the Deeming Rule's potentially significant impact on the ENDS marketplace is very much at the heart of the plaintiffs' challenge.

The Court's Ruling

On July 21, 2017, the U.S. District Court for the District of Columbia issued its opinion on the parties' summary judgment motions, finding in favor of FDA on all counts. In its decision, the court largely deferred to FDA and noted that the plaintiffs' concerns were primarily policy arguments more appropriately directed to Congress.

What is a Tobacco Product?

The court first rejected the plaintiffs' assertions that FDA exceeded its statutory authority when taking the position that it may regulate as tobacco products open system vaping devices that do not contain e-liquid and e-liquids that do not contain nicotine.[9] The plaintiffs contended that the devices themselves could not be tobacco products because they are not made or derived from tobacco and are not intended for human consumption. Likewise, the plaintiffs argued that nicotine-free e-liquids are not made or derived from tobacco. However, the court noted that Nicopure "repeatedly quote[d] just a portion of the statutory definition of 'tobacco product'" and omit[ted] the portion [of the definition] that includes any "component" or "part."[10]

In the Deeming Rule, FDA defined the terms "component or part" to mean "any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product."[11] The court found this definition to be consistent with the statutory definition of "tobacco product" and that FDA's application of this definition to separately sold elements of an open ENDS product was based on a permissible construction of the TCA.

In particular, FDA asserted that the definition of "component" covers both empty vaping devices and e-liquids that are "intended or reasonably expected to be used with or for the human consumption of a tobacco product (e.g., liquid nicotine)."[12] With respect to the device, which contains the heating element and the battery, the court stated that, at the very least, it is a "component": " . . . [A] consumer cannot use a vaping device for its primary purpose without adding the liquid, and there is nothing to do with the liquid without the device."[13] The court further opined: "Indeed, it might be fair to say that the device *is* the electronic nicotine delivery system."[14]

With respect to e-liquids, the court first rejected the government's arguments that: (1) the plaintiffs lacked standing to make this claim because they did not demonstrate

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[8] Nicopure Labs, LLC v. FDA, 266 F. Supp. 3d 360, 367 (D.D.C. 2017). Consumers fill open-system devices with e-liquid(s) of their choosing.

[9] The court did not address the issue of whether the agency may lawfully regulate e-liquids that contain synthetic nicotine or nicotine derived from non-tobacco sources. *See Nicopure*, 266 F. Supp. 3d at 391, n.25.

[10] *Id*. at 380, n. 19.

[11] 81 Fed. Reg. 28,974, 29,015 (May 10, 2016); 21 C.F.R. § 1100.3.

[12] *Nicopure*, 266 F. Supp. 3d at 386.

[13] *Id.* at 383.

[14] *Id.* (emphasis in original).

that their e-liquids are subject to the Deeming Rule and (2) the claim was not ripe because the plaintiffs did not yet know if FDA will initiate enforcement action against their nicotine-free e-liquids. The court found that because Nicopure manufactures nicotine-free liquids it had standing, even if the plaintiffs "have not specified whether their nicotine-free liquids are or are not intended to be mixed with liquid nicotine, since the agency has already specifically stated that it is not bound to take manufacturers at their word."[15] The court also held the challenge to this aspect of the rule to be ripe because "the question in this case is not about whether the regulation will apply to a particular nicotine-free e-liquid; the challenge is whether nicotine-free e-liquids can be regulated *at all*."[16]

The court ultimately agreed with FDA that it can regulate e-liquids that are reasonably expected to be mixed with liquid nicotine because those liquids would be "components or parts" of a tobacco product.[17] In particular, it observed that, "if an ENDS device with nicotine or a tobacco derivative in it is, as plaintiffs acknowledge, a tobacco product, then a nicotine-free liquid that gets added to the mix – to provide flavor or make the inhalation experience less harsh – becomes a 'component' of the tobacco product when it is added."[18]

FDA's Decision to Deem ENDS Products to Be Subject to Chapter IX of the Act

The plaintiffs next alleged that FDA's decision to subject ENDS products to its tobacco product authority was arbitrary and capricious in violation of the APA. The court first noted that the language of the deeming provision, which uses the terms "may" and "deem," is "the kind of language that, even if judicial review is permitted, 'fairly exudes deference.'"[19] It then identified the reasons the agency cited to support its determination that regulating ENDS products, and particularly requiring premarket review of new tobacco products and modified risk claims, would benefit public health. "First and foremost, [FDA found that] nicotine is indisputably harmful."[20] Second, FDA stated that adolescents are particularly vulnerable to the effects of nicotine and there has been, as described by FDA, an "alarming" rise in use of ENDS products by teens. Finally, the agency claimed to have found significant inconsistency in the concentration of chemicals delivered by various ENDS products in the marketplace.

The court therefore concluded that there is a rational relationship between the facts articulated by FDA in support of the rulemaking and the choice to include ENDS products in the Deeming Rule. The court additionally observed that the Congressional findings in the TCA itself buttress this conclusion, noting that the legislative history of the statute indicates that "Congress was well aware of the advent of e-cigarettes at the time that the TCA was passed."[21]

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15 *Id.* at 387.

16 *Id.* at 389 (emphasis in original).

17 *Id.* at 391.

18 *Id.*

19 *Id.* at 393.

20 *Id.* at 393-94.

21 *Id.* at 395, n. 26.

In upholding the validity of the Deeming Rule under the APA, the court rejected the plaintiffs' arguments that the decision to deem ENDS products was arbitrary and capricious because: (1) regulating them under the Chapter IX controls would undermine the TCA's core goal of reducing death and disease caused by tobacco products and (2) the agency failed to consider alternatives that would avoid a "significant degree of product exit" as a result of the onerous regulatory requirements for ENDS products to remain on the market. Discounting these arguments, including those that asserted that the agency should have exercised enforcement discretion in implementing the statutory premarket review requirements for products introduced after February 15, 2007, the court expressed the view that the plaintiffs' concerns were "better directed to Congress than the FDA."[22]

The plaintiffs additionally argued that the Deeming Rule was invalid under the APA because the agency's cost-benefit analysis was insufficient. As a fundamental matter, the court found that FDA was not required to undertake a cost-benefit analysis when it implemented the statutory deeming provision. It distinguished the statutory language of the Clean Air Act in *Michigan v. EPA*,[23] cited by the plaintiffs, from the deeming language in the TCA. The Clean Air Act required the Environmental Protection Agency (EPA) to regulate power plant emissions "if the Administrator finds such regulation is appropriate and necessary after considering the results of the study."[24] In light of the use of the term "appropriate and necessary," the Supreme Court ruled that EPA's decision to not consider cost at all was unreasonable. The TCA, in contrast, does not contain language that would indicate a requirement that FDA take cost into account when it exercises its deeming power.

The court further held that, even if the agency was required to conduct an analysis of costs, its cost-benefit analysis was adequate and was not "a clear error of judgment." It stated, "Here, the administrative record reflects that the agency expressly considered both the burdens the decision would impose on the vaping industry and the benefits to the public."[25] Citing D.C. Circuit precedent that "cost-benefit analyses epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency,"[26] the court concluded that the balance that the agency struck, as documented in its Regulatory Impact Analysis, was reasonable, despite the fact that FDA explicitly acknowledged that it could not "quantify the benefits of the final rule due to lack of information and substantial uncertainties associated with estimating its effects."[27]

The court also rejected the plaintiffs' arguments that FDA violated the Regulatory Flexibility Act (RFA)[28] by failing to consider significant alternatives to the Deeming Rule and by failing to appropriately balance the costs and benefits of the rule for small businesses. Noting that the RFA's requirements are "purely procedural," the court held

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[22] *Id.* at 398.

[23] Michigan v. EPA, 135 S. Ct. 2699 (2015)

[24] *Nicopure*, 266 F. Supp. 3d at 401.

[25] *Id.* at 403.

[26] *Id.*

[27] *Id.* at 404.

[28] 5 U.S.C. § 601 *et seq.*

that the fact that FDA completed a Regulatory Impact Analysis that "contains a discussion of all of the required topics" was sufficient to satisfy the statute.[29]

Constitutional Claims

Under their constitutional claims, the plaintiffs first argued that the TCA's premarket review requirements violated RSF's right to due process under the Fifth Amendment to the Constitution. In particular, RSF asserted that, because Congress created a premarket review system that RSF believes manufacturers will never be able to satisfy, the provision lacked a rational basis as applied to ENDS products. The court disagreed, concluding that the provision does not violate the their substantive due process rights because Congress articulated a number of rational reasons for the premarket review requirement in the purposes section of the TCA.

The plaintiffs additionally alleged that two provisions of the Deeming Rule violated their right to free speech under the First Amendment: (1) the ban on free samples and (2) the pre-approval requirement for modified risk claims. As an initial matter, the plaintiffs asserted that, under the Supreme Court's decision in *Sorrell v. IMS Health*,[30] the TCA's restrictions on speech are subject to heightened First Amendment scrutiny because they are content- and speaker-based restrictions,.[31] The *Sorrell* opinion specifically noted that "'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech."[32] The district court, however, rejected the plaintiffs' argument, holding that "the *Sorrell* opinion did not alter or replace the *Central Hudson* [intermediate] scrutiny standard" in this context.[33]

With respect to the free sample ban, the plaintiffs argued that courts have unanimously recognized that distributing free samples qualifies as protected speech.[34] The district court took issue with this conclusion, holding that "[e]ven if the Court were to view the distribution of free samples as inherently expressive – 'try this!' – that limited message is not a 'significant element' of the conduct being regulated."[35] The court also dismissed the plaintiffs' argument that free samples allow sellers to "inform consumers about a product's characteristics and quality," and are an "effective means of communicating and encouraging consumers 'to try different and new . . . products,'" noting that "coupons and promises of lower prices do the same."[36] The court therefore determined that the ban regulates conduct not speech.

In any event, the court held that the free sample ban does not violate the First Amendment because the ban satisfies the *Central Hudson* test: the government has a substantial interest in eliminating youth access to tobacco products, and the ban

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[29] *Nicopure*, 266 F. Supp. 3d at 408.

[30] Sorrell v. IMS Health, 564 U.S. 552 (2011).

[31] *Nicopure*, 266 F. Supp. 3d at 411.

[32] *Sorrell,* 564 U.S. at 555.

[33] *Nicopure*, 266 F. Supp. 3d at 411.

[34] *See*, *e.g.*, Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 538 (6th Cir. 2012) (holding that sampling is protected speech because it is a "promotional method[] that convey[s] the twin messages of reinforcing brand loyalty and encouraging switching from competitors' brands"); Bailey v. Morales, 190 F.3d 320, 321, 325 (5th Cir. 1999) (restrictions on "promotional gifts and items" offered by chiropractors violated the First Amendment); Rockwood v. City of Burlington, Vt., 21 F. Supp. 2d 411, 415, 421–22 (D. Vt. 1998) (distribution of free samples was protected speech).

[35] *Nicopure,* 266. F. Supp. 3d at 413.

[36] *Id.* at 415.

directly and materially advances, and is not more extensive than necessary to serve, that interest.[37] In particular, the court noted the plaintiffs' concession that FDA asserted a substantial interest to "eliminate a pathway for youth access to [t]obacco products"[38] and that the government produced "substantial evidence that its free sample ban will directly reduce access to vaping products by minors."[39]

With respect to whether the free sample ban was a "reasonable fit," the plaintiffs argued that it is more extensive than necessary because there are a number of less restrictive alternatives to achieve the government's interest such as "(1) limiting of free samples to adults at qualified-adult only facilities, (2) prohibiting samples from leaving store premises, and (3) prohibiting the distribution of free samples at public events."[40] The court summarily dismissed these arguments, deferring to FDA's assertion that it does not believe that it could achieve the same results with these alternatives and noting that there are other ways in which sellers could deliver information about ENDS products to "an appropriate adult audience, such as by discounting sample kits sold in stores to curious adults [and] inform[ing] consumers via demonstrations, promotional literature, and other advertising."[41]

Finally, the court held that the modified risk provisions of the TCA do not violate the First Amendment. The TCA requires that manufacturers obtain prior approval of any claim that represents that a tobacco product is less harmful than other tobacco products or contains a reduced level of, or reduces exposure to, a substance. The plaintiffs argued that this provision bars them from making truthful and non-misleading claims without FDA approval, a process which is so onerous that FDA has not yet approved even one modified-risk claim.

In reviewing this assertion, the court relied on the *Discount Tobacco* case in which the Sixth Circuit upheld the TCA's modified risk provision as applied to cigarettes based on the cigarette industry's long history of misleading marketing campaigns, finding that prior approval by FDA is appropriate because "in the context of a deadly and highly addictive product, it would be a virtual impossibility to unring the bell of misinformation after it has been rung."[42] The *Nicopure* court's analysis did not, however, distinguish between cigarettes and ENDS products, which, as new entrants to the marketplace, do not have such a marketing history and are, as FDA acknowledges, less harmful to the individual user. Rather, the court concluded that, under the TCA, the "need to protect the public from unsubstantiated health claims applies with equal force no matter how the nicotine is being delivered."[43]

The court also rejected the plaintiffs' assertion that the modified-risk-claim requirements are more extensive than necessary because FDA could have instead simply required appropriate disclaimers, citing Congress's finding that "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended

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[37] *Id.* at 418.

[38] *Id.*at 416 (citing *Discount Tobacco* for the proposition that free samples of cigarettes were an "easily accessible source of the[] products to young people").

[39] *Id.* at 417.

[40] *Id.* at 418.

[41] *Id.* at 418.

[42] *Id.* at 420.

[43] *Id.* at 420, n. 38.

to provide clarification."[44] The court summarized its view as follows: " . . . [T]his provision does not ban truthful statements about health benefits or reduced risks; it simply requires that they be substantiated."[45]

IMPACT

The *Nicopure* case was the first court opinion on the validity of FDA's Deeming Rule.[46] Although as part of its July 28, 2017, announcement of a comprehensive nicotine plan (as well as based on some technical issues that subsequently arose), FDA delayed the implementation of many of the rule's requirements,[47] all of the provisions of the Deeming Rule as applied to ENDS products currently remain in force. The issues raised in the *Nicopure* case are therefore still of great concern to the ENDS industry, as well as a number of members of the public health community, who strongly believe that consumers should have ready access to and accurate information about lower-risk alternatives to cigarettes and that FDA regulation should be consistent with those objectives.

Importantly, the plaintiffs have appealed this case to the D.C. Circuit, continuing to assert their arguments that (1) the modified risk provisions violate the First Amendment; (2) the free sample ban violates the First Amendment; and (3) FDA violated the TCA and the APA when it failed to tailor the premarket review requirements for ENDS products. *Amicus curiae* briefs in support of the plaintiffs have been filed with the appellate court by the State of Iowa (led by Attorney General Tom Miller), NJOY LLC (an ENDS company), the Consumer Advocates for Smoke-Free Alternatives Association (an ENDS consumer advocacy organization), the Washington Legal Foundation (WLF, a nonprofit public-interest law firm and policy center that focuses on First Amendment issues), and a group of public health advocates and tobacco policy authorities that includes the former Director of the United Kingdom's Action on Smoking in Health, a former Associate Commissioner of FDA, and a number of professors and research scientists at academic institutions.

In addition to reviewing the district court's rulings in this case, the court of appeals will likely address the question of whether the Supreme Court's decision in *Sorrell* requires a new approach to regulation of commercial speech in these circumstances,

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[44] *Id.* at 420-21 (citing Tobacco Control Act § 2(41)).

[45] *Id.* at 421.

[46] A number of challenges to the deeming regulation are pending in various jurisdictions. See Cigar Ass'n of America et al v. U.S. Food and Drug Administration, No. 1:16-cv-01460 (D.D.C.); Cyclops Vapor 2, LLC et al v. U.S. Food and Drug Administration et al, No. 2:16cv556-MHT (M.D. Ala.); En Fuego Tobacco Shop LLC, et al. v. U.S. Food & Drug Administration, 4:18-cv-00028 (E.D. Tex.); Hoban et al v. Food and Drug Administration et al, No. 0:18-cv-0026 9-JNE-LIB (D. Minn.); Jooce et al v. Food and Drug Administration, No. 1:18-cv-00203-CRC (D.D.C.); Lost Art Liquids, LLC v. Food and Drug Administration et al., No. 2:16-cv-03468 (C.D. Ca.); Rave Salon Inc. v. Gottlieb et al, 3:18-cv-0 0237-G (N.D. Tex.).

[47] For instance, FDA extended the deadline for premarket submissions for deemed "new tobacco products" on the market on the Deeming Rule's effective date to August 8, 2021, for combustible products and August 8, 2022, for non-combustible products (including ENDS products), and announced a compliance policy to permit such products to remain on the market until the applicable deadline for premarket submissions (and thereafter if a submission is timely filed and remains under review). *See* Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (November 2017).

an issue of first impression for the D.C. Circuit. In this regard, WLF has asked the court to apply the same strict scrutiny to speaker- and content-based restrictions on commercial speech that courts routinely apply in any other speech setting. The resolution of this issue could land the *Nicopure* case back on the list of top cases for 2018, so stay tuned.

Singleton v. Fifth Generation, Inc.

AUGUST T. HORVATH* AND REBECCA KIRK FAIR**

WHY IT MADE THE LIST

For the past five years, class-action plaintiffs have struggled to construct damages models in advertising cases that comport with the Supreme Court's decision in *Comcast v. Behrend*.[1] In *Comcast*, the Supreme Court held that the predominance requirement for class certification of Federal Rule of Civil Procedure 23(b) requires that at the class certification stage, a plaintiff seeking class-wide damages on a common basis must proffer a damages case that (1) can demonstrably calculate class-wide damages by common proof and (2) is consistent with its liability case. The Supreme Court directed that District Courts "must conduct a rigorous analysis to determine whether that is so."[2]

The *Comcast* showing has proven challenging to satisfy in consumer class actions whose theory of injury and damages is that a class of consumers paid a price premium because they were deceived by the advertising or marketing of a product, relative to what they would have paid if they had known the truth about the product. Foods and beverages have been among the most common subjects of such suits in recent years. In 2017, several District Courts issued important decisions on this question of whether the damages case at issue satisfies the Rule 23(b)(3) predominance requirement, and any of three or four of them could have been our Top Case. We chose *Singleton v. Fifth Generation, Inc.*,[3] because it was one of the better elucidations of the issues. Below, we also discuss the other key 2017 and early 2018 decisions in this area, both in cases involving foods and beverages and those dealing with other consumer products where similar price-premium class actions have been litigated.

DISCUSSION

Context

In *Comcast*, the Supreme Court held that "a model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to [plaintiff's theory of liability]. If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class

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1 569 U.S. 27, 133 S. Ct. 1426 (2013).

2 *Id.*, 133 S. Ct. at 1433.

3 5:15-CV-474 (BKS/TWD) (N.D.N.Y. Sept. 27, 2017).

for purposes of the predominance requirement of Rule 23(b)(3)."[4] Thus, as one requirement, "any model supporting a plaintiff's damages case must be consistent with its liability case."[5] The other requirement of the damages model under *Comcast* is some level of specificity. *Comcast* advised that at the class certification stage, "calculations need not be exact."[6] However, subsequent cases have held that, while the plaintiff "does not need to 'implement or test his methodology at the class certification stage, he must still provide sufficient detail about the proposed methodology to permit a court to determine whether the methodology is suitable to the task at hand.'"[7]

Comcast was an antitrust case. Later cases held that *Comcast* applied in cases where the plaintiffs seek restitutionary damages.[8] In a false-advertising case where plaintiffs seek restitution of an alleged price premium for the falsely advertised product attribute, post-*Comcast* cases have held that "plaintiffs must be able to show that their damages stemmed from the defendant's actions that created the liability"[9]—i.e., from the specific advertising or marketing claim that is challenged. Some courts have held that the price premium is the difference between the market price actually paid by consumers and the market price that would have prevailed if consumers had not been deceived.[10] Where this claim promotes a product attribute that is allegedly not as advertised, the plaintiffs' damages methodology must convincingly isolate the falsely advertised attribute from any other reason why consumers might pay more for the product.[11] Damages for the entire class must be calculable by a common method, although it is still permissible for each individual's damages to require individual calculation under that common formula.[12]

To satisfy the *Comcast* requirements, plaintiffs in consumer class actions have proposed several different damages estimation methods including conjoint and regression analyses. Conjoint analysis, used alone as a means of estimating restitutionary damages in class actions, has been rejected by some courts on the basis that it estimates only the amount that consumers say they were willing to pay for the falsely promoted feature, and not how much more they actually paid.[13] Other courts,

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4 *Comcast*, 133 S. Ct. at 1433.

5 *Id*.

6 *Id*.

7 *Weiner*, 2010 U.S. Dist. LEXIS 79647, at *27.

8 *See* Pulaski & Middleman, LLC v. Google, Inc., 802 F.3d 979, 989 (9th Cir. 2015).

9 *See In re* POM Wonderful LLC, No. ML 10-02199-DDP-RZX, 2014 U.S. Dist. LEXIS 40415 (C.D. Cal. Mar. 25, 2014).

10 *In re* NJOY, Inc. Consumer Class Action Litig., No. 14-428, 2016 U.S. Dist. LEXIS 24235 (C.D. Cal. Feb. 2, 2016); Brazil v. Dole Packaged Foods, LLC, 660 F. App'x 531, 534 (9th Cir. 2016); Werdebaugh v. Blue Diamond Growers, No. 12-cv-02724-LHK, 2014 U.S. Dist. LEXIS 173789 (N.D. Cal. Dec. 15, 2014).

11 *See In re* Scotts EZ Seed Litigation, 304 F.R.D. 397, 413 (S.D.N.Y 2015) ("Courts routinely reject price premium methodologies under *Comcast* when the proposed methodologies do not attempt to isolate the premium due only to the allegedly misleading marketing statement.")

12 *See* Levya v. Medline Indus., 716 F.3d 510, 514 (9th Cir. 2013).

13 *See In re* NJOY, Inc. Consumer Class Action Litig., 120 F. Supp. 3d 1050, 1119 (C.D. Cal. 2015); Apple, Inc. v. Samsung Elecs. Co., No. 11-cv-01846-LHK, Savedra v. Eli Lilly & Co., 2014 U.S. Dist. LEXIS 179088 (C.D. Cal. Dec. 18, 2014).

however, have accepted conjoint analysis, even without supplementation by some other method to calibrate it to real-world prices, as a means of estimating a price premium.[14] Others have approved conjoint analysis when used "in conjunction with" a marketplace-data-based method such as a regression analysis on real-world prices to tie the conjoint results to actual market price.[15]

Facts

The defendant, Fifth Generation, Inc., does business as, and markets a product named, Tito's Handmade Vodka. The case concerns the defendant's representation that its vodka is "handmade" and "crafted in an old fashioned pot still." The plaintiff, a New York resident, sued in 2015, purporting to represent a class of all persons in New York who purchased Tito's Handmade Vodka after April 12, 2012. The plaintiff asserted that Fifth Generation's characterizations of its vodka are false because the vodka actually is made in large, automated modern stills and bottling facilities at the rate of 500 cases per hour, with little or no direct human involvement.

Key allegations in the case are that consumers prefer products made in small quantities and with direct human involvement, believing them to be of higher quality. Accordingly, it is alleged, consumers will pay more for a product having those attributes than they would pay for an otherwise indistinguishable product that does not have them. This allegedly enabled Fifth Generation to sell Tito's Handmade Vodka at higher prices in comparison to competing products. Consumers who purchased Tito's Handmade Vodka allegedly would not have purchased the vodka, or would have paid less for it, if they did not see and believe the defendant's express claims that it was handmade in an old-fashioned pot still and the associated implied claim that it was made in small batches.

Key Issues

The plaintiff's theory of liability in cases like *Singleton* is that consumers actually paid more for the falsely marketed product than they would have paid for that product, or for a competing product, absent the false marketing. Courts have rejected the theory that it constitutes cognizable economic damages for consumers merely to have received less perceived value from a falsely marketed product than they thought they were getting, even though they would have paid just as much for the product if their perception of it was accurate.[16] Plaintiffs must therefore prove an actual price premium paid by consumers that would not have been paid in the but-for world of fully truthful marketing.

The task of establishing this actual price premium falls to social scientist expert witnesses working in the marketing, economics, and/or survey research fields. These experts are assigned to isolate and quantify the economic value associated with the

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[14] *See* Guido v. L'Oreal, No. 2:11-cv-01067-CAS, 2014 U.S. Dist. LEXIS 165777 (C.D. Cal. July 24, 2014); *In re* Myford Touch Consumer Litig., No. 13-cv-03072-EMC, 2016 U.S. Dist. LEXIS 179487 (N.D. Cal. Sept. 14, 2016); Odyssey Wireless, Inc. v. Apple, Inc., No. 15-cv-01735-H-RBB, 2016 WL 7644790, at *9 (S.D. Cal. Sept. 14, 2016); *In re* Lenovo Adware Litig., No. 15-MD-02624-RMW, 2016 U.S. Dist. LEXIS 149958 (N.D. Cal. Oct. 27, 2016).

[15] *See In re* ConAgra Foods, Inc., 90 F. Supp. 3d 919, 1026 (C.D. Cal. 2015).

[16] *See, e.g.,* Weiner v. Snapple Bev. Corp., No. 07-civ-8742, 2010 U.S. Dist. LEXIS 79647, at *17 (S.D.N.Y. Aug. 5, 2010) ("Only by showing that plaintiffs paid more as a result of [defendant's false advertising] can plaintiffs establish the requisite elements of causation and accurate injury under [N.Y. G.B.L.] § 349.

feature or features that are allegedly falsely promoted. In this case, the hypothesis they test is that because consumers believe Tito's Handmade Vodka is made in small batches with direct human intervention in old-fashioned stills, the vodka commands a market premium over a hypothetical product that is otherwise identical, but that consumers understand is made in vast quantities in massive, automated, largely unattended distilling plants.

Expert witnesses face several methodological challenges in performing these studies. First, experts must ensure that their proposed methodologies follow best practices with respect to sampling, recruitment, question design, and analyses. Therefore, at the class certification phase of the case, experts must give a complete description of their proposed approach and demonstrate that their approach and design complies with best practices in social science research. In particular, when designing a survey, the expert must detail several survey elements such as the target population, sample selection, screening questions, survey questionnaire, data collection and analysis, and other survey-related procedures. The failure to properly detail such considerations implies such considerations may not be made in the final survey.

There are further methodological challenges in both conjoint analyses and in other methods, such as hedonic modeling, which must be addressed when examining false labeling claims. The proposed research design must be able to measure both the materiality of the alleged misrepresentation(s) and be able to quantify the damages (price-premium paid) as a result of the alleged misrepresentation(s). The proposed design must allow for causal inferences and isolate the price premium paid specifically due to the alleged misrepresentations. Specifically, an expert witness must be able to clearly isolate the allegedly false misrepresentations in her or his survey design. In the case of *Singleton*, the survey design must be sufficiently precise to isolate the effect of Tito's "handmade" claims without causing respondents to focus on a claim they otherwise would not have considered as part of their purchasing decision. Similarly, if an expert intends to rely upon hedonic modeling or analyses of transaction data, one needs to ensure that the comparisons being made are appropriately tied to the allegations and the results are not conflated by other changes in the marketplace. Ultimately the evidence proffered by an economist or survey expert must be carefully designed in a manner consistent with academic standards.

Although cases like *Singleton* are decided on the basis of an evaluation of the expert damages evidence proffered by the plaintiff, courts caution that the analysis is not a consideration of the admissibility of the expert's testimony under *Daubert v. Merrill Dow Pharmaceuticals, Inc*.[17] Some courts, including District Judge Brenda K. Sannes in *Singleton*, separately address *Daubert* admissibility motions within the same decisions in which they address the *Comcast* Rule 23 analysis, but the criteria are different. An expert opinion can be of adequate reliability and comport with the practice of experts in the field, and thus be admissible under *Daubert*, but not match the plaintiff's theory of liability or calculate damages for all class members with a common proof, and thus miss the mark set in *Comcast.* Thus, in addition to complying with best practices of social science research, the expert must adequately describe their proposed research design and provide enough information to demonstrate its applicability to the plaintiff's theory of liability.[18]

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[17] 509 U.S. 579 (1993).

[18] 5:15-CV-474 (BKS/TWD) (N.D.N.Y. Sept. 27, 2017), p. 22.

Decision

Simultaneously before the court in September 2017 were the plaintiff's motion for class certification, filed in February 2017, defendant's motion for summary judgment, filed in May, and the parties' challenges to each other's expert witness testimony under *Daubert* in connection with the class certification motion. The court noted that it is not completely settled whether District Courts need to conduct a *Daubert* evaluation when expert testimony is presented at the class certification stage, but it seems likely that the Supreme Court expects courts to do so as part of the Rule 23 analysis. The court therefore undertook a *Daubert* evaluation of the proffered expert testimony, limited to the purpose of whether the expert testimony was admissible for purposes of establishing the Rule 23 requirements.

None of the key expert witnesses was excluded on *Daubert* grounds. The court permitted the testimony of a food industry consultant who reviewed available vodkas and opined that the main reason for the price premium of Tito's over two selected competitors was the handmade representation, even though the expert's method was "somewhat shaky." It also found the plaintiff's key statistical expert, who performed the conjoint survey and hedonic regression analysis, adequate in reliability. Only one of the plaintiff's experts, whose testimony simply expressed support for the methods of the other two, was excluded. The opinions of all of the defendant's experts, primarily critiquing those of the plaintiff, were admitted.

On the class certification motion, the court quickly found that the requirements of Rule 23 other than predominance—numerosity, commonality, typicality, adequacy of representation, and ascertainability—were met. The court rejected the plaintiff's claim for injunctive relief on the ground that because the representative plaintiff now knows about the allegedly deceptive representation, he is not at any risk of future injury and lacks standing to seek an injunction. These preliminaries set up the main event: the evaluation of whether the plaintiff's damages claim satisfied the Rule 23(b)(3) predominance requirement.

As a warm-up, before addressing damages, the court considered the defense argument that the materiality of an advertising claim, which is a necessary element of a New York GBL 349/350 violation, is inherently subjective and therefore not predominant. The court ruled that materiality in advertising cases is an "objective inquiry," and that materiality is a property of an advertising claim. Either a claim is "likely to mislead a reasonable consumer acting reasonably under the circumstances" or it is not, the court concluded.[19]

Rule 23 subsection 23(b)(3) has become the focus of the suitability for an alleged course of conduct and type of damages for class treatment because, courts have found, it sets up a predominance requirement "far more demanding" than Rule 23(a)'s requirement of commonality, which can be satisfied just by showing a generally similar pattern of injury caused by common alleged conduct.[20] Under Rule 23(b)(3),

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[19] Arguably, in making this finding, the court mistook the definition of "materiality," which is normally expressed as whether a represented fact is likely to influence a consumer's purchasing decision, for the definition of deceptiveness, which is what the court quoted. In this instance, the distinction may not matter much, because the court could just as easily have found, using the standard definition of materiality, that the claim would likely influence the purchasing decision of a reasonable consumer, and therefore would still be an objective property of the claim, not a subjective perception of each consumer.

[20] Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 624 (1997).

the court inquires whether "the common, aggregation-enabling, issues in the case are *more prevalent or important* than the non-common, aggregation-defeating, individual issues."[21]

The plaintiff's expert witness in *Singleton* presented three different damages estimation methods, an increasingly common strategy in price-overcharge class actions. Plaintiffs and expert witnesses in recent cases have proposed to use multiple methods either in the alternative or in combination as a way of solving the difficulties associated with estimating a class-wide real price premium. The court in *Singleton* named the three methods the Comparator Model, the Conjoint Analysis, and the Hedonic Regression.

In the Comparator Model, the expert testifying for the plaintiff proposed to compare the defendant's Tito's vodka against high-end competitors Skyy and Smirnoff. The court rejected this analysis because it was not satisfied that the expert had established that the competitor vodkas were comparable with Tito's on dimensions of quality and other measures. These differences would be entangled with the "handmade" claim, which would be impossible to isolate for purposes of computing a price premium.

In the Conjoint Analysis, a different expert testifying for the plaintiff proposed to conduct a specialized survey and appropriate statistical analysis to estimate consumers' willingness to pay a premium for the Tito's "handmade" claim. Survey respondents would be asked which they would purchase among competing sets of hypothetical vodkas, varying on different attributes including the "handmade" claim and various price points. By analyzing a large number of survey respondents' comparisons of these sets, conjoint analysis can (one might say) distill each respondent's willingness to pay a premium for the "handmade" claim, and compute an average for the entire class. The court was skeptical of this approach. Interestingly, the court did not object to the use of a conjoint analysis, as some prior courts have done, on the basis that a conjoint analysis measures only willingness to pay and not an actual market premium; on the contrary, this court held that under the Ninth Circuit's conception of restitutionary damages, the economic harm to the plaintiff is that "the consumer has purchased a product that he or she paid more for than he or she otherwise might have been willing to pay if the product had been labeled accurately."[22] Instead, the court was concerned that "a conjoint analysis with two hypothetical products is too detached from the facts of this case to measure damages tied to Plaintiff's theory of liability."[23] The court also criticized the expert's "vague" elucidation of the means by which real-world pricing information would be tied to the willingness-to-pay analysis.[24]

In *Singleton* the Court noted that the plaintiff's expert's proposed design failed to sufficiently isolate the causal relationship between the "handmade representation" and price premium paid by consumers. By not specifying whether his conjoint survey

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[21] *In re* Petrobras Securities, 852 F.3d 250, 270 (2d Cir. 2017), quoting Tyson Foods, Inc., 136 S. Ct. 1036, 1045 (2016).

[22] *Singleton*, 2017 U.S. Dist. LEXIS 97433 at *74, quoting Pulaski & Middleman, 802 F.3d at 988-89, in turn quoting Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 329, 120 Cal. Rptr. 3d 741, 246 P.3d 877 (2011).

[23] 2017 U.S. Dist. LEXIS 170415 at *64, citing Ault v. J.M. Smucker Co., 310 F.R.D. 59, 67 (S.D.N.Y. 2015).

[24] *Id*. at *64-65.

respondents would view generic bottles of vodka or the actual Tito's product, the expert failed to account for the premium respondents may attribute to the Tito's brand name with or without the corrective statement. The failure to propose a research design that addresses the specific claims of harm and the plaintiff's causal theory of injury suggest that the issues of injury and damages must be assessed based on individualized inquiry.[25]

The *Singleton* court also determined that the expert's description of his proposed conjoint analysis "lacks the sort of step-by-step detail necessary to evaluate whether the methodology is workable."[26]

Finally, the court rejected the proposed hedonic regression analysis, in which the expert for the plaintiff proposed to analyze data on purchases of all vodkas in New York, using attributes of the vodkas as predictors of the final prices. The outcome of the regression analysis would be regression coefficients that predict how much each attribute, including the "handmade" claim, contributes to a vodka's final price. Here, the *Singleton* court acknowledged that hedonic regression analysis had been approved by courts in similar cases, but it criticized the expert for making "little attempt to identify a relevant set of product attributes" beyond a few suggestions, and in particular, for providing no means of quantifying the product quality.[27]

Based on these critiques of the proposed expert analysis, the *Singleton* court held that common issues do not predominate over individual ones because "although materiality may be proven with class-wide evidence, the issues of injury and damages will devolve into individualized inquiries because Plaintiff has failed to propose a sufficiently-detailed and suitable model to measure the alleged price premium for Tito's vodka due to the 'handmade representation.'"[28] Judge Sannes accordingly denied the request for class certification.[29]

Aftermath

On March 22, 2018, the mediator in the *Singleton* case advised the court that the matter "has been settled, or is in the process of being settled," and accordingly the court dismissed the case.[30] The amount of any monetary payment associated with the settlement was not disclosed. The court's September 27, 2017, decision will thus be the final word on class certification in that case.

OTHER 2017-18 DECISIONS

Several other cases decided in 2017 and thus far in 2018 bear on the same issues as *Singleton*. We focus first on the cases involving marketing of foods and dietary supplements.

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[25] *Id*. at *69.

[26] *Id*. at *67-68.

[27] *Id*.

[28] *Id*. at *69-70.

[29] *Id*. at *70.

[30] 5:15-CV-474 (BKS/TWD) (N.D.N.Y. March 22, 2018) (Dkt. 172, Order of Dismissal by Reason of Settlement).

Hughes v. The Ester C Company.[31]

In *Hughes v. Ester C*, the plaintiffs challenged the marketing of Ester-C vitamin supplements as "The Better Vitamin C." Judge Pamela Chen of the Eastern District of New York first denied the plaintiffs' motion for class certification on September 30, 2016, and then denied it again upon reconsideration on July 21, 2017. The plaintiffs in the case proposed a damages model that combined a conjoint analysis with a hedonic regression analysis. In the 2016 decision, the court had ruled that the proposed analysis was not viable because "The Better Vitamin C," standing alone, is puffery, and becomes actionable only in the context of more substantive claims, also present on the product label, that provide consumers with the factual basis of the "better" claim. The plaintiffs asserted that approximately 150 other Ester-C vitamin products exist that contain, individually or in combination, all ingredients and attributes of the challenged product except that they did not make the "Better Vitamin C" claim. The plaintiffs claimed that this group of competing products furnished adequate comparators for use in their conjoint analysis and/or hedonic regression. The court disagreed, finding that the plaintiffs' analysis could then only find the purported value of the "Better Vitamin C" claim alone. This, the court found, was precisely what the plaintiff did *not* need to establish, because the "Better Vitamin C" claim became actionable only in the context of substantive factual allegations.

Both the litigants' and the courts' reasoning in the *Hughes* case is somewhat tangled because of the plaintiffs' attempts to recast their analysis between the two decisions, but the bottom line is that the court considered the plaintiffs' damages methodology not to match their theory of injury. The plaintiffs failed to consider exactly what made their case actionable (i.e., not merely the "Better Vitamin C" claim, but the combination of that claim with the claims of other, less subjective attributes) and to tailor their damages methodology to finding the impact of that combination.

The plaintiffs sought an immediate appeal of the denial of class certification to the Second Circuit Court of Appeals, but this was denied, so the case has proceeded as an individual action. In early 2018, the parties briefed NBTY's motion for summary judgment, with the plaintiffs apparently planning to continue the case until some final resolution is reached that will permit them to appeal the class certification ruling.

Briseno v. ConAgra Foods, Inc.[32]

The plaintiffs in *Briseno v. ConAgra* alleged that ConAgra misleadingly marketed its Wesson brand cooking oils as "100% Natural" when, in fact, the oils were extracted from genetically-modified organisms (GMOs), which they contended are not "natural." Judge Margaret Morrow of the Central District of California denied the plaintiffs' initial motion for class certification on August 1, 2014, but granted leave to file an amended class certification motion. She then granted the amended motion and certified eleven statewide damages classes on February 23, 2015, and the Ninth Circuit affirmed the grant of class certification on January 3, 2017, with scant discussion of the damages methodology. The plaintiffs in the case proposed a damages methodology that combined a hedonic regression with a conjoint analysis. First, the plaintiffs

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31 No. 2:2012-CV-0041 (PKC) (E.D.N.Y. July 21, 2017).

32 674 Fed. Appx. 654, No. 15-55727 (9th Cir. Jan. 3, 2017) and *In re* ConAgra Foods, Inc., 90 F. Supp. 3d 919, No. CV 11-CV-05379 MMM (AGRx) (C.D. Cal. Feb. 23, 2015). The Supreme Court denied the petition for writ of certiorari in the case on October 10, 2017. See 138 S. Ct. 313, No. 16-1221.

proposed to calculate the price premium associated with the "100% Natural" claim with a hedonic regression. Then the plaintiffs proposed a conjoint survey and analysis conducted by another expert to determine the percentage of the "100% Natural" price premium specifically attributable to consumers' beliefs that the Wesson oils are not derived from GMOs.

In a lengthy opinion, with significant discussion about the damages methodologies in both the context of *Daubert* challenges and Rule 23(b)(3) requirements, the court concluded that the hedonic regression in combination with the other expert's conjoint analysis would satisfy *Comcast.* The court determined that the expert's previously inadmissible proposed hedonic regression model was now admissible because it contained a preliminary regression model with more details including the twenty product attributes used in the model, which included the brand of oil, oil variety, the size of the bottle, promotional prices, the time period, the "natural" claims at issue in the case, and other product label claims. The court, however, again found that the hedonic regression model on its own was incapable of calculating the price premium associated with consumers' belief that the oils are not derived from GMOs, the theory of liability, because it only measured the price premium attributable to the "100% Natural" label.

The conjoint expert testifying for the plaintiffs proposed to use consumer surveys to isolate the percentage of the price premium specifically attributable to a customer's belief that "100% Natural" means that the oils contain no GMOs and then she proposed to take the total price premium generated in the hedonic regression and multiply it by the percentage determined from the conjoint analysis to produce a damages figure that would be solely attributable to ConAgra's misleading marketing. The court found that this hybrid damages model would quantify damages associated with the plaintiffs' theory that they were misled to believe that the oils contained no GMOs. Of particular interest is that the court accepted that in this hybrid damages model it is sufficient to account for supply and market factors in the hedonic regression model; the conjoint analysis does not need to as well. In addition, the court was satisfied with the conjoint expert's explanation as to her decision to limit the survey to six attributes, with the safeguards provided by pilot tests and focus groups which would ensure that each attribute selected reflects a significant meaning and is an attribute that consumers would consider in making purchasing decisions, and with the idea that the expert could adjust the attributes if necessary following the focus groups and pilot tests.

Morales v. Kraft Foods Group, Inc.[33]

In the *Morales* case, the plaintiffs alleged that Kraft's Natural Cheese Fat Free Shredded Cheddar Cheese was not, in fact, natural cheese. The court had certified a class in 2015, which the defendants moved to decertify along with their motion for summary judgment in early 2017. By that time, an expert witness testifying for the plaintiffs had performed a conjoint analysis that tested various combinations of cheese attributes, including the label claim that Kraft's product was "natural cheese," to estimate the value to consumers of the "natural cheese" claim. The analysis assigned an average value of 74.7 cents to the claim, finding that 26% of respondents valued the "natural cheese" attribute at greater than $1. On its motion to decertify and to strike the testimony of the expert for the plaintiffs, the defendants largely launched a *Daubert*

[33] No. 2:14-CV-04387, 2017 U.S. Dist. LEXIS 97433 (C.D. Cal. June 9, 2017).

challenge, critiquing various aspects of the plaintiffs' methodology. Holding, as several courts have done, that a conjoint analysis is a form of "survey," and that deficiencies in a survey's methodology go only to the weight of a survey and not its admissibility, the court rejected the *Daubert* argument.[34] Just as in *Singleton*, however, the court differentiated the *Daubert* analysis from the Rule 23(b)(3) predominance inquiry, and the predominance analysis came out very differently.

The court had originally held that the proposed damages methodology was appropriately tied to the plaintiffs' theory of liability and supported the proposed class. The defendants ultimately prevailed on their argument that the expert for plaintiffs "did not determine the price premium that Kraft charged for the 'natural cheese' label, but rather measured customers' subjective willingness to pay, an academic and irrelevant exercise that is not consistent with Plaintiffs' theory of liability."[35] After an extensive analysis of past cases that had used conjoint analysis in various applications, the court concluded that a conjoint analysis "does not provide any insight into the money received by the Defendant in connection with the sale of the Product. Rather, it bears only on the claimed loss to Plaintiffs. Thus, the evidence provided by Plaintiffs about their potential willingness to pay a premium due to the use of the 'natural cheese' label is insufficient to establish a basis for calculating restitution."[36]

After the decision, the plaintiffs moved for recertification of the class, while at the same time, the parties entered into settlement discussions. The case docket went quiet in August of 2017, after several sealed filings, and it appears that the parties may have settled.

Zakaria v. Gerber Products Co.[37]

In the *Zakaria* case, the plaintiffs alleged that Gerber falsely marketed its "Good Start Gentle" infant formula as the "1st and only routine formula to reduce risk of developing allergies." On March 23, 2016, the court certified a California damages class. On November 29, 2016, the defendant filed a motion to decertify the damages class as well as a motion for summary judgement. The defendant's motions for decertification and summary judgement were granted. The court found that the proposed damages methodology did not measure the price premium paid by the class members due specifically to the "1st and Only" claim and other misleading statements concerning reducing the risk of developing allergies.

The plaintiff's proposed damages methodology consisted of a "choice-based conjoint analysis" where the survey participants were presented with several hypothetical packages of Gerber infant formula with corresponding, hypothetical prices which did not directly correspond with the actual market prices for the at-issue product. Given the use of hypothetical prices instead of actual market prices, the court found that the analysis did not sufficiently reflect the actual price premium or the actual market conditions in which the product was sold. Additionally, the court took issue with the limited sample size and the lack of confirming studies (including hedonic regression) or market data. Ultimately, the court decided that the plaintiff's

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[34] *Id*. at *43.

[35] *Id*. at *66.

[36] *Id*. at *75-76.

[37] No. 2:15-cv-00200-JAK-E (C.D. Cal. Aug. 9, 2017).

analysis did not show the amount of money the defendant received as a result of the alleged misrepresentations and was insufficient to calculate damages.

The plaintiff appealed these decisions to the Ninth Circuit Court of Appeals.[38] Briefing took place in early 2018.

Cases in Other Industries:

In re Dial Complete Marketing and Sales Practices Litigation.[39]

In the *Dial* case, the plaintiffs challenged marketing statements about the antibacterial properties of "Dial Complete" soap: that it "Kills 99.99% of Germs," is "#1 Doctor Recommended," and "Kills more germs than any other liquid hand soap." In December 2015, the court denied the plaintiffs' initial motion for class certification finding that the plaintiffs' proposed damages methodology failed to give sufficient detail for the court to determine whether damages could be calculated on a class-wide basis. However, the court allowed the plaintiffs to file an amended motion to address the deficiencies, which they did on June 24, 2016.

As part of the amended motion for class certification, the plaintiffs' expert proposed a choice-based conjoint analysis where participants were shown hand soap profiles with five attributes including price and the at-issue attributes. The prices reflected the real-world prices observed in preliminary research including market research data. The results of the conjoint survey were then inputted into a market simulation in order to determine the difference between the equilibrium market price of the soap with the allegedly misleading claims and the soap without the allegedly misleading claims. Although the court noted that the plaintiffs' methodology was "imperfect in some respects, weak in others, and subject to challenge on cross-examination," it found the model capable of calculating the price premium for the allegedly falsely-claimed features and establishing the full extent of damages on a class-wide basis. Therefore, the court granted the plaintiffs' amended motion for class certification.

Dial Corporation sought leave for interlocutory appeal to the First Circuit Court of Appeals. This request was denied on July 31, 2017.[40] As of early 2018, the case continues to be litigated.

Kurtz v. Kimberly-Clark Corp.[41]

The plaintiffs in the *Kimberly-Clark* matter, which includes several consolidated actions brought against Kimberly-Clark and other vendors and manufacturers of flushable toilet wipes, challenge the misleading characterization of the wipes as "flushable" because the wipes allegedly clogged household plumbing. The plaintiffs filed a motion for class certification in February 2015. The court found that the plaintiffs provided enough evidence to allow the certification of an injunctive class noting that "an injunction prohibiting defendants from labeling their products as 'flushable' and 'safe for sewer and septic systems' would provide a single solution, applicable to each class member." The court also certified two New York damages

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38 No. 0:17-cv-56509 (9th Cir.).

39 MDL Case No. 11-md-2263-SM (D.N.H. March 27, 2017).

40 Carter v. Dial Corp., 17-8009 (1st Cir.).

41 Nos. 14-CV-1142, 14-CV-4090, 15-CV-2909, 15-CV-2910, 15-CV-2928, 15-CV-4579 (E.D.N.Y. March 27, 2017).

classes finding that the "[p]laintiffs have shown that proposed methodologies can probably be used to learn common answers to common questions."[42]

In order to demonstrate that damages could be calculated on a class-wide basis, the plaintiffs' expert proposed a hedonic regression to calculate the proportion of the price attributable to the "flushable" characteristic, and he provided a preliminary list of the product attributes on which he would rely. He also stated in his report that his analysis would include evidence from the defendants' business records, industry resources, and independent market research data from companies like Nielsen. The expert also provided details of two alternative approaches, contingent valuation and conjoint analysis, to determine how much consumers value product attributes. The court found that all three methods proposed by the expert to determine the price premium attributable to the "flushable" representation were adequate for class certification. The decision to accept the plaintiffs' damages methodologies may have been easier for the court given that New York law provides for statutory damages of $50 to each class member for each time a defendant violates the New York General Business Law by a sale. As a result, the court noted that the "instant cases' battle of experts on price differential is largely beside the point. Once an injury is established, statutory damages can be precisely calculated for each class member."[43]

In June 2017, the Second Circuit Court of Appeals granted the defendants' petition for interlocutory appeal. Briefing of the appeal was completed in early 2018.[44]

IMPLICATIONS

The plaintiff in *Singleton* failed to clear the Rule 23(b)(3) hurdle despite proposing a combination of damages methodologies—in particular, conjoint analysis and hedonic regression analysis—that has passed muster in some other false-advertising class actions. Obviously, given the *Singleton* decision and other cases above, such as *Zakaria*, that also proposed to use one or both of these methods, merely saying the words "conjoint analysis" and "hedonic regression" does not, at least in all instances, persuade courts that plaintiffs can estimate damages on a class-wide basis. What more is needed?

First, the analysis needs to be carefully thought out and proposed in some detail. Judge Sannes in *Singleton* repeatedly referred to the slapdash quality of the damages analysis proffered in the case. The court noted that the expert witness who proposed both the conjoint analysis and the hedonic regression had not originally been offered as a damages expert and had not been relied upon in the plaintiff's original motion for class certification; rather, the relevant expert opinions "are tacked on to the end of his second expert report, which was submitted with Plaintiff's reply in further support of the class motion."[45] The expert's descriptions of the methodologies were at various points characterized by the court as lacking sufficient detail, vague, "skeletal analysis," "bare-bones," and "superficial." The court was left without a clear idea of how the analyses were supposed to work or to do what they were supposed to. Indeed, the court's criticism of conjoint analysis for its use of "hypothetical products," which

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42 2017 U.S. Dist. LEXIS 44576, at *554.

43 *Id.* at *551.

44 No. 17-1856 (2d Cir.).

45 2017 U.S. Dist. LEXIS 170415, at *66 n.24.

actually are a fundamental tool in conjoint analysis, suggests that the expert witness for the plaintiff failed to educate the court about the nature of the proposed analysis. In contrast, in both *Dial* and *Briseno v. ConAgra Foods*, following initial failures and the denial of initial certification motions, the courts found the plaintiffs' experts provided sufficient details in subsequent filings. Specifically, incremental details on conjoint design and preliminary regression results, which helped to isolate the claims, were found to provide sufficient evidence that both classes were certified.

Second, the expert witness must address the difficult issues and unique circumstances in every case. One common example is the lack of availability of sufficient marketplace data to conduct a hedonic regression analysis, or the tendency of the challenged attribute to co-vary with some other attribute, making the challenged attribute difficult to isolate. Here, a special problem was presented that is relatively unique to this case: the role of the variable "quality" of vodkas. The court raised the expert's failure to even suggest how vodka quality would be operationalized as among the fatal flaws with both the Comparator Analysis and the Hedonic Regression, while noting with some skepticism that the Conjoint Analysis proposed merely to sidestep this variable. Quality presents a special research issue for a product such as an alcoholic beverage, where quality is not merely the product of a bundle of on-off or quantifiable attributes. Quantifying overall vodka quality is not an impossible research task, but it is a challenge, and one that the court felt that the expert for the plaintiff made little effort to resolve. Similarly, in *Briseno v. ConAgra Foods*, the courts indicated that it was necessary to marry a hedonic regression, which could determine a price premium for an "All Natural" label, with a conjoint analysis, which could further isolate the value of no-GMO within that overall context.

Finally, to the extent that multiple methodologies are proposed to be used together, they must be integrated. The *Singleton* court criticized the proposed conjoint analysis for failing to calculate the actual amount that consumers overpaid using real-world pricing and sales data.[46] That function might have been served by either of the two alternative analyses proposed by the plaintiffs—the Comparator Analysis and the Hedonic Regression, which is really just a more sophisticated form of the Comparator Analysis utilizing controls. Apparently, the plaintiff and the expert witness he retained failed to explain convincingly how the other analyses might be used to calibrate or triangulate the results from the conjoint analysis, lending it some real-world validation. To be sure, such an exercise is not easy, and it requires convincing the court of the feasibility of at least two different types of analysis, plus some way in which they could be married. This issue of the intersection between consumer willingness to pay and market outcomes was discussed in nearly every matter. Failure to demonstrate that an expert can determine but-for prices was generally found to be sufficient to deny certification, as in the *Morales* case, the *Zakaria* matter, and the outcomes in initial *Dial* and *Briseno v. ConAgra Foods* decisions. Even in *Kimberly Clark,* it was the availability of statutory damages in that matter which appears to have resolved the tension between consumer values and market prices.

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[46] *Id.* at *65, citing *Ault*, 310 F.R.D. at 67.

2017 Significant Settlements

JACQUELINE J. CHAN*

INTRODUCTION

Whereas much of this book discusses cases resolved by a court or a jury, this chapter highlights some significant settlements between the food and drug industry and the U.S. Food and Drug Administration (FDA) in conjunction with the U.S. Department of Justice (DOJ) in 2017. FDA and DOJ have far reaching enforcement powers including civil penalties and criminal prosecution.

As in recent years, many of the settlements discussed here arise from DOJ's substantial use of the False Claims Act (FCA) that imposes liability on persons and companies who defraud governmental programs and contracts. Between fiscal years 2010 and 2017, DOJ recovered $32 billion through FCA settlements and judgments.[1] Fiscal year 2017 resulted in more than $3.7 billion in FCA settlement and judgments,[2] which was a dip from the $4.7 billion in FCA recoveries in fiscal year 2016 (which was the third highest annual recovery in FCA history).[3] However, FCA recoveries generally have been consistently high in recent years, with no annual recoveries below $3 billion since 2010.[4] In 2017, the largest recoveries again came from the health care industry ($2.4 billion) with over $900 million from the drug and medical device industry.[5] This was the eighth consecutive year that health care industry recoveries exceeded $2 billion, further reinforcing the government's continued interest in the health care industry.

Fiscal year 2017 marked the fourth highest number of new FCA matters filed in a fiscal year, with nearly 800 new cases between the government and whistleblowers (known as relators in *qui tam* actions).[6] As in past years, relator lawsuits accounted for the majority of FCA matters (674 cases versus the 125 cases filed by the government). Relators receive up to 30 percent of any recovery and such recoveries accounted for $3.4 billion out of the $3.7 billion total (the second highest yearly total for *qui tam* actions). Relators also showed a marked interest in continuing to pursue lawsuits even where the government did not intervene; such recoveries were the

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1 Fraud Statistics-Overview (DOJ Dec. 19, 2017).

2 Press Release, DOJ, Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017).

3 Press Release, DOJ, Justice Department Recovers Over $4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016).

4 Fraud Statistics-Overview (DOJ Dec. 19, 2017).

5 Press Release, DOJ, Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017).

6 Fraud Statistics-Overview (DOJ Dec. 19, 2017).

second highest ever in fiscal year 2017. Further of note, where relators are typically an employee or former employee of the company, one of the major FY 2017 FCA settlements came from a rival company relator (Sanofi-Aventis) in the EpiPen case against Mylan Inc. and Mylan Specialty L.P.[7] From the $465 million settlement, Sanofi-Aventis received $38.7 million as its share of the federal recovery.

The 2017 settlements also illustrate DOJ's commitment to holding individuals accountable for corporate wrongdoing in line with DOJ's memorandum issued in September 2015. Commonly referred to as the "Yates memorandum," the memorandum reinforced DOJ's "commitment to us[ing] the False Claims Act and other civil remedies to deter and redress fraud by individuals as well as corporations."[8] In its year end press release, DOJ reiterated its focus on "ensur[ing] individual accountability for corporate wrongdoing by pursuing False Claims Act and other civil remedies to redress fraud by individuals as well as corporations."[9] Indeed, DOJ announced it recovered more than $60 million in settlements and judgments with individuals that did not involve a corporate entity.[10] It also highlighted settlements where individual owners and executives of private corporations agreed to be held jointly and severally liable for settlement payments with their corporations, including a $155 million settlement with a national electronic health records software vendor, eClinicalWorks, and a $145 million settlement with a skilled nursing facility chain, Life Care Centers of America.[11]

This chapter discusses some of the key FCA settlements as well as other representative settlements and consent decrees between the food and drug industry and the government from 2017.

DRUGS

a. Mylan Inc. and Mylan Specialty L.P.[12]

Mylan Inc. and Mylan Specialty L.P. paid $465 million to resolve allegations that they violated the FCA when knowingly misclassifying EpiPen as a generic drug to avoid paying rebates owed primarily to Medicaid. The government alleged that Mylan erroneously reported EpiPen as a generic drug to Medicaid despite the absence of any therapeutically equivalent drugs, thus enabling Mylan to demand significant price increases while avoiding its rebate obligations to Medicaid. Under the Medicaid Drug Rebate Program, single-source (or brand name) drugs are subject to a higher rebate that is payable to Medicaid, which increases to the extent the drug price outpaces the inflation rate. On the other hand, generic drugs originating from multiple manufacturers are subject to lower rebates. According to the government,

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[7] Press Release, DOJ, Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates (Aug. 17, 2017).

[8] *See id*; Press Release, DOJ, Justice Department Recovers Over $4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016).

[9] Press Release, DOJ, Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017).

[10] *Id.*

[11] *Id.*

[12] Press Release, DOJ, Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates (Aug. 17, 2017).

Mylan increased the price of EpiPen by approximately 400 percent between 2010 and 2016 but paid only a fixed 13 percent rebate to Medicaid.

Mylan also entered into a corporate integrity agreement with the U.S. Department of Health and Human Services, Office of Inspector General. The agreement requires an independent review organization to annually review Mylan's Medicaid drug rebate program practices.

The lawsuit against Mylan was initiated by Sanofi-Aventis US LLC under the whistleblower provisions of the FCA. As a result, Sanofi-Aventis received $38.7 million as its share of the federal recovery.

b. Baxter Healthcare[13]

Baxter Healthcare Corporation (Baxter) paid $18.158 million to resolve criminal and civil allegations arising from Baxter's failure to follow current Good Manufacturing Practices (cGMPs) when manufacturing sterile drug products. The $18 million includes a FCA settlement of $2.158 million and $431,535 payout to an employee whistleblower who filed the lawsuit.

Baxter allegedly introduced adulterated drugs into interstate commerce when it failed to follow cGMPs. It manufactured large-volume sterile intravenous solutions in a clean room that had air pushed into it through high-efficiency particulate absorption (HEPA) filters that were installed in the ceiling. A whistleblower employee reported the presence of mold on the HEPA filters to plant management but Baxter continued to manufacture IV solutions without removing or replacing the filters. Subsequent filter testing by FDA inspectors showed several mold species on the filters. There was no evidence of impact on the products or harm to patients.

FCA lawsuits based on a failure to comply with cGMPs are generally rare. Here, the government tied Baxter's actions to the fact that Baxter sold these products to the government under contracts that required compliance with the Federal Food, Drug and Cosmetic Act (FDCA). As such, DOJ alleged that Baxter submitted false claims and thus violated the FCA. Under the terms of the deferred prosecution agreement, Baxter paid the monetary penalties and forfeiture and implemented enhanced compliance provisions, including periodic certifications to the government concerning its implementation of those provisions.

c. Mallinckrodt LLC[14]

Pharmaceutical manufacturer Mallinckrodt LLC (Mallinckrodt) agreed to pay $3 million to resolve allegations that it violated the Controlled Substances Act. DOJ has stated that "[t]his is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify [the Drug Enforcement Administration (DEA)] of suspicious orders of controlled substances such as oxycodone." The government alleged that Mallinckrodt had failed to design and implement an effective system to detect and report suspicious orders (i.e., orders unusual in frequency, size, or other patterns). As part of the settlement, Mallinckrodt is required to use downstream customer purchase information ("chargeback data") and other similar data to monitor

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[13] Press Release, DOJ, Baxter Healthcare Corporation to Pay More Than $18 Million to Resolve Criminal and Civil Liability Relating to Sterile Products (Jan. 12, 2017).

[14] Press Release, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017).

and report suspicious sales of oxycodone at the next level in the supply chain to DEA. This is in line with the DEA's position that controlled substance manufacturers need to "know your customer's customer" to ensure that these substances do not get in the wrong hands.

The government also contended that Mallinckrodt violated certain record keeping requirements creating discrepancies between the actual number of tablets manufactured and the reported number of tablets manufactured. The settlement required specific procedures to ensure accuracy of batch records.

d. Novo Nordisk[15]

Novo Nordisk Inc. agreed to pay $58.65 million to settle allegations related to its Type II diabetes medication Victoza, including a $46.5 million settlement for FCA violations and disgorgement of $12.15 million for alleged violations of the FDCA. The government contended that FDA required a Risk Evaluation and Mitigation Strategy (REMS) in which Novo Nordisk was required to provide information regarding Victoza's potential risk of Medullary Thyroid Carcinoma (MTC) to physicians. The government alleged that Novo Nordisk sales representatives gave physicians information to believe that this REMS-required message was erroneous, irrelevant, or unimportant and obscured the risk information. The government further contended that Novo Nordisk's sales force encouraged the sale to and use of Victoza by adult patients who did not have Type II diabetes even though FDA has not approved Victoza as safe and effective for such patients. This settlement resolves seven lawsuits filed under the whistleblower provision of the FCA.

e. United Therapeutics[16]

United Therapeutics Corporation (United Therapeutics) agreed to pay $210 million to settle FCA claims that it used a foundation as a conduit to pay Medicare patient copays taking United Therapeutics' pulmonary arterial hypertension drugs in violation of the FCA. Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering or paying remuneration (directly or indirectly) to induce Medicare patients to purchase the company's product. The government alleged that United Therapeutics made donations to a foundation that in turn used those donations to pay Medicare copays for United Therapeutics' drugs to induce patients to purchase the drugs.

United Therapeutics entered into a corporate integrity agreement with the Department of Health and Human Services, Office of Inspector General. Among other things, the agreement requires that United Therapeutics (1) implement measures designed to ensure that arrangements with third-party patient assistance programs are compliant with the law, (2) have review conducted by an independent review organization, (3) obtain compliance-related certifications from company executives and Board members, and (4) implement a risk assessment and mitigation process.

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[15] Press Release, Novo Nordisk Agrees to Pay $58 Million for Failure to Comply with FDA-Mandated Risk Program (Sept. 5, 2017).

[16] Press Release, Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 20, 2017).

MEDICAL DEVICES

a. Shire Pharmaceuticals LLC—Largest False Claims Act Recovery by U.S. in Medical Device Kickback Case[17]

Shire Pharmaceuticals LLC and other subsidiaries of Shire plc (Shire) paid $350 million to settle federal and state FCA allegations that Shire and a company it acquired in 2011, Advanced BioHealing, used kickbacks and other unlawful methods to induce clinics and physicians to use or overuse its product, Dermagraft. Dermagraft is a bioengineered human skin substitute approved by FDA for the treatment of diabetic foot ulcers. The allegations claimed that Dermagraft salespersons unlawfully induced clinics and physicians to use Dermagraft with (1) dinners, drinks, entertainment, and travel, (2) medical equipment and supplies, (3) unwarranted payments for purported speaking engagements and case studies, and (4) cash, credits, and rebates. The United States alleged that Advanced BioHealing and Shire submitted or caused to be submitted hundreds of millions of dollars of false claims for Dermagraft to federally-funded health care programs.

U.S. Attorney's Offices across several jurisdictions, including the Middle District of Florida, the District of Columbia, the Eastern District of Pennsylvania, and the Middle District of Tennessee contributed to the investigation and resolution of these matters. The settlement also resolved allegations that Shire and Advanced BioHealing unlawfully marketed Dermagraft for uses not approved by FDA, made false statements to inflate the price of Dermagraft, and caused improper coding and certification of Dermagraft claims and services.

Beyond the civil settlement, U.S. attorneys for the Middle District of Florida are pursuing convictions against the individuals responsible for these illegal actions. Criminal convictions have included three high-level executives who supervised the implementation of the illegal kickback scheme and healthcare provider who received kickbacks.

DIETARY SUPPLEMENTS

a. Regeneca Worldwide[18]

Dietary supplement distributor, VivaCeuticals Inc., doing business as Regeneca Worldwide, and its CEO, agreed to a consent decree of permanent injunction to settle allegations that it was unlawfully distributing unapproved new drugs and adulterated and misbranded dietary supplements. The government's complaint alleged that the defendants manufactured and distributed a product that contained the unsafe food additive 1,3 dimethylamylamine (DMAA) and failed to disclose the presence of DMAA on the product's labeling. The complaint further alleged that the defendants violated the FDCA by marketing the product to be used in the cure, mitigation,

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[17] Press Release, DOJ, Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations (Jan. 11, 2017).

[18] Press Release, DOJ, United States Files Consent Decree of Permanent Injunction Against California Dietary Supplement Manufacturer to Stop Distribution of Adulterated and Misbranded Dietary Supplements (Jan. 18, 2017); Press Release, FDA, Federal judge approves consent decree with California dietary supplement distributor, Regeneca Worldwide (Feb. 9, 2017).

treatment or prevention of diseases, causing the product to be an unapproved new drug and a misbranded drug.

This enforcement action came after several FDA inspections of the manufacturing facility and a warning letter for marketing the dietary supplement containing DMAA. Regeneca had repeatedly assured FDA it would correct the violations yet continued to distribute the dietary supplement containing DMAA.

The consent decree requires Regeneca to cease all operations and, if it wishes to resume manufacturing dietary supplements or drugs in the future, FDA must first determine that its manufacturing practices have come into compliance with the law. Regeneca must, among other things, hire good manufacturing practice and labeling experts and implement procedures to comply with good manufacturing practice and labeling requirements.

b. Pick and Pay Inc./Cili Minerals LLC[19]

Manufacturer and distributor of drug and dietary supplements, Pick and Pay Inc./Cili Minerals (Cili Minerals) and its owner agreed to a consent decree of permanent injunction to settle allegations that it distributed misbranded and unapproved new drugs and misbranded and adulterated dietary supplements. The government's complaint alleged that the defendants violated the FDCA by manufacturing, promoting, and distributing numerous dietary supplements marketed as drugs intended to treat or prevent diseases even though not approved by FDA. The complaint further contended that the claims were unsupported by well-controlled clinical studies or other credible scientific substantiation. According to the complaint, the defendants' products were adulterated dietary supplements because they were not manufactured in compliance with good manufacturing practice regulations. The allegations underlying the government's case were based on FDA's findings during four facility inspections. For example, the inspections revealed that Cili Minerals failed to ensure the identity, purity, strength, and composition of their finished products. FDA had subsequently issued a warning letter to Cili Minerals.

The consent decree requires the company and its owner to cease all production and distribution of misbranded and unapproved new drugs and adulterated and misbranded dietary supplements and recall and destroy their drugs and dietary supplements. If the company and its owner wish to resume manufacturing dietary supplements and/or drugs in the future, they must hire labeling and good manufacturing practices experts and receive written permission from FDA to resume operations.

c. EonNutra LLC, CDSM LLC, and HABW LLC[20]

EonNutra LLC, two related companies (CDSM LLC and HABW LLC), and their owner (defendants) agreed to a consent decree of permanent injunction to settle

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[19] Press Release, DOJ, United States Files Consent Decree of Permanent Injunction Against a Louisiana Drug and Dietary Supplement Manufacturer to Stop Distribution of Misbranded and Unapproved New Drugs and Misbranded and Adulterated Dietary Supplements (Feb. 16, 2017); Press Release, FDA, Louisiana drug and dietary supplement maker ordered to cease operations due to federal violations (Feb. 21, 2017).

[20] Press Release, DOJ, District Court Enters Permanent Injunction Against Colorado Companies to Stop Distribution of Adulterated and Misbranded Dietary Supplements and Unapproved and Misbranded Drugs (March 15, 2017); Press Release, FDA, Colorado unapproved drug and dietary supplement makers ordered to cease operations for federal violations (March 14, 2017).

allegations that it sold and distributed misbranded and unapproved new drugs and misbranded and adulterated dietary supplements. The government's complaint alleged that the defendants violated the FDCA by marketing its labeled dietary supplements as drugs with claims that the products could help treat or prevent serious conditions or diseases. The complaint further alleged that defendants offered these claims without FDA approval and sold the supplements without implementing procedures to validate the dietary supplements' composition. The claims were allegedly unsupported by well-controlled clinical studies or other credible scientific substantiation. The complaint also alleged that the defendants' products were adulterated dietary supplements because they were not manufactured in compliance with cGMP regulations. The allegations were based on FDA's findings during four facility inspections. For example, the inspections revealed that EonNutra LLC, CDSM LLC, and HABW LLC failed to ensure the identity, purity, strength, and composition of their finished products. Despite FDA's warnings, defendants continued to post claims on their websites about their products curing, mitigating, treating, and preventing serious diseases.

The consent decree requires the companies and its owner to cease all production and distribution of misbranded and unapproved new drugs and adulterated and misbranded dietary supplements and recall and destroy their drugs and dietary supplements. If the companies and its owner wish to resume manufacturing dietary supplements and/or drugs in the future, they must hire labeling and good manufacturing practices experts and receive written permission from FDA to resume operations.

FOOD

a. Valley Milk Products[21]

DOJ and FDA filed a seizure action against Valley Milk Products LLC (Valley Milk, a manufacturer of Grade A and non-Grade A milk products) and its general manager, plant manager, and quality control compliance officer. The complaint alleged that FDA inspected a Valley Milk facility in 2016 and confirmed the presence of *Salmonella meleagridis* as in three previous inspections (2010, 2011, and 2013). FDA found the same strain in Valley Milk's undistributed finished product samples. FDA also noted that the milk processing facility had insanitary conditions and that the company's sanitation practices were inadequate to control or eliminate the *Salmonella* in its processing environment.

In March 2017, the U.S. District Court for the Western District of Virginia entered a consent decree of condemnation and permanent injunction against Valley Milk and the three individuals. Under the decree, certain seized milk powder products were condemned and the company was prohibited from resuming manufacturing milk powder products. To resume manufacturing, the company must complete certain remedial measures, including establishing and implementing a written sanitation control program.

[21] Press Release, DOJ, District Court Enters Permanent Injunction Against Virginia Company and Employees to Prevent Distribution of Adulterated Milk Powder Products (March 15, 2017).

b. The Smokehouse of NY, LLC[22]

In June 2017, the U.S. District Court for the Southern District of New York entered a consent decree of permanent injunction between the United States and The Smokehouse of NY, LLC (Smokehouse) and two of its employees (director of operations and president/owner). The consent decree resolves allegations of recurring food safety violations, that included a FDA Warning Letter related to findings of *Listeria monocytogenes* in the Smokehouse processing facility and in its cold-smoked salmon, as well as violations of the seafood Hazard Analysis Critical Control Point regulations and cGMP regulations for food. Subsequent inspections also found *Listeria monocytogenes* in the Smokehouse processing facility. Despite agreeing to correct the condition, Smokehouse did not consistently implement the changes. In 2017, FDA inspectors found widespread *Listeria monocytogenes* in the facility. No illnesses had been reported from Smokehouse products.

The consent decrees will require defendants to retain an independent laboratory to collect and analyze samples for the presence of *Listeria monocytogenes*, retain an independent expert and development a program to control the bacteria, and eliminate insanitary conditions at the facility.

CONCLUSION

Overall, the 2017 settlements illustrate FDA's and DOJ's focus on food safety and dietary supplements as well as DOJ's continued pursuit of FCA lawsuits, specifically against the health care industry. The recoveries also point to DOJ's commitment to enforcing the FCA against individuals, through joint and several liability with their corporations and individual liability.

The recovery figures are generally consistent with recent years, which may indicate that the change in presidential administration has not affected FCA enforcement goals and activity. However, FCA lawsuits often take several years to be resolved after filing and are often driven by long-time DOJ FCA attorneys, so these figures may not be a true indication of how the change in administration will affect FCA recoveries.

Regardless, the 2017 settlements demonstrate the strong interest of relators in pushing forward FCA lawsuits, even where the government does not intervene. Relators will likely continue to be the primary force behind FCA lawsuits. What remains to be seen is if more competitor companies, as opposed to current or former employees, will seek FCA lawsuits as in the case initiated by Sanofi-Aventis against Mylan.

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[22] Press Release, FDA, Federal judge orders New York smoked fish company to stop sales due to food safety violations (June 30, 2017).

2017 Regulatory, Policy, and Enforcement Developments

FDA Launches Digital Health Innovation Plan and Pre-Cert Program, Announces Major Tobacco Policy Shift, and Cracks Down on Unsubstantiated CBD Treatment Claims

JONATHAN A. HAVENS*

Scott Gottlieb, M.D., who was nominated by President Trump to serve as Commissioner of the U.S. Food and Drug Administration (FDA or the agency) on March 10, 2017 and confirmed by the U.S. Senate on May 9, 2017, wasted no time once he arrived at the agency last May. Although he was at FDA for less than eight months last year, Commissioner Gottlieb oversaw significant regulatory, policy, and enforcement developments, including with regard to digital health, tobacco products, and marijuana-derived products.

DIGITAL HEALTH INNOVATION PLAN AND PRE-CERT PROGRAM

As is often the case, technology in the digital health space has outpaced regulation, commonly forcing developers to seek guidance from FDA on a case-by-case basis. Congress took an important first step to promote more digital health regulatory certainty when it passed the 21st Century Cures Act (21st Century Cures), which President Obama signed into law in late 2016.

On June 15, 2017, Commissioner Gottlieb announced that the agency would be developing a new Digital Health Innovation Plan (the Plan), released later last summer,[1] through which FDA hopes to encourage industry growth by providing more regulatory certainty to device developers. Gottlieb also indicated that the agency would soon thereafter pilot a new, risk-based approach toward regulating

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[1] *See* FDA, *Digital Health Innovation Action Plan*, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf (last visited Mar. 11, 2018).

digital health technologies, which FDA launched on July 27, 2017.[2] FDA announced the names of the companies selected to participate in its digital health software precertification pilot program (Pre-Cert program) on September 26, 2017.[3]

In releasing its Plan, and two final guidances and one draft guidance late last year,[4] on when to submit a 510(k) for a change to an existing device, when to submit a 510(k) for a software change to an existing device, and the breakthrough devices program, respectively, FDA continued to implement the digital health provisions of 21st Century Cures. Developers are cautiously optimistic that the Plan, the Pre-Cert program, and agency guidances will help clarify what falls outside the scope of FDA regulation, and will help obviate the need for case-by-case regulatory discussions with FDA.

In describing the digital health pilot, Gottlieb assessed that it represents "an entirely new approach toward regulating this technology" that "will be the cornerstone to a more efficient, risk-based regulatory framework" for such products. One of the things the agency is said to be considering is whether it can, under existing authority, create a third-party certification regime under which lower risk digital health products could be marketed without premarket review and higher risk products could be marketed with a streamlined agency premarket review. Per Gottlieb, certification might be used to assess, say, whether a company consistently and reliably engages in high quality software design and testing (i.e., validation) and ongoing maintenance of its software products. Under such a certification program, development time and market entry cost could be reduced for software as a medical device (SaMD).

Gottlieb also indicated that under the pilot program, real-world data collected post market—such as data gathered through the National Evaluation System for health Technology (NEST)—could be leveraged by developers to help expedite market entry and subsequent expansion of indications more efficiently. While FDA does not own or operate NEST, Gottlieb noted that the agency has been establishing strategic alliances among data sources to accelerate NEST's launch, and that the initial version of a fully operational system is anticipated by the end of 2019.

TOBACCO POLICY SHIFT

In arguably one of the biggest FDA policy developments last year, on July 28, 2017, the agency announced a new, comprehensive plan for tobacco and nicotine regulation that places nicotine, and the issue of addiction, at the center of FDA's

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[2] FDA, "FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare," July 27, 2017, https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/.

[3] FDA, "FDA selects participants for new digital health software precertification pilot program," Sept. 26, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577480.htm.

[4] *See* FDA, Guidance- "Deciding When to Submit a 510(k) for a Change to an Existing Device," Oct. 25, 2017, https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf; FDA, Guidance- "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," Oct. 25, 2017, https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514737.pdf; and FDA, Draft Guidance- "Breakthrough Devices Program," Oct. 25, 2017, https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

tobacco regulatory efforts.[5] Since nearly the beginning of his tenure as Director of the Center for Tobacco Products (CTP), Mitch Zeller has discussed that tobacco products represent a "continuum of risk." However, until FDA's July 2017 announcement, the meaning of that phrase was never fully understood. We now know that the agency believes that, within that continuum of risk, nicotine is *most* harmful when delivered through smoke particles in combustible cigarettes. Although FDA did not indicate so directly in its groundbreaking announcement, this approach suggested for the first time the agency's assessment that e-cigarettes and vapor products are less harmful than combustible cigarettes.

Within the announcement of its multi-year tobacco and nicotine regulatory plan, the agency stated its intentions to:

- Extend timelines to submit tobacco product review applications for newly-regulated tobacco products that were on the market as of August 8, 2016 to afford FDA more time to explore clear and meaningful measures to make tobacco products less toxic, appealing, and addictive. Applications for newly-regulated combustible products, such as cigars, pipe tobacco, and hookah tobacco were extended until August 8, 2021, and applications for non-combustible products such as electronic nicotine delivery systems (ENDS) or e-cigarettes were delayed until August 8, 2022. Manufacturers are able to continue to market such products until product applications for the same are required to be submitted and while FDA reviews such product applications.
- Issue advance notices of proposed rulemaking (ANPRMs) to: (1) seek input on the potential public health benefits and any possible adverse effects of lowering nicotine in cigarettes; (2) seek public comment on the role that flavors (including menthol) in tobacco products play in attracting youth and may play in helping some smokers switch to potentially less harmful forms of nicotine delivery; and (3) solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from premium cigars, which were included in FDA's 2016 Deeming Rule.[6]
- Issue foundational rules to make the tobacco product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. Among other things, FDA intends to issue regulations outlining what information FDA expects to be included in Premarket Tobacco Applications (PMTAs), Modified Risk Tobacco Product (MRTP) applications, and reports to demonstrate Substantial Equivalence (SE). The agency also plans to finalize guidance on how it intends to review PMTAs for ENDS products.

While the stated purpose of FDA's multi-year plan is to better protect kids and significantly reduce tobacco-related disease and death, the product review application delay portions of the same were a major win for ENDS, cigar, pipe

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[5] FDA, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death," July 28, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm.

[6] FDA, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (codified at 21 C.F.R. Parts 1100, 1140, and 1143).

tobacco, and hookah tobacco manufacturers. When President Trump nominated now FDA Commissioner Scott Gottlieb, industry was hopeful that under his watch, the agency would roll back or delay certain portions of the Deeming Rule. Industry had been lobbying hard against the Rule's premarket requirements since they were first proposed, as they will result in major industry consolidation because of the $1 million-plus cost involved in preparing certain marketing applications (a trend that has already started). Before the announced delays, manufacturers would have had to comply with the onerous premarket review requirements starting in November 2017.

Also notable in the agency's July 2017 tobacco and nicotine regulatory announcement is its inclusion of menthol, which Congress specifically carved out of the flavored cigarette ban enacted as part of the Family Smoking Prevention and Tobacco Control Act, the legislation that gave FDA its authority to regulate tobacco products. In July 2013, the agency issued an ANPRM to obtain public input on menthol in cigarettes but the agency never moved forward with regulatory action on the same, due in large part to a successful industry challenge to the menthol report issued by FDA's Tobacco Products Scientific Advisory Committee (TPSAC). While the U.S. Court of Appeals for the D.C. Circuit eventually upheld the agency's right to rely on TPSAC's menthol report, FDA did not pursue further regulatory action. It remains to be seen, how, if at all, the agency will now decide to regulate menthol in cigarettes and/or other tobacco products.

UNSUBSTANTIATED CBD TREATMENT CLAIMS

On October 31, 2017, FDA issued Warning Letters to four companies—Greenroads Health,[7] Natural Alchemist,[8] That's Natural! Marketing and Consulting,[9] and Stanley Brothers Social Enterprises LLC[10]—citing unsubstantiated claims related to more than 25 different products sold online that allegedly contain cannabidiol (CBD), a component of the marijuana plant that is not currently FDA-approved in any drug product for any indication.

These actions were not surprising given Commissioner Scott Gottlieb's testimony before Congress last year, during which he addressed the agency's role in cracking down on such claims and said that FDA would "have some answers . . . soon because I think we do bear some responsibility to start to address these questions."[11]

The companies receiving the Warning Letters made claims regarding their products preventing, reversing, or curing cancer, killing/inhibiting cancer cells or tumors, or other similar anti-cancer claims. More specifically, the companies said about their products:

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[7] FDA, Warning Letter issued to Green Roads of Florida LLC, Oct. 31, 2017, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583188.htm.

[8] FDA, Warning Letter issued to Natural Alchemist, Oct. 31, 2017, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583205.htm.

[9] FDA, Warning Letter issued to That's Natural, Oct. 31, 2017, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583197.htm.

[10] FDA, Warning Letter issued to Stanley Brothers Social Enterprises, LLC, Oct. 31, 2017, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583192.htm.

[11] Michelle Cortez, "FDA Hints It May Look Into Marijuana Health Claims," BLOOMBERG, Oct. 3, 2017, https://www.bloomberg.com/news/articles/2017-10-03/fda-hints-it-may-look-into-medical-marijuana-health-claims.

- "Combats tumor and cancer cells;"
- "CBD makes cancer cells commit 'suicide' without killing other cells;"
- "CBD . . . [has] anti-proliferative properties that inhibit cell division and growth in certain types of cancer, not allowing the tumor to grow;" and
- "Non-psychoactive cannabinoids like CBD (cannabidiol) may be effective in treating tumors from cancer – including breast cancer."

Some of the products were also marketed as an alternative or additional treatment for Alzheimer's and other serious diseases.

This is not the first time the agency has taken enforcement action against firms selling CBD products with unsubstantiated claims.[12] However, FDA's October 2017 actions will no doubt have a chilling effect on marketing efforts in the rapidly-expanding medical marijuana industry. Leaving no doubt about what industry can expect, Commissioner Gottlieb said that "[w]e don't let companies market products that deliberately prey on sick people with baseless claims that their substance can shrink or cure cancer and we're not going to look the other way on enforcing these principles when it comes to marijuana-containing products."[13]

The agency is not alone in addressing cannabis product marketing practices. For example, in September 2017, the Office of the Attorney General (OAG) of Washington State sent a letter to marijuana retailers in which OAG reminded industry of the State's ban on making curative or therapeutic claims in marijuana advertisements, including on websites. In the letter, Shannon Smith, Senior Assistant Attorney General and Chief of the Consumer Protection Division, said that despite the State's prohibition, her office has investigated several marijuana retailers for making medical claims on their websites.

As noted above, FDA has not approved marijuana, a Schedule I controlled substance, for any indication. However, the agency has approved Marinol® and Syndros™ for therapeutic uses, including for the treatment of anorexia associated with weight loss in AIDS patients.[14] Marinol® and Syndros™ include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of marijuana. Another FDA-approved drug, Cesamet™, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

FDA has indicated that it supports access to investigational drugs derived from marijuana. For example, the agency granted an investigational new drug application (IND) for a Phase II/III clinical trial of Epidiolex® (cannabidiol) in the treatment of Dravet Syndrome. In October 2017, GW Pharmaceuticals announced that it completed its rolling new drug application (NDA) submission to FDA for Epidiolex® (cannabidiol) as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome, two highly treatment-

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[12] *See*, *e.g.*, FDA, Warning Letters and Test Results for Cannabidiol-Related Products, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm (last visited Mar. 11, 2018).

[13] FDA, "FDA warns companies marketing unproven products, derived from marijuana, that claim to treat or cure cancer," Nov. 1, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583295.htm.

[14] FDA, "FDA and Marijuana: Questions and Answers," https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm (last visited Apr. 9, 2018).

resistant forms of childhood-onset epilepsy.[15] GW Pharmaceuticals announced on December 28, 2017 that FDA had accepted the company's Epidiolex® NDA filing for priority review, and that the Prescription Drug User Fee Act (PDUFA) goal date for completion of agency review of the same is June 27, 2018.[16] If FDA approves the NDA, the drug would be subject to U.S. Drug Enforcement Administration (DEA) scheduling, a decision which industry will follow closely. While marijuana is a Schedule I drug, meaning DEA believe it has "no currently accepted medical use and a high potential for abuse," it will be interesting to see how DEA schedules Epidiolex®, particularly in light of GW Pharmaceuticals' completion of a clinical trial assessing the abuse potential of CBD in October 2017. If DEA believes Epidiolex® has a low potential for abuse and low risk of dependence, it could schedule the drug as Schedule IV.

CONCLUSION

As Commissioner Gottlieb completes his first year at FDA, the agency he leads shows no signs of slowing down. It will be interesting to see if/how Gottlieb, his deputies, and FDA staff:

- Build on the lessons learned from Pre-Cert program participation, and use those lessons to inform digital health policy development, broadly;
- Reshape the agency's approach to tobacco products regulation, and finally put in place tenable regulations that acknowledge that certain tobacco products present more risk than others;
- Continue to respond to claims made about CBD products that have not been approved by the agency; and
- Decide on CBD drug product applications before the agency.

[15] GW Pharmaceuticals, "GW Pharmaceuticals and Its U.S. Subsidiary Greenwich Biosciences Completes Rolling New Drug Application Submission to U.S. Food and Drug Administration for Epidiolex® (cannabidiol) in the treatment of Lennox-Gastaut syndrome and Dravet syndrome," Oct. 30, 2017, https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-and-its-us-subsidiary-greenwich-biosciences-completes-rolling-new.

[16] GW Pharmaceuticals, "GW Pharmaceuticals Announces Acceptance of NDA Filing for Epidiolex® (cannabidiol) in the treatment of Lennox-Gastaut syndrome and Dravet syndrome," Dec. 28, 2017, https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-announces-acceptance-nda-filing-epidiolex%C2%AE-cannabidiol-treatment.

Cases to Watch

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The top cases covered in this volume cover many controversial issues that touch on food and drug litigation. Most of them are not expected to be the final word on the subject, and some raise almost as many new questions as they answer. Our contributing authors expect appeals and further cases implicating many of these issues. As well, we considered several important cases that were not ripe for inclusion in this volume, but that seem ordained to establish important precedent in the food and drug areas. Here are a few cases to watch in the latter half of 2018 and into 2019.

RESOLVING THE CATCH-22 IN GENERIC DRUG FAILURE-TO-WARN CLAIMS

In the years following the U.S. Supreme Court's 2011 holding that failure-to-warn claims against generic drug manufacturers are federally preempted,[1] the various state courts have confronted the disquieting result that generic drug consumers may be left with no remedy at all for a pharmaceutical warning failure, even though fellow consumers, who were prescribed the brand version of the same medicine, could sue. Generic drug consumers then attempted to hold the brand manufacturers liable for their generic drug-induced injuries, contending that by preemptively controlling the generic drug label's content, those brand manufacturers owed a tort duty to generic consumers. Most U.S. states to whom this argument was pitched rejected it; only Alabama and California permitted tort remedies for generic consumers against brand manufacturers. In March 2018, the Supreme Judicial Court of Massachusetts joined this minority twosome, albeit a bit more tepidly, in *Rafferty v. Merck & Co., Inc*.[2] The *Rafferty* court attempted a tight-rope walk over this treacherous regulatory regime. Mindful of the staggering costs and uncertainties of innovator drug commercialization, the Hatch-Waxman objectives (less-expensive access coupled with appropriate pioneer exclusivity) and the financial havoc Hatch-Waxman wreaks on the pioneer's post-patent-expiration revenues, and the states' historic duty to provide meaningful relief to those tortiously injured by others, the Massachusetts court settled on a middle ground. Ordinary negligence claims by generic users against brand manufacturers will not be permitted in that state, but claims for recklessness will be allowed. The court explained that "recklessness" differs from

[**] 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] Pliva v. Mensing, 564 U.S. 604 (2011).

[2] 2018 WL 1354064 (Mass. 2018).

ordinary negligence in two ways—the conduct of the defendant must have been *intended* and that conduct must pose a *significantly greater risk* to the victim. Thus, if a brand manufacturer intentionally fails to revise its brand drug label when it knows of an unreasonable risk of death or grave bodily injury (or knows of facts that would disclose such a risk), Massachusetts will now allow a generic drug user to hold the brand manufacturer accountable for consequential harms. The reverberating national effect of Massachusetts' foray into this controversial domain will be closely watched in 2018.

SORTING OUT THE PATENT REGIME FOR BIOSIMILARS

Congress's "carefully calibrated" scheme for patent litigation related to biosimilars has once again led to litigation featuring numerous procedural issues. On October 6, 2017, two biotech giants, Amgen and Genentech, filed patent litigation against each other over Amgen's proposed biosimilar, MVasi™, to Genentech's Avastin® (bevacizumab), an antibody used to treat metastatic colorectal cancer. [3] Amgen filed suit first in Los Angeles, seeking a declaratory judgment of non-infringement, invalidity, and/or unenforceability for 27 Genentech patents. Amgen argued that it was entitled to file a declaratory judgment action because it had given Genentech the statutorily-prescribed notice of commercial marketing. Genentech responded the same day by filing a Complaint against Amgen in Delaware for infringement of 24 patents. Genentech argued that Amgen failed to provide manufacturing information and to complete the exchange of lists of patents for litigation. On October 18, Genentech filed a second suit against Amgen, also in Delaware, for infringement of 25 patents, the original 24 plus one more. On February 2, the California court dismissed Amgen's case and it appears Amgen has not appealed. As of April 9, both of Genentech's cases are proceeding actively, with docket entries numbering in the low 80s.

CAN TRUTHFUL OFF-LABEL STATEMENTS BE PROHIBITED CONSTITUTIONALLY?

In *United States v. Facteau*,[4] a criminal case involving alleged off-label promotion, on July 20, 2016, the defendants were acquitted of all felony charges, but were convicted of misdemeanor claims that did not require proof of falsity as an element of the crime. Thus, this case raises the fraught issue of whether the FDCA can, consistently with the First Amendment's guarantee of free speech, prohibit truthful off-label statements by sponsors of regulated products. The pharmaceutical-industry-supported Medical Information Working Group has recognized the importance of this case, and filed a First Amendment amicus brief in support of the defendants in September, 2016. Nothing of significance happened in 2017, but a decision on the defendants' motions for acquittal will almost certainly occur in 2018, thereby prompting a First-Amendment-related appeal on the off-label promotion issue. FDA Commissioner Gottlieb has suggested that the FDA needs to revisit its

[3] Amgen, Inc. v. Genentech, Inc., Case No. 2:17-cv-07349-GW-AGR (C.D. Cal. Oct. 6, 2017); Genentech, Inc. v. Amgen, Inc., Case No. 1:17-cv-01407-GMS (D. Del. Oct. 6, 2017); and Genentech, Inc. v. Amgen, Inc., Case No. 1:17-cv-01471-GMS (D. Del. Oct. 18, 2017).

[4] No. 15-10076-ADB (D. Mass.).

prohibition in light of evolving First Amendment precedent, so *Facteau* could provide the acid test of whether such a revisiting will, in fact, occur.

FOSAMAX

The *Fosamax* case,[5] has, not surprisingly, been appealed to the United States Supreme Court.[6] The petition for certiorari remains pending. In a development suggesting that the Supreme Court is giving the Fosamax petition serious consideration, on December 4, 2017, the Court invited the Solicitor General to file an amicus curiae brief stating the federal government's—and thus FDA's—view on whether the issues raised warrant grant of the petition. Should the Supreme Court elect to hear the Fosamax appeal, the eventual decision would certainly rank among the most important drug/medical device preemption decisions of this decade.

FURTHER CASES ON CLASS-ACTION DAMAGES ESTIMATION

Many consumer class actions alleging price premium damages stemming from alleged deceptive marketing and other activities are under way, and some will no doubt produce published opinions in the coming months. Of the cases we discussed, *Zakaria v. Gerber Products Co.*[7] is under appeal before the Ninth Circuit Court of Appeals, with a decision likely in late 2018. This decision may address the question of whether a conjoint analysis, not directly triangulated or collaborated by an additional study such as a hedonic regression, adequately estimates the price premium actually paid by consumers as a result of allegedly being deceived about a product attribute for purposes of satisfying the Rule 23(b)(3) predominance requirement under *Comcast*. Another of the cases we discussed, *Kurtz v. Kimberly-Clark Corp.*,[8] is under interlocutory appeal before the Second Circuit Court of Appeals, which should furnish guidance on the viability of a hedonic regression analysis used alone.

Two other cases that we discussed in connection with this topic in which interlocutory appeals of class certification rulings were denied, *Hughes v. The Ester C Company*[9] and *In re Dial Complete Marketing and Sales Practices Litigation*,[10] continue in litigation before their District Courts, with the parties that did not prevail on class certification presumably awaiting their opportunities to appeal the rulings as of right. Unless these cases settle, they also may tee up further appellate review of the price premium damages models required by *Comcast*.

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5 In re Fosamax (Alendronate Sodium) Products, 852 F.3d 268 (3d Cir. 2017).

6 No. 17-290 (U.S.).

7 No. 17-56509 (9th Cir.).

8 No. 17-1856 (2d Cir.).

9 No. 2:2012-CV-0041 (PKC) (E.D.N.Y.).

10 MDL Case No. 11-md-2263-SM (D.N.H.).

THE SUPREME COURT PONDERS CLASS ACTION LIMITATIONS TOLLING

Since 1974, the U.S. Supreme Court has recognized that statutes of limitation may be deemed equitably tolled for class members during the time that their class action is pending.[11] The logic behind this tolling is that members of the class may have refrained from filing their own, individual lawsuits in reliance on the pending class action, and if class treatment is ultimately refused by the court, those class members should not lose out on their ability to litigate individually merely because it took the court so long to determine that class treatment was not appropriate. On March 26, 2018, the U.S. Supreme Court heard oral argument in *China Agritech, Inc. v. Resh*,[12] a case that proposes a notable broadening of this tolling principle. The plaintiffs there invoked equitable tolling to file—outside the applicable limitations period—a subsequent *class action* after certification of their first two classes were denied. The defendant convinced the trial court to dismiss the new class action as time-barred, arguing that the equitable tolling principle was designed only to rescue a class member's right to bring a post-dismissal individual claim, not to preserve the ability to try repeatedly for class treatment. The Ninth Circuit reversed the dismissal. Certiorari was granted to examine this proposed extension of the class action equitable tolling principle. Although the claim on appeal involves securities fraud, the Court's decision in *China Agritech* will meaningfully impact the availability of class treatment in every federal litigation sector, including drug and device cases.

LABMD APPEALS THE FTC'S FINDING ON DATA SECURITY AND UNFAIRNESS

The Eleventh Circuit Court of Appeals may finally resolve the long anticipated dispute between LabMD, a small lab that performed cancer-detection testing, and the FTC. Oral argument was heard before the Eleventh Circuit Court of Appeals on June 21, 2017 in *LabMD, Inc. v. Federal Trade Commission.*[13] LabMD appealed a Final Order by the FTC which found LabMD's data security policies an "unfair act of practice" within the meaning of Section 5 of the FTC Act. LabMD argued that the FTC's Final Order was improper because (1) an intangible harm does not constitute a "substantial injury" under Section 5, and (2) LabMD had insufficient notice that its data security practices violated the FTC's rules. The FTC countered that LabMD's security practices were "unreasonable, lacking even basic precautions to protect the sensitive consumer information" in violation of Section 5. The FTC further argued that LabMD always knew that it should maintain "reasonable" data security practices. The Eleventh Circuit's interpretation of Section 5 will affect the FTC's ability to rely on the FTC Act to police the data security practices of businesses that handle consumers' sensitive information.

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[11] American Pipe & Constr. Co. v. Utah, 414 U.S. 538 (1974).

[12] No. 17-432 (U.S.). Oral argument transcript, https://www.supremecourt.gov/oral_arguments/argument_transcripts/2017/17-432_mlho.pdf.

[13] No. 16-16270 (11th Cir.).

MATERIALITY UNDER THE FALSE CLAIMS ACT

The U.S. Supreme Court may provide more clarity in 2018 over the materiality standard to apply in False Claims Act cases. A petition for writ of certiorari has been teed up for the Supreme Court in *Gilead Sciences, Inc. v. United States* ex rel. *Campie*,[14] the Ninth Circuit decision that was summarized in an earlier chapter.[15] The question presented by Gilead is: "Whether an FCA allegation fails when the Government continued to approve and pay for products after learning of alleged regulatory infractions and the pleadings offer no basis for overcoming the strong inference of immateriality that arises from the Government's response." In its opposition, Relators argue that Gilead misrepresents the holding of the Ninth Circuit and assert that the holding "properly followed *Escobar*'s holistic approach to materiality." They rely on the Ninth Circuit's conclusion that the contested issues, including materiality, "are matters of proof, not legal grounds to dismiss relators' complaint," and claim the complaint satisfies the pleading requirements of Rule 12(b)(6). Several groups have filed amicus briefs, including the U.S. Chamber of Commerce, American Health Care Association, Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and the Washington Legal Foundation. The Supreme Court will make a determination on whether to grant certiorari, and potentially issue a decision later this year.

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[14] No. 17-936 (Dec. 26, 2017)

[15] United States *ex rel*. Campie v. Gilead Sciences, Inc., 862 F.3d 890 (9th Cir. 2017).