

Top Food and Drug Cases, 2016 & Cases to Watch, 2017

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Introduction

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We are excited to bring you another edition of the *Top Food and Drug Cases* series—the top food and drug cases of 2016 and cases to watch in 2017. Last year we began a new streamlined magazine format that summarized the top food, drug and device cases from the past year along with regulatory developments, key settlements and cases to watch in the coming year. This year, we are pleased to offer you a law review format on FDLI’s flagship publication, the *Food and Drug Law Journal*.

As in past years, 2016 yielded a number of significant decisions affecting the rights and potential liabilities of food, drug, and device manufacturers as well as their corporate officers. In *Glennen v. Allergan, Inc.*, for example, a California Court rejected a plaintiff’s effort to expand a medical device manufacturer’s liability through a theory that it failed to train physicians in the proper use of its device. The court in *Neidner v. Ortho-McNeil Pharmaceutical, Inc.*, rejected another novel question—whether a plaintiff in a design defect case can point to an entirely different product as a “technically feasible and practical design” and argue that the product at issue was defective because it was not that other product.

There were also several noteworthy criminal cases affecting the drug and device industry in 2016. FDA scored a victory in *United States v. Facticeau*, in which a federal district court ruled that while truthful, non-misleading speech is not a crime, FDA may use executives’ speech as evidence of criminal conduct (i.e., adulterating and misbranding). After a jury trial, Vascular Solutions and its CEO were acquitted of charges that they misbranded the company’s Vari-Laser product line. In *DeCoster v. United States* the Court of Appeals for the Eighth Circuit upheld the sentencing of two food executives to jail time after they pled guilty under the controversial responsible corporate officer doctrine. A petition for certiorari is pending before the United States Supreme Court so stay tuned for future developments.

This is just a sampling of what you will find inside.

I would like to thank the Food and Drug Law Institute for continuing to publish the *Top Food and Drug Cases* series and thank the authors for sharing their expertise in food and drug law and regulation with our readers. I hope this publication will serve as a resource and keep you up to date on significant litigation and regulatory developments in the drug, device and food arena, as well as recent settlements and administrative actions.

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U.S. v. Facteau:

Will FDA's Partial Victory Hold Up?

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WHY IT MADE THE LIST

After suffering a string of losses dating back at least 15 years, FDA finally overcame a first amendment defense to record a partial victory in an off-label promotion case. The case is *U.S. v. Facteau*¹ (the *Facteau* case) and as of press time the question is whether FDA will be able to hold on to its win in the face of the defendants' motion for acquittal (and likely appeal should that motion fail). This article will review the factual background and procedural history (as relevant to the first amendment issue) of the *Facteau* case, the law as it had developed leading up to the trial, the trial results, and the pending dispositive motion.

DISCUSSION

The Indictment

William Facteau was the CEO, and Philip Fabian was the CFO, of a medical device company named Acclarent. In the indictment, the government alleged that beginning in or about 2005, Facteau, Fabian, and others at Acclarent caused Acclarent and its engineers to develop and design a device known as the Stratus to provide sustained release of the steroid Kenalog-40 in the nasal passages by designing a reservoir with a pattern of micropores or holes that would slowly release the Kenalog-40 over an extended period of time. The Stratus did not elute saline for any significant period of time.

The indictment further alleged that Facteau, Fabian, and others at Acclarent understood that FDA would likely require significantly more testing and clinical data to permit the interstate distribution of the Stratus as a steroid delivery device than it would require for a device that did nothing more than maintain a space in the sinuses and release saline. Facteau, Fabian, and others at Acclarent allegedly therefore developed and implemented a strategy to more quickly obtain marketing authorization by concealing from FDA that they intended the Stratus to be used as a steroid delivery device and by falsely claiming that the Stratus was a sinus spacer that was substantially equivalent to an existing legally marketed spacer. The Stratus device, however, was not designed to work as a sinus spacer and had no design specifications to ensure that

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

it would mechanically maintain any particular space and/or permit drainage in the sinuses.

The indictment alleged that, after securing clearance for the Stratus as a sinus spacer, Facteau, Fabian, and others marketed it almost exclusively as a steroid delivery device. The government claimed that Acclarent made no claims for the Stratus as a spacer or saline release device and that there was no market for the Stratus as such a device.

Because Acclarent never received premarket approval or clearance to market the Stratus as a steroid delivery device, the government alleged that it was adulterated and misbranded. The government's theory was that a medical device is "misbranded" if a 510(k) notification had not been provided to FDA at least ninety days before the device was introduced into interstate commerce for commercial distribution or if it was intended for a new use for which a 510(k) notification was required but not filed with FDA.²

Among several defenses, Facteau and Fabian argued that the promotion of the Stratus as a steroid delivery device was truthful and non-misleading, and therefore protected by the first amendment. Doctors are free to use devices that are lawfully on the market for unapproved, off-label uses.

The Pre-Facteau Case Law

The government's case against Facteau and Fabian had to take into account the adverse results in several prior cases where FDA's ban on off-label promotion collided with the first amendment. The first case to address the conflict between restrictions on off-label promotion and the first amendment was *Washington Legal Foundation v. Henney*³ (WLF). In that case, WLF sought to enjoin FDA from enforcing policies restricting certain forms of manufacturer promotion (continuing medical education and distribution of reprints) of off-label uses for FDA-approved drugs and devices.⁴ The court entered summary judgment in favor of WLF and against FDA. Applying the four prong test for the regulation of commercial speech adopted in *Central Hudson Gas and Electric Corp. v. Public Service Comm'n of New York*,⁵ the court found that (1) the speech was neither unlawful nor inherently misleading; (2) the government's interest was substantial; (3) the policies directly advanced the government's substantial interest; but, (4) the policies were more extensive than necessary and unduly burdened important speech.⁶ On appeal, however, the court dismissed the case for lack of a case or controversy because FDA took the position that its policies (and subsequently-enacted provisions of the Food and Drug Administration Modernization Act (FDAMA) on the same issue) "established nothing more than a 'safe harbor' ensuring that certain forms of conduct would not be used against manufacturers in misbranding and 'intended use' enforcement actions."⁷

² The indictment alleged other crimes too, such as securities fraud, that are beyond the scope of this article.

³ 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed, judgment vacated in part*, 202 F.3d 331 (D.C. Cir. 2000).

⁴ 13 F. Supp. 2d at 54.

⁵ 447 U.S. 557 (1980).

⁶ 447 U.S. at 65-71.

⁷ 202 F.3d at 335.

WLF was followed closely by *Thompson v. W. States Med.Ctr.*⁸ In *Thompson*, a group of licensed pharmacies that specialized in compounding drugs sought to enjoin enforcement of certain provisions in FDAMA restricting advertisement of particular compounded drugs, arguing that those provisions violated the first amendment’s guarantee of free speech.⁹ The Court also relied on the *Central Hudson* test to resolve the issue.¹⁰ Although it found “[p]reserving the effectiveness and integrity of the FDCA’s new drug approval process is clearly an important governmental interest,”¹¹ the Court found the challenged provisions unconstitutional because “the Government has failed to demonstrate that the speech restrictions are not more extensive than is necessary to serve [those] interests.”¹² The Court identified other, non-speech-related restrictions that could have achieved the government’s goals and stated “[t]he Government has not offered any reason why these possibilities, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale as to undermine the new drug approval process.”¹³

Nine years after *Thompson*, the Supreme Court decided *Sorrell v. IMS Health, Inc.*¹⁴ *Sorrell* involved a challenge to a Vermont law that in effect banned pharmaceutical detailing by restricting the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors.¹⁵ As to the proper test, the Court began by observing that the Vermont law imposed content-based and speaker-based restrictions on speech. The restrictions were content-based because they applied only to the use of prescriber-identifiable information for marketing purposes and not to other purposes, such as educational uses that were expressly allowed. The restrictions were speaker-based because they applied only to pharmaceutical manufacturers and not to anyone else. In short, “[t]he law on its face burdens disfavored speech by disfavored speakers.”¹⁶ This was no accident, according to the Court, because the Vermont legislature had expressly found that the goals of pharmaceutical detailers conflicted with those of the state, so the state targeted them for disfavored treatment.¹⁷ In light of the speaker- and content-based burdens on speech, “[i]t follows that heightened judicial scrutiny is warranted.”¹⁸

⁸ 535 U.S. 357 (2002).

⁹ *Id.* at 360.

¹⁰ *Id.* at 367-68.

¹¹ *Id.* at 369.

¹² *Id.* at 370.

¹³ *Id.* at 373.

¹⁴ 564 U.S. 552 (2011).

¹⁵ *Id.* at 557-58. Justice Kennedy’s opinion for the Court described detailing as follows: “Pharmaceutical manufacturers promote their drugs to doctors through a process called ‘detailing.’ This often involves a scheduled visit to a doctor’s office to persuade the doctor to prescribe a particular pharmaceutical. Detailers bring drug samples as well as medical studies that explain the ‘details’ and potential advantages of various prescription drugs. Interested physicians listen, ask questions, and receive followup data.” *Id.*

¹⁶ 564 U.S. at 564.

¹⁷ *Id.*

¹⁸ *Id.* at 565 (citing *Cincinnati v. Discovery Network Inc.*, 507 U.S. 410, 418 (1993), and *Turner Broadcasting System Inc. v. FCC*, 512 U.S. 622, 658 (1994)).

The Court next described the level of heightened scrutiny and applied it. Foreshadowing the outcome, the Court wrote that “[i]n the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory.”¹⁹ In this respect, *Sorrell* proved to be an ordinary case. To satisfy the heightened scrutiny to be applied, the Court stated that Vermont had to “show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest.”²⁰ The Court then considered and rejected a number of arguments offered by Vermont to justify its law.²¹ The Court summarized its decision as follows:

While Vermont’s stated policy goals may be proper, [the law at issue] does not advance them in a permissible way. As the Court of Appeals noted, the “state’s own explanation of how” [the law] “advances its interests cannot be said to be direct.” The State seeks to achieve its policy objectives through the indirect means of restraining certain speech by certain speakers—that is, by diminishing detailers’ ability to influence prescription decisions. Those who seek to censor or burden free expression often assert that disfavored speech has adverse effects. But the “fear that people would make bad decisions if given truthful information” cannot justify content-based burdens on speech.²²

The Court thus affirmed the lower court’s judgment finding the Vermont law unconstitutional.

Justice Breyer, joined by two others, wrote a dissenting opinion. Arguing the Vermont law should not receive heightened scrutiny, Justice Breyer wrote:

For another thing, the same *First Amendment* standards that apply to Vermont here would apply to similar regulatory actions taken by other States or by the Federal Government acting, for example, through Food and Drug Administration (FDA) regulation. (And the Federal Government’s ability to pre-empt state laws that interfere with existing or contemplated federal forms of regulation is here irrelevant.)

Further, the statute’s requirements form part of a traditional, comprehensive regulatory regime. The pharmaceutical drug industry has been heavily regulated at least since 1906. See Pure Food and Drugs Act, 34 Stat. 768. Longstanding statutes and regulations require pharmaceutical companies to engage in complex drug testing to ensure that their drugs are both “safe” and “effective.” Only then can the drugs be marketed, at which point drug companies are subject to FDA’s exhaustive regulation of the content of drug labels and the manner in which drugs can be advertised and sold.²³

The six Justices in the majority, however, presumably rejected this argument. Although FDA did not participate directly in *Sorrell*, from its perspective the law took a turn for the worse at least because of (1) the application of heightened scrutiny and (2) Justice Breyer’s dissent pointing out that under the Court’s rationale FDA’s restrictions on pre-approval drug marketing may well be unconstitutional.

¹⁹ *Id.* at 571.

²⁰ *Id.* at 572.

²¹ *Id.* at 573-77.

²² *Id.* at 577 (citations omitted).

²³ 564 U.S. at 586 (certain citations omitted).

In *U.S. v. Caronia*,²⁴ the Second Circuit addressed the criminal conviction of a pharmaceutical sales representative for the off-label promotion of a prescription pharmaceutical based on the first amendment. Following *Sorrell*, the court first held that FDA’s ban on off-label promotion is subject to heightened scrutiny: “The government’s construction of the FDCA’s misbranding provisions to prohibit and criminalize the promotion of off-label drug use by pharmaceutical manufacturers is content- and speaker-based, and, therefore, subject to heightened scrutiny.”²⁵ The court then applied the *Central Hudson* test and found that construing the FDCA’s misbranding provisions to preclude off-label promotion would fail the test.²⁶ To avoid this constitutional difficulty, the court summarized its decision as follows:

We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA approved prescription drugs We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.²⁷

Accordingly, the court reversed Caronia’s conviction.

Taking advantage of the Second Circuit’s holding in *Caronia*, Amarin Pharmaceuticals filed a declaratory judgment action in New York and sought a preliminary injunction against FDA to preclude any enforcement action arising out of proposed truthful and non-misleading, but off-label, promotion of an Amarin drug, Vascepa®.²⁸ Citing Amarin’s first amendment rights, the court issued a preliminary injunction authorizing Amarin to make several specific statements or disclosures to doctors and to disseminate 13 scientific publications concerning Vascepa®.²⁹ The statements or disclosures were supported by clinical trials FDA had approved and/or FDA did not dispute their truthfulness. In ruling for Amarin, the court relied heavily on *Caronia*. FDA argued for a narrow interpretation of *Caronia*, limited to its facts, and for the position that it could pursue Amarin for off-label promotion by analogy to other crimes, such as jury tampering, blackmail, and insider trading, where speech constitutes the criminal act. The *Amarin* court rejected those arguments, however, and concluded “[w]here the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, cannot be the act upon which an action for misbranding is based.”³⁰ In other words, “if the speech at issue is found truthful and non-misleading, under *Caronia*, it may not serve as the basis for a misbranding action.”³¹

²⁴ 703 F.3d 149 (2d Cir. 2012).

²⁵ *Id.* at 165.

²⁶ *Id.* at 165-68.

²⁷ *Id.* at 168-69.

²⁸ *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

²⁹ *Id.* at

³⁰ *Id.* at 226.

³¹ *Id.* at 229.

The final case before *Facteau* involving similar issues was *U.S. v. Vascular Solutions, Inc.* (VSI).³² According to the allegations, VSI marketed a laser used in vein ablation procedures. Vein ablation involves “burning” poorly performing veins to re-route blood flow to healthier veins. VSI initially marketed its product, Vari-Lase, under a 510(k) clearance with an intended use for the treatment of varicose veins and varicosities associated with superficial reflux of the Greater Saphenous Vein (GSV). The GSV is a large, subcutaneous, superficial vein of the leg.

In 2006, one of VSI’s competitors obtained FDA clearance of a device for ablation of perforator veins—veins that are located further away from skin and closer to bones. Perforator vein treatment is riskier and more difficult than superficial vein treatment because of perforator veins’ location in deep vein systems. In June, 2007, VSI filed a premarket notification seeking to add an indication for perforator vein treatment to its existing clearance. In response, FDA requested data showing Vari-Lase’s safety and efficacy in perforator vein procedures. VSI conducted a clinical trial in late 2007, but did not submit the trial data. In March 2008, FDA informed VSI that the agency considered the application to be withdrawn

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

In a motion *in limine*, VSI argued that the court should apply heightened scrutiny because the government was applying content- and speech-based ban on speech used in off-label promotion. Alternatively, even if heightened scrutiny did not apply, VSI argued that the government’s prosecution failed the *Central Hudson* test because it sought to suppress speech through more extensive means than necessary. VSI attacked the government’s position that it could use speech as evidence of intent. In VSI’s view, permitting this would allow FDA to evade the first amendment and unlawfully burden the speech. The motion also argued the government should disclose the speech it intends to use at trial, and that the Court should examine the speech to determine its admissibility based on truthfulness. If the speech was truthful, it would not be presented to the jury. Finally, VSI asked the Court to establish a standard for what constitutes false or misleading speech, and in particular, that the government should prove the speech was *actually* misleading, instead of only *potentially* misleading. In doing so, the defendants asked the Court to adopt the Lanham Act’s standard for truthfulness, which requires a plaintiff to prove a substantial subset of the intended audience was misled.

In response, the government argued that its indictment was constructed around VSI’s *conduct* rather than speech, and that *Caronia* and *Amarin* were inapplicable for that reason. In addition, the government argued that the first amendment permits evidentiary use of speech to infer a defendant’s intent, and that it could use the speech

³² Case No. 5:14-cr-00926 (W.D. Tx.). District Judge Royce Lamberth of the District for the District of Columbia, who had presided over the *WLF* case, also presided over the VSI case by special assignment. As there are no published opinions in VSI, the comments in the text are taken from filings and orders in the case.

as an overt act in a conspiracy case.³³ If the Court considered the case to be criminalizing speech, the government suggested that the Court should instruct the jury that truthful off-label promotion is lawful, instead of making individual and burdensome determinations on the truthfulness of each part of the contested speech.

The Court denied VSI's motion *in limine* and adopted much of the government's position. First, the Court rejected VSI's first amendment argument because the government stated it intended to prove the misbranding violation by relying only on conduct. Second, the Court followed prior case law that speech may serve as an overt act in a conspiracy case, stating that "[t]he Court . . . sees no First Amendment threat from this proposed use of speech." Despite these legal wins for the government, it lost the case when the jury acquitted VSI and its CEO of all charges.

Facteau Results and Current Status

In light of this background, we return to the *Facteau* case. The defendants filed a motion to dismiss the indictment on multiple grounds, including the first amendment. For example, the defendants argued:

[A]t bottom, and notwithstanding the government's repeated protestation that it does not seek to prosecute speech *per se*, the Indictment is predicated in large measure on alleged promotion of Stratus for off-label use. It repeatedly alleges that mere promotion—*regardless* of whether false or misleading—can form the basis for adulteration and misbranding charges. By framing its allegations in language so broad that it encompasses—and hence seeks to criminalize—even truthful, non-misleading speech, the Indictment impermissibly targets conduct protected by the First Amendment.³⁴

In response to the motion to dismiss, and following up on its legal success in *VSI*, the government argued that the defendants' speech could be used as evidence of unlawful conduct:

The Indictment does not put Defendants on trial for their speech. Their speech is, however, part of the evidence the Government will offer to prove that Defendants caused the distribution of the Stratus intended for an unapproved and improperly labeled use, with the intent to defraud and mislead FDA and others.³⁵

The court denied the defendants' motion to dismiss and held a trial over a thirty-day period in the summer of 2016.

The following excerpt from the *Facteau* court's jury instructions reflect that it followed *Caronia* by ruling that the FDCA does not make off-label promotion a crime, but also followed *VSI* and other cases by ruling that the defendants' speech could be used as evidence of a crime:

The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or

³³ See *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) (speech can be used as evidence of element of a crime).

³⁴ Dkt. No. 185 at 10-11.

³⁵ Dkt. No. 224 at 9.

misbranded. Although you may not convict a Defendant of a crime based solely on truthful, non-misleading statements regarding off-label use, even truthful statements about an off-label use can be considered as evidence. To put it another way, to convict, there must be a criminal act. Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.³⁶

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

In late November, 2016, the defendants filed a motion for acquittal on multiple grounds, again including the first amendment. The gist of the defendants' first amendment argument was that the jury rejected the government's claim that the defendants had engaged in false or misleading speech and thus the first amendment precluded any conviction:

In acquitting Defendants on all felony counts, the jury rejected the Government's allegations of false and misleading speech, fraudulent conduct, false submissions to the FDA and wire fraud. With the case thus stripped of the Government's "fraud" gloss, it is clear that, just as in *Caronia*, the factual predicate for the Indictment's misdemeanor adulteration and misbranding charges—the sole counts of conviction—was truthful, non-misleading speech. This, the First Amendment does not permit.³⁷

Several amici curiae have filed briefs supporting the defendants. Not surprisingly, the government disagreed:

The crimes for which Defendants were convicted were distribution of a medical device that lacked the required FDA approval and premarket notice. Not a single element of either crime was speech. As discussed below, the Court's instructions and the Government's case were clear and repeatedly reminded the jury that the crime was not speech, but distribution of a medical device for a use for which it was not cleared or approved by FDA.³⁸

As noted in the beginning, as of press time the district court has not ruled on the defendants' motion for acquittal. If the court denies the motion, it seems likely the defendants will file an appeal. Thus, it remains to be seen whether FDA will retain its partial victory.

³⁶ Dkt. No. 436 at 27 (emphasis added). *See also id.* at 26 ("It is not illegal in and of itself for a device manufacturer to provide truthful, not misleading information about an off-label use. The FDCA does not prohibit or criminalize truthful, not misleading off-label promotion.").

³⁷ Dkt. No. 484 at 4-5 (citing *Amarin* and *VSI*).

³⁸ Dkt. No. 497 at 3.

CONCLUSION

For now at least, despite the acquittals on the felony charges, *Facteau* represents a significant victory for FDA. It is another vindication of the government's theory that it can use speech as evidence of criminal conduct. At a minimum, the defendants have likely spent millions in legal fees and may still face potential criminal remedies, including some prison. These results should have a deterrent effect on others employed in FDA-regulated industries, at least if they are paying attention. It should be noted that Amarin's victory also came with some cautionary footnotes. Towards the end of its opinion, the court wrote:

[T]here is practical wisdom to much of the FDA's guidance, including that a manufacturer vet and script in advance its statements about a drug's off-label use. A manufacturer that leaves its sales force at liberty to converse unscripted with doctors about off-label use of an approved drug invites a misbranding action if false or misleading (e.g., one-sided or incomplete) representations result.³⁹

The court also cautioned that its "approval today of these communications is based on the present record. Amarin bears the responsibility, going forward, of assuring that its communications to doctors regarding off-label use of Vascepa® remain truthful and non-misleading."⁴⁰ On the whole then, the first amendment still appears to be better deployed as a shield after a company's employee(s) have gone astray (despite thorough training) than as a sword with which to blaze a trail of off-label promotion.

³⁹ 119 F. Supp. 3d at 228.

⁴⁰ *Id.* at 236.

U. S. v. Vascular Solutions, Inc. and Howard C. Root

ANNE K. WALSH* AND JENNIFER M. THOMAS**

WHY IT MADE THE LIST

On February 26, 2016, after only one full day of deliberation, a jury in the Western District of Texas returned a verdict acquitting Vascular Solutions, Inc. and its Chief Executive Officer, Howard Root, from all charges alleging a conspiracy to violate the Federal Food, Drug, and Cosmetic Act (FDCA) and the sale of misbranded medical devices. It is uncommon, but not unusual, for FDA to take a criminal case to trial, but in the still-evolving areas surrounding off-label promotion, the parties typically settle a matter outside of litigation. Perhaps that is why the 2014 indictment of this medical device company and its CEO were not given due attention. But Vascular Solutions and Root were prepared to go to trial, and they won. *United States v. Vascular Solutions*¹ makes the list of top food and drug cases for 2016 because of its litigated verdict against FDA, and the effect on FDA's authority to criminalize speech about uses of an FDA-regulated product.

DISCUSSION

Facts

On November 13, 2014, a federal grand jury sitting in San Antonio returned an indictment against Vascular Solutions and Mr. Root on charges relating to the company's marketing of its Vari-Lase product line, products intended for use in the treatment of varicose veins by laser ablation. The criminal charges represented the culmination of an approximately four-year long investigation conducted by the U.S. Department of Justice (DOJ) in cooperation with the U.S. Attorney's Office for the Western District of Texas, FDA's Office of Criminal Investigations, and the Health and Human Services Office of the Inspector General.

A few months earlier, in July 2014, the defendants had settled the civil claims brought under the Federal False Claims Act for approximately half a million dollars—a paltry sum when compared to other civil settlements with medical device firms

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¹ *United States v. Vascular Solutions, Inc. and Howard C. Root*, No. 5:14-cr-00926 (W.D. Tex. 2016).

occurring in 2014 (e.g., an \$8 million settlement with Smith & Nephew, and an \$11.5 million settlement with Atrium Medical Corp.). In the civil action, the government alleged the company had knowingly caused the sales of the products for uses that were not reimbursable by the federal health care programs.

Vari-Lase products are used to close veins affected by incompetent valves, which cause blood pooling and swelling. FDA had cleared the products with the following indications for use: “The Vari-Lase procedure is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity.” The question at issue was whether the indications for use covered the treatment of perforator veins, which are shorter, tortuous veins that connect the superficial and deep vein systems. The company believed the FDA clearance for the Vari-Lase products broadly covered “varicose veins and varicosities,” including perforator veins; the government alleged the clearance was a general clearance, and that the treatment of perforator veins was a specific use for which the company required a separate clearance or approval.

The indictment charged that the Vari-Lase products were adulterated or misbranded. According to the government, the devices were adulterated under the FDCA because they failed to have a premarket authorization (PMA). The devices were misbranded under two theories: 1) because they failed to have a premarket notification (510(k)) before they were distributed in interstate commerce, and 2) because their labeling did not have adequate directions for use related to the treatment of perforator veins.

Before marketing its product for perforator vein treatment, Vascular Solutions had submitted a 510(k) premarket notification seeking clarification that the cleared indication included the treatment of perforator veins. FDA, however, rejected the 510(k) and refused to clear the product for that intended use. According to the government, the use of lasers on perforator veins is more risky because they come into direct contact with deep veins. Vascular Solutions had submitted clinical trial data that showed a higher incidence of deep vein thrombosis, a potentially serious adverse event, after perforator vein treatment. The clinical trial also showed that the Vari-Lase product was not as effective on perforator veins as on other veins; Vari-Lase achieved only a 67% rate of total perforator vein closure after six months, as compared to 98% total closure of other types of veins after six months. The main competitor product in the perforator vein space—which, unlike Vari-Lase, was FDA-cleared for use on perforator veins—achieved a reported 70-93% closure rate.

Based on FDA’s denial of the 510(k), the government alleged that the defendants deceived FDA by using the term “short vein segments” or “short veins” to avert FDA’s denial of the perforator vein indication. The government cited to internal company documents that allegedly showed the sales force was trained on these terms, and that the sales force used these terms to disguise that they were actually marketing the product for perforator vein treatment.

Pre-Trial Motions

The pre-trial activities are significant because the court ruled on what theories were viable and what evidence could be introduced, which of course laid the groundwork for the ultimate jury verdict. The pre-trial motions also reflect the contentiousness of the litigation, as both parties made allegations of misconduct.

Vascular Solutions and Mr. Root first moved to dismiss the indictment on the grounds that the government's off-label marketing theory violated the First Amendment of the U.S. Constitution. The defendants argued that prosecutors had misled the grand jury regarding the legal standard applicable to truthful commercial speech. Citing earlier off-label marketing cases, the defendants argued that no court had ever allowed a criminal conviction on the basis of truthful and non-misleading commercial speech—even if that speech related to an unapproved use of an FDA-cleared medical device or an approved drug. In *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), and *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015), the courts held that “the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.” 703 F.3d at 169. The *Amarin* court went even further by concluding that all truthful and non-misleading speech about off-label uses is protected, including proactive, promotional statements made by a pharmaceutical manufacturer. *See* 119 F. Supp. 3d at 226-28.

The defendants challenged the government's argument that the speech in question was merely to be used as evidence of the new intended use, and argued the government simply sought to evade the First Amendment's prohibition on criminalizing protected speech, which had been flatly rejected by the *Caronia* and *Amarin* courts. Root filed a separate motion to dismiss the criminal indictment, arguing that the statute and regulations as applied to him were unconstitutionally vague.

In its response, the government accepted the basic First Amendment principles of protecting truthful, non-misleading commercial speech, but the government objected on factual grounds claiming that the defendants' activities were not entitled to First Amendment protection. Specifically, the government asserted that the criminal misbranding charges under the FDCA were predicated on the defendants' *false or misleading* promotion of the Vari-Lase product.

The U.S. District Court for the Western District of Texas agreed with the government, and denied Vascular Solutions' and Howard Root's motions to dismiss the indictment. The Court held that the First Amendment does not protect false or misleading speech, and reasoned that whether the speech at issue was false or misleading was a factual issue for the jury to determine.

The defendants later moved the court to exclude certain categories of evidence produced by the government, including (1) evidence of *subjective* intent to market the Vari-Lase kit for use in perforator veins, such as the internal company communications reflecting the understanding or intent of particular salespersons, and (2) evidence of truthful and non-misleading speech used to prove objective intent that Vari-Lase be used to treat perforator veins. The Court denied both of these motions, pointing to Supreme Court precedent permitting the “evidentiary use of speech to establish the elements of a crime,” *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993), and relying on the government's representation that it would use only *conduct* to establish objective intended use. *See* *United States v. Vascular Solutions, Inc.*, 181 F. Supp. 3d 342 (W.D. Tex. 2016).

The parties also lodged allegations at each other for misconduct during the investigation. The defendants alleged the government attorneys badgered and bullied the company's employees; the government countered that Root pressured its employees to obstruct the government's investigation. While these allegations made for juicy pleadings, the Court considered and rejected the defendants' motion because

even if the alleged prosecutorial misconduct had occurred, it did not provide sufficient bases to dismiss the indictment.

Trial and Verdict

Shortly before trial, the government dropped without explanation the adulteration charges brought against defendants, which related to the products' failure to have a PMA. Therefore only the misbranding theories were at play. Regarding the first theory of misbranding (failure to have a 510(k)), the defendants maintained throughout trial that the law did not require the company to submit a 510(k) notification. They relied on evidence that there was no significant change in the product's design or intended use to warrant the submission of a new 510(k). Significant changes that require a 510(k) include (1) a change in the device that could significantly affect the safety or effectiveness of the device (e.g., a significant change or modification in design or manufacturing process); or (2) a major change in the intended use of the device.

The government and defendants each identified twenty potential trial witnesses. The government called each of its witnesses, including an expert witness specializing in FDA law. The government's witnesses and evidence focused on (1) the company's submission of the rejected 510(k) clarification for perforator veins, based on arguably weak clinical data, to FDA; and (2) marketing discussions by company sales representatives and others relating to marketing Vari-Lase for use in perforator veins.

Vascular Solutions and Mr. Root focused their defense on the issue of whether the perforator vein indication was already covered by the company's 510(k). They presented no witnesses or exhibits of their own. Instead, the government's own witness provided information supporting the defendants' arguments. Specifically, the government's FDA expert testified that Vascular Solutions' existing 510(k) was broad enough to cover the indication in question (for perforator veins).

The government ultimately lost on the factual question of whether the defendants' communications and conduct subjected them to criminal liability. The basis for the jury's verdict is not clear. It is at least possible that the jury made its decision based solely on the government's failure to make a case that Vascular Solutions and Mr. Root's marketing of the Vari-Lase products for use in perforator veins was *not* actually covered by the existing 510(k) and indications for use for those products. Thus, the Court's pre-trial rulings and the jury instructions read by the Court remain the best sources of legal precedent stemming from this case.

IMPACT

This case represents a big win for FDA-regulated industry. Although facts can be distinguished, the key takeaways broadly relate to FDA's authority to criminalize off-label communications and the punitive nature of individuals caught up in a prosecution by the government.

First Amendment Jurisprudence

A critical issue before and during trial was the First Amendment and its protection of truthful, non-misleading speech about off-label uses. FDA traditionally has taken the position that promotion of a drug or device for a use that has not been cleared or approved by FDA is a violation of the FDCA, because the company's promotion creates a new intended use that requires FDA approval or clearance. While this black-

and-white approach may serve FDA well, it neglects to factor in free speech protections offered under the First Amendment.

DOJ, however, has taken a position that is not as stark and that is more consistent with the Constitution and recent jurisprudence. *See, e.g.*, Government’s Brief, *United States v. Stryker Biotech, LLC*, No. 09-cr-10330 (D. Mass. 2012). Consistent with this more relaxed approach, the jury instruction proposed by the government and adopted by the court in the *Vascular Solutions* trial limited FDA’s ability to restrict speech that is truthful and not misleading:

It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that VSI’s promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense.

Like the *Caronia* and *Amarin* decisions before it, the *Vascular Solutions* court also indicated that promotional speech itself would not be evidence of misbranding so long as the speech was solely truthful and not misleading. These jury instructions and the not-guilty verdicts should impact the government’s exercise of enforcement discretion in future cases involving off-label promotion.

The First Amendment arose in another off-label promotion case discussed in this publication, *United States v. Facticeau*, but the jury reached a contrary verdict. Notably the jury instructions differed and, as of the date this publication was submitted, the defendants’ motion to overturn the verdict was pending review by the court.

Individual Liability

Immediately after trial, Howard Root became an outspoken critic against the government. He issued a scathing press release demanding an investigation of “what went wrong in our case” and calling for changes at DOJ “to ensure that its next ‘hand-picked’ and ‘offensive’ criminal prosecution isn’t based on false allegations made by a money-motivated disgruntled former employee.”² He also provided several interviews of his experience, and published a book titled *Cardiac Arrest: Five Heart-Stopping Years as a CEO on the Feds’ Hit-List*. His outrage centers on DOJ’s policy of investigating individuals engaged in conduct attributable to the company, a policy that has long been part of DOJ policy but was further emphasized and recently memorialized in a memorandum authored by former Deputy Attorney General Sally Yates. Coupled with potential strict liability exposure under the FDCA for any “responsible corporate officer” at a company, Root claims that DOJ can make a potential criminal out of every CEO.

This case exemplifies the grave impact on individuals who are in a position of responsibility at FDA-regulated entities. Under the U.S. Supreme Court precedents of *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975), the government has held individuals personally liable for the activities of their corporate employer. The *Park* Doctrine permits the government to seek misdemeanor convictions of a company official even if the corporate official was unaware of the violation, as long as the official was in a position of authority to prevent or correct the violation and did not do so. The theory is based on the standard of care imposed by the FDC Act on highly regulated industry.

² See *Vascular Solutions, Inc.*, Press Release, *Vascular Solutions and Howard Root Found Not Guilty on All Charges in Short Kit Litigation* (Feb. 26, 2016), <http://vasc.com/wp-content/uploads/2012/04/VASC-and-Howard-Root-Not-Guilty-February-26-2016.pdf>.



Howard Root claims that the defense of the company and him personally exceeded \$25 million in legal fees. Not every corporate executive has access to this level of resources. Indeed, in February 2017, Root announced that he quit the company he founded to avoid getting tangled in another government investigation given the continued existence of the government's policy. Although Root prevailed, this criminal prosecution is a good reminder to corporate executives of their personal exposure for playing in this highly regulated field.

DeCoster v. U.S.

RALPH F. HALL *

WHY IT MADE THE LIST

It seems that every generation there is at least one major “Responsible Corporate Officer” decision from the Supreme Court. *DeCoster v. U.S.*¹ may well be that case for this generation. In this case, two executives have pled guilty under the Responsible Corporate Officer doctrine and have been sentenced to three months in jail. The defendants challenged the sentence but that sentence was upheld on appeal.²

As discussed in more detail below, a petition for a writ of certiorari is currently pending before the U.S. Supreme Court. This writ challenges the core *Park/Dotterweich* doctrine in addition to more narrow issues about the sentence.³

No matter what the Supreme Court does, this case will impact enforcement actions and the compliance advice given to corporations. If the cert petition is denied, the impact of the *Park/Dotterweich* doctrine will continue as described by the Eighth Circuit. If cert is granted, all bets are off.

The importance of the Responsible Corporate Officer (RCO) doctrine in the FDA world is obvious and long standing. The *Park/Dotterweich* doctrine has been woven into the fabric of FDA law and practice for generations. The *Park/Dotterweich* doctrine rolls off the tongue of every student in an FDA law class and every practitioner of FDA law. Going back to at least 1943,⁴ Courts have held that a responsible corporate officer could be held criminally liable, albeit for a misdemeanor, for violations of the Food Drug and Cosmetic Act (FDCA) without the traditional requirements of mens rea, actual knowledge of the wrong doing, or other intent based findings.⁵ It is interesting to note that the recognition of some form of “strict” criminal liability dates to the origins of the FDCA. Within only a couple of years of passage of the FDCA in 1938, prosecutors were bringing (and the Supreme Court was upholding in *Dotterweich v. U.S.*) a form of “strict” criminal liability for responsible corporate officers. In the next generation, the Supreme Court upheld *Dotterweich* in *United States v. Park*, 421 U.S. 658 (1975). The Supreme Court may, in this generation, now revisit the *Park/Dotterweich* doctrine.

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¹ 828 F.3rd 626 (8th Cir. 2016).

² *Id.*

³ Given that the defendants actually pled guilty, the Supreme Court could grant the petition, address the precise sentencing issues, and not address whether the overall *Park/Dotterweich* doctrine is still good law.

⁴ *United States v. Dotterweich*, 320 U.S. 277 (1943) is generally credited with being the case that established vicarious or strict criminal misdemeanor liability for corporate executives in cases of violations of the FDCA.

⁵ 21 U.S.C. 301 seq.

The *Park/Dotterweich* doctrine significantly impacts corporate America, those advising corporate America, and enforcement agencies in at least three ways.

First, the risk to individual executives of criminal liability is believed to drive corporate compliance. The thought is that any executive will insist on compliance if he or she is subject to criminal liability for non-compliance. Many an FDA lawyer has advised (or warned) an executive about the need to comply in order to reduce personal exposure to a criminal prosecution. Those supporting the *Park/Dotterweich* doctrine fear that any relaxation of this doctrine will remove a powerful impetus for compliance. Their view is that the *in terrorem* effect of the *Park/Dotterweich* doctrine is an important factor in driving compliance.

Those supporting a change in this doctrine point out that strict liability, almost by definition, involves activities or risks outside of the knowledge or control of the executive. Liability under this doctrine, this group argues, is arbitrary and almost random. And, these advocates argue, random enforcement and unknowable obligations cannot act as any deterrent or impetus towards compliance.

Some may question whether history demonstrates any impact of the *Park/Dotterweich* doctrine on compliance. Even with the *Park/Dotterweich* doctrine (and the related compliance mandates such as the emphasis in the U.S. Sentencing Guidelines on the role of executive,⁶ the current exhortation in the U.S. Sentencing Guidelines to hold executives personally liable,⁷ and the more general “Yates Memo”),⁸ there has been substantial non-compliance within the food and drug law field over the past several decades. Those questioning the value of the *Park/Dotterweich* doctrine also point out that substantial enforcement tools exist without this doctrine under the FDCA, False Claims Act, general criminal law, SEC rules, etc.

Second, the *Park/Dotterweich* doctrine has been a powerful tool to compel settlements. The threat of individual criminal actions is a strong inducement for a corporation to cooperate with prosecutors and to reach a settlement, even for very large sums of money and the imposition of onerous requirements under a Corporate Integrity Agreement or Deferred Prosecution Agreement.⁹ The risk of a *Park/Dotterweich* conviction is even greater when one remembers that the ancillary impact of a *Park/Dotterweich* conviction can be substantial. For example, a guilty plea by three individual executives of Purdue Pharma led to a very lengthy exclusion from federal health care programs.¹⁰

Third, the *Park/Dotterweich* doctrine is a powerful enforcement weapon. Prosecutions are easier, lower risk, and faster if the government doesn’t have to establish mens rea and actual involvement with the illegal act(s). It is often hard actually to lose a true strict liability case. As interpreted by some, once the company has been shown to have violated the FDCA, executive liability is almost a given.

⁶ U.S. Sentencing Guidelines §8B2.1.

⁷ U.S. Attorney’s Manual §4-8.210 (2017).

⁸ We recognize that a new administration is taking the reins in Washington DC in general and at the Department of Justice in particular. Whether the enforcement policies of the prior administration in the area of individual executive responsibility will remain is an open question.

⁹ The Yates Memo and its emphasis on holding individuals criminally liable even if the corporation is pleading guilty may well be reducing the impact of the *Park/Dotterweich* doctrine on settlements.

¹⁰ *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).

It is important to note that the posture of *DeCoster* is a challenge to the actual sentence and was not an effort to vacate the guilty pleas. After all, the defendants pled guilty. However, the petition for writ of certiorari and supporting amici briefs challenge not only the sentence but the *Park/Dotterweich* doctrine itself. Whether the Supreme Court will address the broader question, even if it grants cert., is unclear.

DISCUSSION

This case arose out of a series of significant problems with salmonella contaminated eggs from Quality Eggs, LLC. The key facts for our purposes are that in 2010 Quality Eggs had a series of quality, cleanliness, and compliance issues resulting in serious salmonella contamination (or risk of contamination) of millions of eggs. Unsanitary conditions included rodent infestation, manure storage problems, lack of testing of eggs prior to shipment and, potentially, failure to address failed quality tests. The company eventually (voluntarily) recalled literally millions of shell eggs.¹¹ The parties do not dispute the finding that the eggs were adulterated and misbranded.

At the relevant times, Austin (Jack) DeCoster and his son, Peter DeCoster served as senior executives of Quality Eggs. The company pled guilty to several felonies including bribing a government agent and distributing, with an intent to defraud or mislead,¹² misbranded eggs. The company also pled guilty to misdemeanor charges for distributing adulterated eggs.

The government, based on the *Park/Dotterweich* doctrine, also pursued the two corporate executives. The two individuals agreed to plead guilty to misdemeanor violations of 331(a) as responsible corporate officers. Interestingly, the government stipulated that no individual (including the DeCosters) had actual knowledge that the eggs being shipped during the relevant time period were, in fact, salmonella contaminated.¹³ “[T]he government investigation has not identified any personnel employed by or associated with Quality Eggs, including the defendant[s], who had knowledge during the [charged] time frame . . . that the eggs sold by Quality Eggs were, in fact, contaminated . . .”¹⁴

Prior to sentencing, the DeCosters filed a motion to preclude any incarceration. The trial court denied the motion and sentenced the defendants to 3 months’ incarceration plus a fine of \$100,000. The defendants appealed this sentence and challenged the constitutionality of the sentence.

The Eighth Circuit upheld the trial court in a fractured decision. The “majority” opinion (authored by Judge Murphy and concurred in result by Judge Gruender) upheld the trial court with a concurrence by Judge Gruender. Judge Gruender concurred in the result based upon his “negligence” limitation (described below) to the *Park/Dotterweich* doctrine. Basically, Judge Gruender would require a finding of at least negligence to uphold a conviction under *Park/Dotterweich*. (Judge Murphy

¹¹ A more detailed description of the facts can be found at 828 F.3d at 630-631.

¹² An intent to defraud is the key factor differentiating felony liable from misdemeanor liability under 21 U.S.C. 333(a)(2).

¹³ *Id.* at 639 ((Beam dissenting)).

¹⁴ *Id.* It is unclear whether the government asserted during sentencing that the defendants were liable under 21 U.S.C. 342(a)(4) for actions by which the food “may have become” adulterated. Whether this would affect either the concurrence or the dissent is unclear.

would not apparently require such a finding.) In this case, Judge Gruender concluded that the record demonstrated a finding of negligence or more and so concurred in the judgement. Judge Beam dissented believing that a higher standard of blameworthiness is required as compared to Judge Murphy and disagreeing with Judge Gruender that the record supported a finding of negligence.

In a general essence, the various opinions reached the following conclusions:

- The “majority” opinion (Judge Murphy) upheld the conviction, rejected the constitutional objections and appears to uphold a traditional view of *Park/Dotterweich*. An executive in a position to prevent or address the underlying non-compliance can, under Judge Murphy’s opinion, be held criminally responsible for a misdemeanor violation of the FDCA without any specific finding of mens rea, direct negligence, or actual involvement in the underlying misconduct.

It is important to also note that even under the majority opinion, *Park/Dotterweich* is not completely vicarious or strict liability. Rather, while traditional mens rea or negligence is not requirement, the doctrine is based on the role of the defendant as an executive within the corporation. In these cases, the basis for criminal liability (or the “blameworthiness”) of the defendant is the failure of the responsible corporate officer to detect, prevent or remedy the violation.¹⁵ (How this differs from “strict” liability for a CEO is not discussed in Judge Murphy’s opinion.)

- The concurring opinion (Judge Gruender) agreed with the result in the case but would insist (for constitutional reasons) that individual criminal liability is permissible only if the responsible corporate officer was negligent. In this case, Judge Gruender found sufficient evidence of negligence in the record to uphold the sentence. The concurrence, however, explicitly limits the *Park/Dotterweich* doctrine to situations involving negligence or more blameworthy conduct. The concurrence states: “I write separately in order to make clear my view that *Park* requires a finding of negligence in order to convict a responsible corporate officer under §331.”¹⁶

- The dissent (Judge Beam) found the sentence unconstitutional under the Due Process Clause because there was no evidence of actual negligence (thus addressing Judge Gruender’s legal opinion that at least negligence is required but disagreeing on the facts in this case) and because some level of mens rea is required for a criminal conviction. Judge Beam concluded that *Park* and *Dotterweich* would violate current Supreme Court precedent. “Incarnation of *Dotterweich* or *Park*, as we now know, would have violated Supreme Court precedent as clearly established in *Zadvydas*¹⁷, *Staples*¹⁸ and *Torres*¹⁹.”²⁰

The appellate court decision (and the cert petition and related amici briefs) raise several constitutional issues and one issue regarding the proper interpretation of *Park*.

¹⁵ *DeCoster* at 632. The difference between vicarious liability (responsibility for the actions of another) and *Park/Dotterweich* type liability (a failure to detect, prevent or remedy a violation) may, in practical application, be small.

¹⁶ *Id.* at 637. Again, note that the appeal technically raised only sentencing issues but the litigants and court considered broader *Park/Dotterweich* issues.

¹⁷ *Zadvydas v. Davis*, 533 U.S. 678 (2001).

¹⁸ *Staples v. United States*, 511 U.S. 600 (1994).

¹⁹ *Torres v. Lynch*, 136 S. Ct. 1619 (2016).

²⁰ *DeCoster* at 641.

First, constitutionally, strict liability criminal cases such as *Park/Dotterweich* are disfavored except only in a narrow set of cases relating to “public welfare offenses.” And these are rare. (The constitutional arguments challenging these statutes generally raise arguments under the Due Process Clause. See for example *Zadvydas*.) The defendants argue that existing Supreme Court precedent prevents “strict” liability as set forth in *Park/Dotterweich* and argue that neither *Park* nor *Dotterweich* is consistent with current supreme court jurisprudence. For example, in *Lady J. Lingerie, Inc. v. City of Jacksonville*, the Supreme Court stated: “due process prohibits the state from imprisoning a person without proof of personal blameworthiness more than a ‘responsible relationship’.”²¹

The key constitutional question raised here is whether a criminal conviction such as that of the DeCoster is constitutional without some knowledge, negligence, or other blameworthy conduct (or perhaps inaction). While one can debate the facts in this case, the record can be read to present a clear “strict” or “vicarious” liability case for Supreme Court review. In fact, amici briefs in support of the cert petition expressly frame this question for the court. (See, for example, Washington Legal Foundation’s brief in support of the petition.) These amici seek a reversal of *Park/Dotterweich*.

The most direct assault on the *Park/Dotterweich* doctrine in this case involves the question of the level of “blameworthiness” required to support constitutionally a criminal conviction. The majority opinion at the appellate court (Judge Murphy) upheld the traditional (essentially “strict”) liability standard traditionally viewed as the *Park/Dotterweich* doctrine. The defendants and the concurring opinion, however, read *Park* as requiring some “negligence” to support a misdemeanor conviction under 21 U.S.C. §333(a).

Here, the majority and concurrence part ways. The majority (Judge Murphy) simply doesn’t read *Park* as requiring the level of negligent behavior that the concurring opinion deems required under *Park*. If cert is granted, one can predict that this difference in interpretation of *Park* will be explicitly addressed and resolved.

The dissent agrees with the concurring opinion that some “blameworthiness” is required. However, the dissent did not conclude that the record in this case established the minimal level of blameworthiness needed to constitutionally support a criminal conviction. It is unclear whether the concurrence and the dissent require the same level of blameworthiness with the difference being their interpretation of the factual record. The more likely reading of the decisions is that the dissent would require a somewhat higher level of blameworthiness.

The second issue (and related issue) raised relates to the actual sentence imposed by the trial court on the defendants. The defendants assert that the sentence is unconstitutionally too harsh and that a “strict” liability conviction cannot support any incarceration. According to those seeking Supreme Court review, strict criminal liability is permitted only if the penalties are “relatively small” and do not cause “grave damage” to the defendant’s reputation.²² Here the defendants argue that three months’ incarceration is not “relatively small” and does cause “grave damage” to the defendants’ reputation and thus the sentence is unconstitutional.

It is possible for the Supreme Court to uphold the ability to find a defendant guilty under the *Park/Dotterweich* “strict” liability standard but also concluding that

²¹ *Lady J. Lingerie, Inc. v. City of Jacksonville*, 176 F.3d 1358, 1367 (11th Cir. 1999).

²² See, cases such as *Staples v. U.S.*, 511 U.S. 600 (1994) and *Morissette v. U.S.*, 342 U.S. 246 (1952).

incarceration is not constitutionally permitted. Whether the Supreme Court is willing to draw this fine distinction is unknown at this time.

In upholding the conviction against these claims that three months incarceration is not “relatively small” and does cause grave damage, the appellate court (Judge Murphy) focused on the relatively small fine (\$100,000) and the short period of incarceration (3 months). The Court noted that a misdemeanor conviction did not impact voting or other related civic rights.²³ Past cases cited by Judge Murphy found that these penalties were indeed relatively small and did not impose grave damage.²⁴

It is important that the majority opinion (Judge Murphy’s opinion) focused on the immediate or direct impact of a misdemeanor and found three months’ incarceration to be minor and not a grave damage to the defendants’ reputation. The majority opinion also states (with little factual explanation), that the misdemeanor conviction does not gravely damage the defendants’ reputation.

In contrast, the defendants argued first that any incarceration is, almost by definition, not “small.” Any deprivation of liberty is, the argument goes, not a small matter. The cases cited by Judge Murphy involve lesser penalties or were decided years ago and thus do not account for modern views on incarceration and do not involve the ripple effect on a defendant of a criminal conviction and incarceration. Those challenging the conviction and sentence point to the “ancillary” but often serious impacts of a misdemeanor conviction. These “ancillary” effects of a conviction are not explicitly addressed by the majority. The following are examples of some of the additional effects or risks of a misdemeanor conviction:

- Risk of exclusion (see, for example, *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012)). Exclusion can destroy the ability of the individual to work in FDA regulated companies if that company does business with the government health care plans. (Essentially all FDA regulated companies in the therapeutic product area such as drugs and devices do business directly or indirectly with the government. Other FDA regulated companies of any size (such as Quality Eggs, often sell products to the government.)
- Risk of debarment (depending on the facts). Like exclusion, debarment destroys a career.
- Imposition of other equitable remedies (disgorgement, injunctive relief, etc.).
- Risk of private litigation including shareholder lawsuits, customer, or purchaser lawsuits and product liability lawsuits. For example, a *Park/Dotterweich* conviction can trigger arguments that the executive failed in his or her fiduciary obligations to shareholders. Shareholder lawsuits often follow criminal convictions of publicly traded FDA regulated companies.
- Modern corporate compliance programs may prevent or limit the employment of such an individual (see USSG §8B2.1). Under these programs, a company is not supposed to hire or retain an individual with a “propensity” to violate the law. Being convicted of a criminal violation of the FDCA would seem, almost by definition, to

²³ An older case, *U.S. v. Greenbaum*, 138 F.2d 437 (3rd Cir. 1943), upheld a three-month sentence for a misdemeanor conviction. The dissent argues factual differences plus asserted that this case, given its age and subsequent Supreme Court decisions, is not precedential.

²⁴ The court cited in support of this proposition cases such as *U.S. v. Flum*, 518 F.2d 39 (8th Cir. 1975) (finding a one-year sentence to be relatively small) and *U.S. v. Wulff*, 758 F.2d 1121 (6th Cir. 1985) finding a two-year sentence not be relatively small.

qualify as having a propensity to violate the law. As a practical matter, few companies would hire the DeCosters to run an egg production operation.

- Finally, there is the reputational harm of being a convicted criminal. Such a conviction often impacts social networks, employment opportunities and public reputation (including adverse publicity).

The defendants also raised 8th Amendment issues. The initial argument here is a proportionality claim. More specifically, the defendants argue that incarceration is constitutionally disproportionate with a strict liability conviction. In several ways, the proportionality claim echoes the argument that a criminal conviction for a “strict” liability conviction is impermissible if the results of the conviction are penalties that are not “relatively small” or cause “grave damage” to the defendant’s reputation. The litigants have also raised arguments that the sentence is arbitrary and that there is not “fair warning” to defendants as to what constitutes criminal liability. Case such as *Kolender v. Lawson*, 461 U.S. 352 (1983) hold that any criminal statute must provide “sufficient definiteness” as to what is and is not criminal behavior.²⁵ Along these lines, the defendants challenge the *Park/Dotterweich* doctrine on the grounds that it is impermissibly vague and thus triggers arbitrary enforcement. According to the defendants, the *Park/Dotterweich* doctrine does not provide the constitutionally required “minimal guidelines to govern law enforcement.”²⁶ Stated differently, the defendants argue that any decision to prosecute a specific individual is purely arbitrary. There is nothing to distinguish the corporate executive who is prosecuted from the executive who is not prosecuted. As such, the executive cannot seek to conform his or her conduct to the law and has no idea whether he or she is subject to criminal prosecution. Of course, the government’s position in opposition is that these decisions are simply standard prosecutorial discretion. The executive knows that he or she is responsible for ensuring that the corporation is in compliance. Do that and there is no risk of prosecution. As such, the government’s argument can run, the defendant knows exactly what is required of them.

In summary, if cert is granted, the Supreme Court will be in a position to address several constitutional challenges.

IMPACT OF THE DECISION

DeCoster is important for two broad reasons.

First, any Supreme Court review of the *Park/Dotterweich* doctrine is, almost by definition, a major event. Enforcement agencies, litigants and corporate advisors will vary their actions and advice based on a Supreme Court decision if it accepts cert in this case. The final decision will, of course, provide critical guidance for those involved in corporate compliance. Given that, at this time, the petition for cert. has not yet been ruled upon, it would be pure speculation to predict the outcome or impact of a Supreme Court decision. The cert effort does, however, present the court with the opportunity to reinforce, clarify or limit the *Park/Dotterweich* doctrine.

Second, even without Supreme Court review, the appellate court decision is noteworthy. The dissent clearly gives litigants the roadmap for future challenges to the

²⁵ *Kolender* follows a series of Supreme Court cases including *United States v. Harriss*, 347 U.S. 612 (1954).

²⁶ *Smith v. Goguen*, 415 566, 574 (1974).

Park/Dotterweich doctrine. A different panel might well adopted Judge Beam’s analysis.

The majority opinion lays out the standard or traditional approach to criminal liability for responsible corporate officers. If the only opinion were Judge Murphy’s majority opinion, the *DeCoster* decision would be simply an affirmation of the traditional view of the law.

The concurring opinion is thus important as it sets forth a “negligence” element to the *Park/Dotterweich* doctrine. Without a trial court record establishing negligence (as viewed by Judge Gruender), the trial court sentence might well have been reversed.

The government, in prosecuting a responsible corporate officer case will be strongly incentivized to set forth evidence of negligence or more, jury instructions may well include issues of negligence, and sentencing records may well include negligence findings.

It must be noted that in this case, the defendants actually pled guilty and were initially just challenging the sentences imposed by the trial court. The appellate court opinions all, however, seem to address the required elements of the responsible corporate officer doctrine or its actual constitutionality.

The bottom line is that at this time next year we will have some clarity as to the role of the *Park/Dotterweich* doctrine well into the 21st Century.

Bristol-Myers Squibb Co. v. Superior Court

JAMES M. BECK*

WHY IT MADE THE LIST

For several decades, product liability plaintiffs, especially those suing manufacturers of FDA-regulated products, have sought out their most favorable venues, without regard to either their residence or the citizenship of the defendants they sue. That strategy originally relied on an interpretation of “general” personal jurisdiction. That interpretation, which for many years asked only if the defendant did “continuous and substantial” business in the state in question, was discredited in *Goodyear Dunlop Tires Operations, S.A. v. Brown (Brown)*,¹ and especially in *Daimler AG v. Bauman (Bauman)*.²

After *Bauman*, a corporation’s “continuous and substantial” business in the jurisdiction alone is no longer sufficient to create general personal jurisdiction; the corporate defendant must conduct so much business that it can be considered “at home” in the particular jurisdiction.³ Save for an extremely rare exception for truly “exceptional” cases,⁴ *Bauman* effectively limits general personal jurisdiction to those states where a corporation is incorporated or has its principal place of business.⁵ “Exorbitant” and “grasping” jurisdictional theories that would make jurisdiction “available in every other State” where large corporations do business, violate such defendants’ rights to Due Process.⁶ “A corporation that operates in many places can scarcely be deemed at home in all of them.”⁷

Bauman thus threatens the viability of the litigation industry in plaintiff-friendly venues, since the great majority of plaintiffs in such venues are non-residents. Searching for a way around *Bauman*, mass tort plaintiffs, particularly in litigation involving prescription drugs and medical devices, have sought to stretch “specific” personal jurisdiction—normally available only to in-state residents or persons injured in a state—to cases brought by non-residents. By a 4-3 margin, the California Supreme

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¹ 564 U.S. 915 (2011).

² ___ U.S. ___, 134 S.Ct. 746 (2014).

³ *Bauman*, 134 S. Ct. at 757; *Goodyear*, 564 U.S. at 919.

⁴ The “exceptional” case cited in *Bauman* involved a Philippine company evacuated during the World War II Japanese invasion and temporarily relocated to Ohio. 134 S. Ct. at 755-56 & n.8 (discussing *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952)).

⁵ *Bauman*, 134 S. Ct. at 760-61.

⁶ *Id.* at 761-62.

⁷ *Id.* at 761 n.19.

Court in *Bristol-Myers Squibb Co. v. Superior Court*,⁸ gave out-of-state plaintiffs alleging defects in the prescription drug Plavix everything they wanted.

In early January, 2017, the United States Supreme Court granted review,⁹ setting up a jurisdictional show-down that will affect the litigation of mass tort cases for decades to come. Because it could possibly be a turning point in the way that mass torts involving prescription medical products are litigated, *BMS* is one of the most important drug and device opinions handed down in 2016.

DISCUSSION OF THE FACTS, HOLDING, AND RATIONALE

The defendant, Bristol-Myers, is a multinational pharmaceutical company incorporated in Delaware and headquartered in New York. One of Bristol-Myers products is Plavix, a blood-clot inhibiting prescription drug approved by FDA for labeling as preventive of strokes, heart attacks, and other cardiovascular diseases.¹⁰ While Bristol-Myers sold nearly a billion dollars' worth of Plavix in California between 2006 and 2012, that represented only 1.1% of the company's nationwide sales revenue.¹¹ Bristol-Myers "maintains substantial operations in California, including five offices that are primarily research and laboratory facilities employing approximately 164 people," and also "employs approximately 250 [California] sales representatives."¹² It "never manufactured Plavix in California."¹³ Based on these contacts, Bristol-Myers is clearly not "at home" in California under *Bauman*.¹⁴

BMS II involves eight multi-plaintiff complaints, all coordinated in a single California mass-tort proceeding, brought by 678 plaintiffs—86 of whom are California residents (12.7%), while the remaining 575 (87.3%) are out-of-state residents.¹⁵ The eight complaints all asserted the same legal theories, although the 678 plaintiffs alleged a wide variety of injuries.¹⁶ To keep the actions non-diverse, and therefore out of federal court, all the complaints named a California distributor as a defendant.¹⁷

Before *Bauman* had been decided, Bristol-Myers sought dismissal of all the non-California plaintiffs on grounds of lack of personal jurisdiction, asserting that the non-Californians lacked any link to the company's California activities. None of the non-resident plaintiffs: (1) were injured by Plavix in California, (2) received medical treatment in California, (3) were prescribed Plavix by California physicians, (4)

⁸ 377 P.3d 874 (Cal. 2016) (*BMS II*).

⁹ *Bristol-Myers Squibb Co. v. Superior Court*, No. 16-466, 2017 WL 215687 (U.S. Jan. 19, 2017).

¹⁰ *BMS II*, 377 P.3d at 878.

¹¹ *Id.* at 879.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at 883-84 (unanimously holding that California courts could not exercise general personal jurisdiction over Bristol-Myers under *Bauman*).

¹⁵ *Id.* at 877-78. This prevalence of out-of-state plaintiffs is not unusual in pharmaceutical mass torts. For example, 74% of new pharmaceutical mass tort filings in Philadelphia in 2016 were by non-Pennsylvania residents. M. Mitchell, "Mass Tort Programs Saw Inventory Spike in 2016," *Legal Intelligencer* (Jan. 20, 2017).

¹⁶ 377 P.3d at 878.

¹⁷ *Id.*

obtained Plavix from California pharmacies, or (5) used Plavix distributed by a California distributor.¹⁸ Nor were Bristol-Myers' actual California activities relevant to the litigation. It neither researched, manufactured, nor packaged Plavix in California.¹⁹

The California Superior Court denied the jurisdictional motion, ruling that Bristol-Myers was subject to general jurisdiction due to the volume of its California sales and extent of its "wide-ranging, systematic and continuous" activities in California.²⁰ Bristol-Myers sought mandamus, which was denied on January 14, 2014—the same day that the United States Supreme Court issued its game-changing decision in *Daimler AG v. Bauman*.²¹ The Court of Appeal reconsidered, accepted the appeal, and affirmed on specific, rather than general, jurisdiction grounds.²² The Court of Appeal held that that the "minimum contacts" and "related to" tests of specific jurisdiction could be satisfied, even though none of the plaintiffs in question was injured in California by the defendant's California activities:

[Defendant's] contacts with California . . . provide evidence of far more than the minimum contacts necessary . . . to support the exercise of specific jurisdiction Further, plaintiffs allege [defendant's] sales in California have led to injuries to California residents that are the same as those suffered by the [non-resident plaintiffs]. . . . If [defendant] is liable to any of the California plaintiffs because of proof which will be common for all plaintiffs, then those elements of each of the [non-resident plaintiffs'] claims may also be established.²³

Bristol-Myers sought, and received, further review in the California Supreme Court. By a narrow 4-3 margin, that court affirmed. The court was unanimous that Bristol-Myers was not subject to general jurisdiction in California. Under *Brown* and *Bauman*, Bristol-Myers was not "at home" in California because it was not incorporated or headquartered in California—"the two 'paradigm all-purpose forums'" under *Bauman*.²⁴ The company's California activities, while "sizable" in the absolute sense, were not so significant compared to its global operations to support it being an "extraordinary case" justifying the exercise of general personal jurisdiction, nor did registration to do business "compel [Bristol-Myers'] surrender to general jurisdiction for disputes unrelated to its California transactions."²⁵

However, four justices held that Bristol-Myers was subject to specific jurisdiction on the non-resident plaintiffs' product liability claims. The court asserted a broad "minimum contacts" limited only by "traditional notions of fair play and substantial justice."²⁶ It requires only the litigation "arise out of or [be] connected with the

¹⁸ *Id.* at 878-79.

¹⁹ *Id.* at 879.

²⁰ Plavix Product & Marketing Cases, 2013 WL 6150251, at *1 (Cal. Super. S.F. Co. Sept. 23, 2013).

²¹ See *Bauman*, 134 S. Ct. 746; Bristol-Myers Squibb Co. v. Superior Court, 175 Cal. Rptr.3d 412, 415 (Cal. App. 2014), *aff'd*, 377 P.3d 874 (Cal. 2016) (*BMS I*).

²² *BMS I*, 175 Cal. Rptr.3d at 433-38.

²³ *Id.* at 434-35.

²⁴ *BMS II*, 377 P.3d at 882 (quoting *Bauman*, 134 S.Ct. at 760).

²⁵ *Id.* at 883-84.

²⁶ *Id.* at 879-880 (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

[company’s] activities within the state.”²⁷ The Due Process language in prior specific jurisdiction cases was thus sufficiently pliable to permit jurisdiction over disputes unrelated to California transactions as long as a California resident is simultaneously pursuing the same allegations.

California uses a multi-factor “sliding scale” test for “relatedness,”²⁸ which evaluates specific jurisdiction as “fair” or not:

This test requires courts to evaluate the nature of the defendant’s activities in the forum and the relationship of the claim to those activities in order to answer the ultimate question under the due process clause: whether the exercise of jurisdiction in the forum is fair. Under the substantial connection test, the intensity of forum contacts and the connection of the claim to those contacts are inversely related. The more wide-ranging the defendant’s forum contacts, the more readily is shown a connection between the forum contacts and the claim.²⁹

Under California’s test “[a] claim need not arise directly from the defendant’s forum contacts in order to be sufficiently related to the contact to warrant the exercise of specific jurisdiction.”³⁰ For “purposeful availment,” it was enough that the defendant corporation advertised and sold its products in California—even where the plaintiffs in question were out-of-state residents who neither saw these advertisements nor bought anything in California.³¹

The more difficult proposition was relatedness. Here, *BMS II* principally relied on prior precedent, *Vons Cos. v. Seabest Foods, Inc.*, a case that actually involved a California company suing for reputational injury that took place in California.³² Extending *Vons* to non-resident plaintiffs, *BMS II* held that any “substantial connection” between a defendant’s activities and the forum, even without any causal connection to a non-resident plaintiff’s injuries, will suffice—provided that some California resident plaintiff has filed a similar suit:

Both the resident and nonresident plaintiffs’ claims are based on the same allegedly defective product and the assertedly misleading marketing and promotion of that product, which allegedly caused injuries in and outside the state. Thus, the nonresident plaintiffs’ claims bear a substantial connection to [defendant’s] contacts in California. [Defendant’s] nationwide marketing, promotion, and distribution of [the drug] created a substantial nexus between the nonresident plaintiffs’ claims and the company’s contacts in California concerning [that drug].³³

²⁷ *Id.* at 880 (quoting *International Shoe*, 326 U.S. at 320).

²⁸ *BMS II* viewed “sliding scale” analysis as having been adopted in *Vons Cos. v. Seabest Foods, Inc.*, 926 P.2d 1085, 1097 (Cal. 1996). 377 P.3d at 889.

²⁹ *BMS II*, 377 P.3d at 885 (citations and quotation marks omitted).

³⁰ *Id.* at 885, 887 (quoting *Vons*, 926 P.2d at 1096).

³¹ *Id.* at 886-87.

³² *Vons*, 926 P.2d at 902-03. *Vons* did not directly state the citizenship of plaintiff, *Vons Cos.*, but through 1996 it had exclusively California origins. See <http://www.vons.com/ShopStores/Our-Story.page> (last visited March 6, 2017).

³³ *BMS II*, 377 P.3d at 888.

BMS II reached a similarly attenuated jurisdictional conclusion with respect to claims concerning the development and design of Plavix.³⁴

BMS II rejected any causal relationship requirement. It was an “invalid assumption” that a defendant’s “forum contacts must bear some substantive legal relevance to the nonresident plaintiffs’ claims.”³⁵ All “forum contacts” that “are part of the nationwide marketing and distribution of [a product]” were necessarily “substantially connected to the nonresident plaintiffs’ claims” also involving that product.³⁶ Thus, *BMS II* allows any “nationwide marketer” of a product to be sued by any non-resident plaintiff, where a resident plaintiff also makes the same allegations.³⁷

Finally, *BMS II* considered the existence of a mass tort to be another basis for relaxing due process limitations on personal jurisdiction. Mass torts “involve diverse injuries or harm” and “present special problems” of judicial administration.³⁸ “[C]oordinated mass tort[s]” “avoid” “punishing a defendant over and over again for the same tortious conduct.”³⁹ Thus, “consolidation of plaintiffs’ claims in a single forum is a mechanism for promoting those interests.”⁴⁰

Three justices dissented.⁴¹ The majority’s “sliding scale” approach “is not supported by specific jurisdiction decisions from the United States Supreme Court . . . or the lower federal and state courts.”⁴² Construing non-causal, in-state activities as “related to” a plaintiff’s injuries “undermines [the] essential distinction between specific and general jurisdiction.”⁴³ “Relatedness” based solely on shared nationwide conduct would “expand[] specific jurisdiction to the point that, for a large category of defendants, it becomes indistinguishable from general jurisdiction.”⁴⁴ The majority’s conclusion was an end run around the limits on general jurisdiction that this Court articulated in *Bauman*. What the United States Supreme Court “wrought in *Daimler* – a shift in the general jurisdiction standard from the ‘continuous and systematic’ test . . . to a much tighter ‘at home’ limit – [the majority] undoes today under the rubric of specific jurisdiction.”⁴⁵

California has no discernible sovereign interest in providing an Ohio or South Carolina resident a forum in which to seek redress for injuries in those states caused by conduct occurring outside California. A mere resemblance between the nonresident

³⁴ *Id.* (“that the company engages in research and product development in these California facilities is related to plaintiffs’ claims . . . that even if those claims do not arise out of [defendant’s] research conduct in this state”).

³⁵ *Id.* (citing *Vons*, 926 P.2d at 1112).

³⁶ *Id.* at 889.

³⁷ *See Id.* at 891-92 (arguing that with California plaintiffs, addition of six times as many non-residents was less “burden” than litigating in the non-residents’ states); at 892 (“other injuries” anywhere in the country, can be evidence of defect).

³⁸ *Id.* at 893.

³⁹ *Id.*

⁴⁰ *Id.* at 894.

⁴¹ *Id.* at 894-910 (Werdegar, Chin & Corrigan, JJ. dissenting).

⁴² *Id.* at 896.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

plaintiffs' claims and those of California residents creates no sovereign interest in litigating those claims in a forum to which they have no substantial connection.⁴⁶

IMPACT

The result in *BMS II*, that non-causal in-state activity is alone sufficient to create specific personal jurisdiction, was unprecedented—as demonstrated by the heavy reliance on *Vons*, which did not involve non-resident plaintiffs. No prior case in California judicial history had allowed non-residents to take advantage of such facts to create personal jurisdiction. More than any extant jurisdictional doctrine, *BMS II*'s extension of “relatedness” resembles a covert form of “pendent jurisdiction”—since jurisdiction is dependent on something more than the claim itself—except that pendent jurisdiction has heretofore been limited to claims against parties as to which personal jurisdiction already existed, and all post-*Bauman* attempts to extend it to non-resident plaintiffs have been rejected.⁴⁷

As the dissent recognized, *BMS II* created, at least in the context of mass torts, the same universal form of specific jurisdiction that *Bauman* rejected as “grasping” and “exorbitant” when asserted as a theory of general jurisdiction.⁴⁸ If every state adopted the scope of specific personal jurisdiction that prevailed in *BMS II*, any corporate defendant engaged in “nationwide” marketing could be sued by anyone in any court, without regard to residence, provided that one resident plaintiff had also brought a similar action. That is precisely what *Bauman* held that due process prohibited.⁴⁹

The references in *BMS II* to mass torts are not accidental. California, like a number of other states has a substantial litigation industry where plaintiffs from all over the nation cluster into certain favored venues.⁵⁰ With general personal jurisdiction effectively restricted under *Bauman* so that non-resident plaintiffs can only sue corporations where they are incorporated or based, without an expansion of some other basis for personal jurisdiction—such as specific personal jurisdiction in *BMS II*—much of California’s litigation industry would lose its legal basis for existing. No jurisdiction means no lawsuits. Without *BMS II* expanding specific personal jurisdiction to the same extent that *Bauman* reduced general personal jurisdiction, only

⁴⁶ *Id.* at 899.

⁴⁷ See *Famular v. Whirlpool Corp.*, 2017 WL 280821, at *6-7 (S.D.N.Y. Jan. 19, 2017); In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings, 164 F. Supp.3d 1040, 1048-49 (N.D. Ill. 2016); In re: Bard IVC, 2016 WL 6393596, at *4-5 n.4 (D. Ariz. Oct. 28, 2016); In re Zofran (Ondansetron) Products Liability Litigation, 2016 WL 2349105, at *5 n.5 (D. Mass. May 4, 2016); *Demaria v. Nissan North America, Inc.*, 2016 WL 374145, at *7-8 (N.D. Ill. Feb. 1, 2016); *Tulsa Cancer Institute, PLLC v. Genentech, Inc.*, 2016 WL 141859, at *4 (N.D. Okla. Jan. 12, 2016); In re Plavix Related Cases, 2014 WL 3928240, at *9 (Ill. Cir. Aug. 11, 2014).

⁴⁸ 134 S.Ct. at 761.

⁴⁹ *Id.* at 761-62 (“Such exorbitant exercises of all-purpose jurisdiction would scarcely permit out-of-state defendants ‘to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.’”) (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

⁵⁰ See R. Tacher, “Are Out-Of-State Plaintiffs clogging California Courts?” (Civ. Justice Ass’n of Cal. 2017) (of approximately 25,000 plaintiffs suing pharmaceutical companies in California between 2010 and 2016, 89.9% were not California residents) (available at cjac.org/what/research/CJAC_Out_of_State_Plaintiffs_Exec_Summary.pdf).

California-based corporations would be unfortunate enough to face suit by non-California residents from all over the country in those plaintiffs' hand-picked locales.

Tens of thousands of non-resident plaintiffs asserting potentially billions of dollars of claims have been allowed to proceed by the *BMS II* decision. As mentioned above, the case has been accepted for review by the United States Supreme Court.⁵¹ A decision will be forthcoming by the end of the Supreme Court's current term in late June, 2017.

⁵¹ See, *supra*, note 9.

Glennen v. Allergan, Inc.

GINGER PIGOTT* AND KEVIN COLE**

WHY IT MADE THE LIST

Prescription medical device manufacturers defending personal injury actions have a wide variety of legal defenses not available to claims brought against manufacturers of other products. Traditional tort claims like strict liability and negligence are often limited or entirely unavailable. As a result, plaintiffs have increasingly turned to novel theories of liability in an effort to get around these robust defenses. And, likewise, those in the industry and their lawyers remain vigilant against attempts to expand tort liability. One of the creative theories advanced by the plaintiffs' bar has been dubbed the "failure to train" claim, and *Glennen v. Allergan, Inc.*¹ presents a recent and excellent discussion of why such claims also fail. In deciding *Glennen*, the California Court of Appeal took a rare opportunity to address failure to train claims involving devices approved pursuant to the Food and Drug Administration's (FDA) Premarket Approval process. *Glennen* is the most recent in a series of cases addressing how state law failure to train claims might run afoul of federal preemption, both express and implied. With little case law on point, *Glennen* will likely guide courts elsewhere.

DISCUSSION

Federal Regulation of Medical Devices

In analyzing the *Glennen* decision, it is helpful to first understand Congress' statutory scheme for the regulation of medical devices. Many of the readers here will know the background, but for those just joining us, a brief overview of medical device regulation provides the framework to understand preemption as applied in medical device cases.

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), which gave FDA specific authority to regulate general medical devices.² In this framework, Congress sought to find a balance that would make medical devices readily available for treatment while ensuring that those

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¹ 202 Cal. Rptr. 3d 68 (Ct. App. 2016).

² *Id.*; see also *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (explaining that Congress passed the MDA in order to "impose[] a regime of detailed federal oversight" to govern medical devices).

devices are safe for patient use.³ To that end, the MDA provides “for the safety and effectiveness of medical devices intended for human use,”⁴ while at the same time “encourag[ing] their research and development.”⁵

The MDA divides medical devices into three classes. Class I devices pose little threat to public health and safety and are subject only to general controls on manufacturing.⁶ Class II devices are more complex and must comply with specific standards known as “special controls.”⁷ Class III devices present a potential unreasonable risk of illness or injury.⁸ As a result, these devices must “complete a thorough review process with the FDA before they may be marketed.”⁹

This review, known as the Premarket Approval (PMA) process, is indisputably thorough.¹⁰ The manufacturer must give FDA a “reasonable assurance” that the product is safe and effective.¹¹ The process by which FDA determines whether a manufacturer has provided a “reasonable assurance,” is—to quote the Supreme Court—a “rigorous” one.¹² Indeed, “[t]he FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a reasonable assurance of the device’s safety and effectiveness.”¹³

After completing its review, FDA either grants or denies PMA.¹⁴ When FDA grants PMA, it may impose post-approval requirements such as restrictions on “the sale, distribution, or use of the device” and “[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use.”¹⁵ After obtaining PMA, a manufacturer may not change the device’s design or labeling without FDA’s consent.¹⁶

Federal Preemption

In addition to a framework for regulation, most readers will be familiar with federal preemption for medical devices, including express and implied preemption principles. The following is a very brief overview.

³ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470-74 (1996) (explaining Congress’ intent in enacting the MDA).

⁴ Pub. L. No. 94-295, preamble, 90 Stat. 539 (May 28, 1976).

⁵ S. Rep. No. 94-33, 94th Cong., 2d Sess. 2 (1976), reprinted in 1976 U.S.C.C.A.N. 1070, 1071.

⁶ *Lohr*, 518 U.S. at 476-77.

⁷ *Id.* at 477 (quotations omitted) (citing 21 U.S.C. § 360c(a)(1)(B)).

⁸ *Id.*

⁹ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344 (2001).

¹⁰ *Lohr*, 518 U.S. at 477.

¹¹ *Id.*

¹² *Riegel*, 552 U.S. at 317 (quoting *Lohr*, 518 U.S. at 477).

¹³ *Id.* at 317-18 (internal citations and quotations omitted).

¹⁴ *Id.*, 552 U.S. at 319.

¹⁵ 21 C.F.R. § 814.82(a)(1)-(2).

¹⁶ *Riegel*, 552 U.S. at 319.

Express Preemption in Brief

In enacting the MDA, Congress recognized that state laws, as well as lawsuits brought by individuals, could undermine FDA’s authority relating to the approval and regulation of medical devices by imposing different or additional requirements on medical device manufacturers. As a result, the statute governing medical devices includes an express preemption clause that prohibits states from imposing “requirements” that are “different from, or in addition to” federal requirements placed on medical devices.¹⁷ The Supreme Court has also explained that state law causes of action of general applicability seek to enforce state “requirements” and thus are preempted by federal standards.¹⁸

Implied Preemption in Brief

In addition to express preemption, conflict and implied preemption principles also apply to limit claims available to plaintiffs. Such was the case in *Buckman*, where the Supreme Court considered the question of a state law “fraud-on-the-FDA” claim and found that it was impliedly preempted.¹⁹ *Buckman* explained that a plaintiff cannot bring a state law cause of action claiming that a defendant defrauded a federal agency because federal law gives federal agencies—not states or private plaintiffs—the authority to police their own processes.²⁰ In barring claims by individuals to enforce requirements of the statute, the *Buckman* decision cites the “no private right of action” provision found in 21 U.S.C. § 337 (a), concluding that actions for alleged violations of federal requirements are not available to private litigants.²¹ Plaintiffs cannot stand in the shoes of FDA.

Ashley Glennen’s State Law Complaint

The *Glennen* case involved the Lap-Band Adjustable Gastric Banding System (Lap-Band), a medical device designed to help clinically obese patients lose weight by limiting the amount of food they eat.²² The Lap-Band was intended for use by severely obese patients.²³

In March 2000, BioEnterics, a subsidiary of a company that later merged with Allergan, filed an application with FDA seeking PMA of the Lap-Band.²⁴ FDA approved the application in June 2001.²⁵ As a condition for approval, FDA required that the Lap-Band’s labeling “specify the requirements that apply to the training of practitioners who may use the device as approved in this order.”²⁶ In complying with that requirement, BioEnterics prepared a brochure for the Lap-Band which made clear

¹⁷ 21 U.S.C. § 360k(a)(1); *see also Riegel*, 552 U.S. at 316.

¹⁸ *Riegel*, 552 U.S. at 323-24 (includes negligence, strict liability, breach of warranty, among others).

¹⁹ *Buckman*, 531 U.S. at 347.

²⁰ *Id.* at 350.

²¹ *Id.* at 349, n.4 (citing 21 U.S.C. § 337(a)).

²² *Glennen*, 202 Cal. Rptr. 3d at 70.

²³ *Id.*

²⁴ *Id.* at 71.

²⁵ *Id.*

²⁶ *Id.*

that surgeons using the device “must, among other things . . . participate in a training program for the LAP-BAND System authorized by BioEnterics Corporation or an authorized BioEnterics distributor (this is a requirement for use).”²⁷ FDA’s approval order did not contain any additional requirements concerning the training of physicians.²⁸

In January 2003, Ashley Glennen’s surgeon implanted the Lap-Band.²⁹ After the surgery, however, Glennen suffered serious injuries—the Lap-Band eroded into her stomach and liver, causing a portion of her stomach and small intestine to die, and also resulting in brain damage due to hemorrhage during an attempted surgical removal.³⁰ In September 2012, Glennen sued Allergan for negligence,³¹ alleging Allergan failed to adequately train physicians how to use the Lap-Band.³² After a couple of iterations of the complaint where arguments by Allergan whittled down the causes of action, Allergan again demurred to Glennen’s Second Amended Complaint (the California equivalent of a motion to dismiss). Allergan’s motion primarily sought to apply express preemption to the claims.³³ The trial court agreed and dismissed Glennen’s case, and Glennen appealed.

Court Ruling

The California Court of Appeal affirmed, agreeing that federal law preempted Glennen’s negligence claim.³⁴ The court’s decision was based on two lines of reasoning. First, it held that Glennen’s claim—that the training standards for physicians fell below what is required under California state law for compliance with the duty of care—was not the standard that FDA would apply in connection with the training requirements it imposed on physicians.³⁵ As a result, Glennen’s negligence claim was expressly preempted by the MDA because it imposed requirements different than, or in addition to, the applicable federal requirements.³⁶ The court separately found that Glennen’s claim was impliedly preempted by federal law because it improperly sought to enforce the MDA.³⁷ Thus, the court concluded that Glennen failed to allege facts sufficient to state a claim, based on the application of federal preemption.

²⁷ *Id.* (internal brackets and quotation marks omitted).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ The obvious statute of limitations question must have been addressed by an argument regarding the discovery rule, but it is not mentioned in the published decision beyond noting the original complaint which sued two doctors and a surgical center, was later dismissed.

³² *Id.* at 70-71.

³³ *Id.*

³⁴ *Id.* at 84.

³⁵ *Id.* at 81-82.

³⁶ *Id.* at 79-80.

³⁷ *Id.* at 83-84.

Rationale for Decision

The cornerstone of the court's decision was the now familiar concept of express preemption. The court, in a detailed analysis of the MDA and the Supreme Court's decisions interpreting it, explained that because FDA imposes specific requirements on Class III devices, state law claims that would impose different or additional requirements on those devices are preempted. The problem for Glennen, as the court saw it, was that her claim fell squarely within the scope of express preemption.

In her suit against Allergan, Glennen did not dispute that the Lap-Band had been approved through FDA's rigorous PMA process or that the requirements under the MDA have preemptive force under the Supremacy Clause.³⁸ Nor did Glennen apparently dispute, even indirectly, that state common law causes of action—like the one she filed against Allergan—seek to enforce state requirements and would be preempted by federal requirements.³⁹ Indeed, the question before the court—and the only question—was whether Glennen's negligence claim was preempted by the MDA because it imposed requirements different than, or in addition to, the applicable federal requirements.⁴⁰

Glennen did not allege that Allergan failed to comply with FDA's training program requirement. There was no dispute whether Allergan had established a physician training program or whether the surgeon who implanted the Lap-Band into Glennen's body had completed that training. Rather, Glennen's claim was that something additional was required. Not only did Allergan need to create a training program, it also—according to Glennen—needed to “implement current good manufacturing practices,” which included adopting and implementing “a quality policy as required by [the FDA's Quality System Regulation (Quality System Regulation)],” and ensure that surgeons “who completed the program were skilled in the implantation of Lap-Bands.”⁴¹ However, as the court noted, when FDA approved the Lap-Band, it did not mandate these additional requirements.⁴²

For her part, Glennen argued that the requirements that formed the basis of her claim were not different from, or in addition to, the requirements imposed by FDA's PMA order.⁴³ Rather, her position was that even if the MDA expressly preempted her federally derived claim, she could still bring claims that paralleled the federal requirements.⁴⁴ This argument presumably rested on the Supreme Court's suggestion in *Riegel* that the tension between FDA's requirements and those created by state law is avoided where the state requirements correspond to the federal ones.⁴⁵ In *Riegel*, for example, the Supreme Court stated that the MDA's preemption provision did not “prevent a State from providing a damages remedy for claims premised on a violation

³⁸ *Id.* at 76.

³⁹ *Id.*; see also *Riegel*, 552 U.S. at 323-24.

⁴⁰ *Id.*

⁴¹ *Id.* at 80.

⁴² *Id.* at 79-82.

⁴³ *Id.* at 76.

⁴⁴ *Id.*

⁴⁵ *Riegel*, 552 U.S. at 330 (declining to address, in the first instance, whether plaintiffs' claims were “parallel” to federal requirements).

of FDA regulations; the state duties in such a case [are] ‘parallel[.]’⁴⁶ But, the Court did not explain what constitutes a parallel claim.

Glennen, however, did not rely on *Riegel* in support of her parallel claim argument. Instead, she cited to a number of federal appellate cases, all of which the court was quick to distinguish.⁴⁷ For example, in one of the cases Glennen cited, *Bausch v. Stryker Corp.*,⁴⁸ the Seventh Circuit reversed a district court’s dismissal of a plaintiff’s claims for defective manufacture of a hip replacement in violation of federal law. The court concluded that state negligence claims premised on a manufacturer’s failure to abide by FDA’s approved manufacturing requirements survive express preemption.⁴⁹ By contrast, Glennen did not allege that the Lap-Band suffered from manufacturing defects in violation of federal law.⁵⁰

Glennen also relied on *Stengel v. Medtronic Inc.*,⁵¹ but as the court noted, the plaintiffs in that case alleged that the defendant violated its duty under federal law to report adverse events associated with its device to FDA, whereas Glennen did not allege failure to warn as a cause of action.⁵² Likewise, in *Hughes v. Boston Scientific Corp.*,⁵³ another case on which Glennen relied, the Fifth Circuit explained that the plaintiff’s claim was “not expressly preempted to the extent she asserts that Boston Scientific violated the state [law] duty to warn by failing to accurately report serious injuries and malfunctions of the . . . device as required by the FDA’s [reporting] regulations.”⁵⁴ And, just as in Glennen’s claim, the Fifth Circuit in *Hughes* held that “[i]t is clear that all of [the plaintiff’s] state products liability claims that purport to impose liability on Boston Scientific despite Boston Scientific’s compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted.”⁵⁵

The court was also unpersuaded by any argument that FDA’s Quality System Regulation (QSR) required device manufacturers like Allergan to train physicians in a certain way.⁵⁶ The court pointed out that Glennen’s claim did not fit into that regulation, which governs the quality of “finished” manufacturing devices and has nothing to do with training of physicians.⁵⁷ As the court explained, the plain language

⁴⁶ *Id.*; see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447-48 (2005) (describing parallel claims); *Lohr*, 518 U.S. at 496-97 (holding that state requirements that are “substantially identical to” those imposed by the MDA are not preempted).

⁴⁷ *Glennen*, 202 Cal. Rptr. 3d at 76-77 (distinguishing cases).

⁴⁸ 630 F.3d 546 (7th Cir. 2010).

⁴⁹ *Id.* at 557-58.

⁵⁰ *Glennen*, 202 Cal. Rptr. 3d at 76.

⁵¹ 704 F.3d 1224 (9th Cir. 2013) (en banc).

⁵² *Glennen*, 202 Cal. Rptr. 3d at 77.

⁵³ 631 F.3d 762 (5th Cir. 2011).

⁵⁴ *Id.* at 770.

⁵⁵ *Id.* at 768.

⁵⁶ *Glennen*, 202 Cal. Rptr. 3d at 78 (“In an apparent effort to align her claim with a violation of federal law, plaintiff’s [complaint] alleges violations of several federal provisions contained in the FDA’s ‘Quality System Regulation.’”).

⁵⁷ *Id.* (“Because none of the regulations on which [Glennen] relies references any requirement to train physicians in the use of a medical device, her allegations fail to state a parallel claim.”).

of the QSR dispels any notion that it regulates, or that it even relates to, the training of physicians.⁵⁸

Indeed, the QSR “govern[s] the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.”⁵⁹ The court explained that “[t]he requirements in this part are intended to ensure that finished devices will be safe and effective,”⁶⁰ and also provides that “[e]ach manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed.”⁶¹ As the court further observed, the QSR is notably silent on the issue of physician training.⁶²

The court was equally unpersuaded by Glennen’s argument that Allergan’s training was inadequate. The court observed that other courts addressing state law failure to train claims like Glennen’s concluded that the MDA expressly preempted those claims.⁶³ The court noted the Fifth Circuit’s decision in *Gomez v. St. Jude Medical Daig. Div., Inc.*,⁶⁴ which recognized that “[t]o permit a jury to decide . . . claims that the . . . training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA’s exclusive role and expertise in this area and risk imposing inconsistent obligations on” device manufacturers.⁶⁵

Finally, no shrinking violet, the court held that Glennen’s claim was impliedly preempted by federal law, explaining that the implied preemption forbids state law claims that seek to enforce the FDCA.⁶⁶ The court observed that there was no duty under California law that required a medical device manufacturer like Allergan to train physicians in the use of its products, and Allergan did not voluntarily train physicians how to use the Lap-Band.⁶⁷ Instead, FDA required specified physician training by Allergan as a condition of its PMA for the Lap-Band.⁶⁸ Thus, but for FDA’s requirement that Allergan provide training to physicians implanting the Lap-Band, Glennen would have no basis for which to allege the facts underlying her negligence claim.⁶⁹ As a result, the court explained, Glennen’s claim did not “exist independently of the MDA, and . . . [was] impliedly preempted.”⁷⁰ This reflects the Supreme Court’s admonishments in *Buckman* that the MDA “leaves no doubt that it is the Federal Government rather than private litigants [which is] authorized to file suit for noncompliance with the medical device provisions.”⁷¹

⁵⁸ *Id.* at 78-79.

⁵⁹ 21 C.F.R. § 820.1(a).

⁶⁰ *Id.*

⁶¹ *Id.* at § 820.160(a).

⁶² *Glennen*, 202 Cal. Rptr. 3d at 81.

⁶³ *Id.* at 82.

⁶⁴ 442 F.3d 919, 931 (5th Cir. 2006).

⁶⁵ *Id.*

⁶⁶ *Id.* at 75-76.

⁶⁷ *Id.* at 83.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

IMPACT OF DECISION

Failure to train claims against medical device manufacturers are nothing new, and the case law—more often than not closing the door on such claims—has developed in two ways. First are cases where courts have explicitly refused to recognize a duty to train.⁷² In such cases, the alleged failure to train is often characterized by courts as an attempt to expand the duty to warn.⁷³ As the Fifth Circuit put it, “[i]t is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams.”⁷⁴ Other courts view the distinction between failure to train claims and failure to warn claims as one of “semantics only.”⁷⁵

Second are cases presenting failure to train claims for devices with an explicit requirement to undertake training. Training as a specific requirement of a PMA is relatively rare, though certainly available to FDA, particularly where a technology is new.⁷⁶ Therefore, while there is not as much precedent, most courts confronted with this kind of failure to train claim agree with *Glennen* that such claims are preempted because they would impose requirements that are different from, or in addition to federal requirements. The Fifth Circuit’s decision in *Gomez*, on which the *Glennen* court relied in part, is illustrative. In that case, the plaintiff sued the manufacturer of the *Angio-Seal* (also a Class III device) under state law theories for, among other things, failure to train medical personnel.⁷⁷ In applying *Riegel*, the court affirmed the dismissal of the plaintiff’s failure to train claim on the ground that “this state-law challenge” to FDA’s requirements for the device was preempted by the MDA.⁷⁸ The court reasoned that permitting “a jury to second-guess the [FDA’s requirements] by applying the [state] statutory standard for unreasonably dangerous [products] would risk interference with” the requirements approved by FDA and “would displace the FDA’s exclusive role and expertise in this area.”⁷⁹

In another negligent training claim case, *Chamian v. Sharplan Lasers Inc.*,⁸⁰ the Massachusetts Superior Court provided a good example of the underlying rationale:

The fact that individuals who have received training on medical equipment subsequently misuse the equipment to the detriment of a patient, standing alone, is insufficient to establish a breach of a duty to the injured patient on the part of the entity

⁷² See, e.g., *Woodhouse v. Sanofi-Aventis U.S. LLC*, No. EP-11-CV-113-PRM, 2011 WL 3666595 at *3 (W.D. Tex. June 23, 2011) (allegation that defendant “failed to train, warn or educate” physicians failed to state a plausible claim because no such duty exists); *Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013) (“It is well established that a medical device manufacturer is not responsible for the practice of medicine.”).

⁷³ See, e.g., *Rounds v. Genzyme Corp.*, 440 F. App’x 753, 754-55 (11th Cir. 2011).

⁷⁴ *Swayze v. McNeil Labs, Inc.*, 807 F.2d. 464, 471 (5th Cir. 1987).

⁷⁵ *Rounds*, 440 F. App’x at 756.

⁷⁶ Speaking only anecdotally, very few PMA orders specify training requirements for the use of a particular device.

⁷⁷ *Gomez*, 442 F.3d at 931.

⁷⁸ *Id.* at 931-32.

⁷⁹ *Id.*

⁸⁰ 2004 WL 2341569 (Mass. Super. Ct. Sept. 24, 2004).

that provided the training. By providing training, [the defendant] did not become a guarantor of the competence of [those it trained.]⁸¹

More recently, in *Mattingly v. Hubbard*,⁸² a Kentucky trial court held that the plaintiff's failure to train claims were preempted by the MDA because they were "in addition to" FDA's requirements applicable to the device. In that case, the plaintiff argued that his negligence claims were not precluded by *Riegel* because unlike in *Riegel*, they related to the alleged inadequate training of his physician rather than FDA's approval of the device.⁸³ While noting the argument that "claims of negligent failure to train physicians properly is separate from the FDA approval process," the court rejected the plaintiff's argument and instead held "that such a claim would nonetheless impose an additional substantive requirement for a specific device."⁸⁴

Similarly, in *Rollins v. St. Jude Medical*,⁸⁵ the plaintiff alleged that the manufacturer failed to train her surgeon how to use the Angio-Seal device implanted during an angiogram. The court held that the plaintiff's failure to train claim was preempted by the MDA.⁸⁶ However, the court noted that a claim by the plaintiff that the manufacturer failed to abide by the training requirements imposed by FDA could survive preemption as a parallel claim.⁸⁷

As the case law demonstrates, courts are generally averse to failure to train claims—perhaps even viewing them as an indication of a plaintiff who lacks a better cause of action. Indeed, that may have been the case in *Glennen*, where the trial judge was sufficiently persuaded that the plaintiff's claim did not survive California's liberal pleading standards, dismissing her case on the pleadings without allowing discovery.⁸⁸

However, the court's decision in *Glennen* was premised on more than inadequate pleading. Instead, it illustrates a growing trend among courts that—to quote from *Glennen*—"medical device manufacturers are not responsible for the practice of medicine."⁸⁹ The court's decision reflects the concern that imposing upon a medical device manufacturer a duty to train physicians in the use of its products—above and beyond what is required by FDA—not only restricts physicians in their ability to practice medicine, but also forces manufacturers to practice medicine. As *Glennen* made clear, the entire point of FDA's regulatory scheme is to prevent that outcome. And with few cases specifically on point, *Glennen* is sure to pave the way for this emerging legal doctrine in which uniform federal laws will hold sway over conflicting state law claims.

⁸¹ *Id.* at *7.

⁸² No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ 583 F.Supp.2d 790 (W.D. La. 2008).

⁸⁶ *Id.* at 801-02.

⁸⁷ *Id.*

⁸⁸ See *Glennen*, 202 Cal. Rptr. 3d at 70-71 (dismissing the case on the pleadings); see also *Pointe San Diego Residential Community, L.P. v. Procopio, Cory, Hargreaves & Savitch, LLP*, 125 Cal. Rptr. 3d 540, 551 (Ct. App. 2011) (discussing California's "liberal pleading rules.").

⁸⁹ *Id.* at 83.

CONCLUSION

The California Court of Appeal decision is an important step toward a consistent application of the preemption doctrine in failure to train claims—an area with few appellate court opinions. In many ways, this was an easy case. Not only does the court’s decision reflect the general consensus refusing to recognize a duty to train, but the plaintiff did not have much of a case. Perhaps the analysis would have been different had the plaintiff alleged that Allergan failed to comply with FDA’s requirements, or that Allergan did not establish a physician training program, or even that the surgeon who implanted the Lap-Band had not completed the required training. Instead, the plaintiff’s claim was that something more was required. But the court left no doubt that it thought the training of physicians is best left only to a specific FDA requirement, and is not subject to the requirements of state law.

Niedner v. Ortho-McNeil Pharmaceutical, Inc.

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

Almost everyone under the age of fifty knows the song, knows the game. PBS debuted the American institution *Sesame Street* in 1969 to validate a brilliantly simple broadcast thesis: “if you can hold the attention of children, you can educate them.”¹ Almost fifty seasons later, the show continues to educate well more than a hundred million youngsters tuning in from more than 150 different countries.² Among *Sesame Street*’s most celebrated recurring segments is the “One of These Things is Not Like the Other” song. Sung to a simple but catchy, toe-tapping, head-bouncing melody, the tune teaches children the skill of analytical differentiation by challenging them to make a guess:

One of these things is not like the others,
One of these things just doesn’t belong,
Can you tell which thing is not like the others
By the time we finish our song?

The Appeals Court of Massachusetts was invited to engage in a legal analogue to this iconic children’s game in September 2016 as it was rendering its opinion in *Niedner v. Ortho-McNeil Pharmaceutical, Inc.*³ Its acuity in doing so made *Niedner* one of the top food and drug cases of 2016.

The state appeals court in *Niedner* considered how a pharmaceutical products liability plaintiff might carry her burden of proving that a medicine was defective in “design.” The plaintiff there had decided not to try to reformulate or reconfigure the medicine in any way or manner—what would have been a classical “re-design” proffer. Instead, the plaintiff in *Niedner* argued that the better, safer “design” for the medicine was to not sell it at all, but rather to compel the marketplace to search out an entirely different product to use as a substitute. It was a creative pitch. It caused the court to confront a challenging question: can a wholly distinctive product serve as a reasonable alternative design (a proof obligation design defect plaintiffs are ordinarily called upon to supply), or is such a submission one that “just doesn’t belong” in design defect theory? The Massachusetts court thoughtfully weighed the plaintiff’s novel contention, and then ruled against it. Plaintiff’s design defect claim was dismissed. By

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¹ MALCOLM GLADWELL, *THE TIPPING POINT: HOW LITTLE THINGS CAN MAKE A BIG DIFFERENCE* 100 (2000).

² See Press Release, Sesame Workshop, Big Bird, Elmo and Cookie Monster are Back as Sesame Street Debuts its 46th Season, Sat., Jan. 16, 2016 on HBO, at 3 (Nov. 24, 2015) http://www.sesameworkshop.org/season46/wp-content/pdfs/SS46_Press_Release_Final.pdf.

³ 58 N.E.2d 1080 (Mass. App. Ct. 2016).

foreclosing this most recent chapter in design-defect theory innovation, the *Niedner* court confirmed that defective design claims must remain moored to a core, foundational legal principle: substitute alternative product designs must be “re-designs” and not new products entirely.

DISCUSSION

Adrianna Duffy died in September 2009, about three months after filling a prescription from her physician for Ortho Evra, a contraceptive patch manufactured and sold by Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson, and Johnson & Johnson Pharmaceutical Research & Development, LLC (patch defendants). She had sought out the contraceptive patch as a “backup birth control method,” one that would be “easy and simple,” shortly after discontinuing her use of oral contraceptive pills.⁴ Transdermal patches function by supplying synthetic forms of estrogen and progestin through the skin; unlike oral birth control pills which must be taken daily, the patch is applied to the skin once per week for three weeks (with the last week off).⁵

Adrianna and her mother, Leslie Niedner, listened to Adrianna’s treating physician discuss with them the risks associated with all hormonal contraceptives, including the risk of developing blood clots.⁶ They also received from their pharmacy, at the time they filled Adrianna’s patch prescription, both a manufacturer-prepared package insert and a pharmacy-prepared leaflet, each highlighting the patch-associated risks of stroke, heart attack, and blood clots.⁷ The trial record established that both Adrianna and her mother read the package insert, which had advised that blood clot risks of the contraceptive patch may be increased over those same type of risks posed by birth control pills.⁸ It was later determined that Adrianna had died from a massive bilateral pulmonary embolus—a blood clot in her lungs.⁹ At the time of her death, Adrianna was a seventeen-year-old college freshman at Trinity College in Connecticut.¹⁰

About a year after Adrianna’s death, her mother (as administratrix of her daughter’s estate) filed a lawsuit against the patch defendants in Suffolk County, Massachusetts State court. Ms. Niedner charged, among other things, that her daughter’s patch was defective in its design, manufacture, and warning. Although Ms. Niedner acknowledged an awareness of the clotting risks associated with the patch, she contended that the patch’s comparative degree of risk had been conveyed inadequately.¹¹ Defendants moved for summary judgment. After testing each of Ms.

⁴ See *id.* at 1083.

⁵ See WebMD, *What Is the Ortho Evra Birth Control Patch?*, <http://www.webmd.com/sex/birth-control/ortho-evra-birth-control-patch>.

⁶ See *Niedner*, 58 N.E.2d at 1083.

⁷ See *id.*

⁸ See *Niedner v. Ortho-McNeil Pharma., Inc.*, 2015 WL 1054040, at *1 (Mass. Super. Ct. – Suffolk Cty. Feb. 3, 2015).

⁹ See *id.*

¹⁰ See Cary Shuman, *Friends, Family Honor the Life of Adrianna Duffy*, CHELSEA RECORD (Oct. 18, 2012), <http://www.chelsearecord.com/2012/10/18/friends-family-honor-the-life-of-adrianna-duffy/>.

¹¹ The U.S. Food and Drug Administration (FDA) has now approved a boxed warning for the Ortho Evra contraceptive patch in light of the results of several case-control studies showing that the relative “risk of venous thromboembolism among women aged 15-44 who used the Ortho Evra patch compared to women

Niedner's claims, the trial court found the lawsuit wanting, and entered judgment in defendants' favor. Ms. Niedner appealed, and a unanimous panel of the Massachusetts Appeals Court affirmed. Certainly a tragic tale of a life lost far too young, but the litigation and its progress seemed otherwise unremarkable.

Buried within the appeals court's decision, coming very near the end of the written opinion, is the portion of the *Niedner* case that qualifies it as one of the leading food and drug cases of 2016. In those closing paragraphs, the appeals court addressed the creative design-defect contention that Ms. Niedner had advanced.

As noted earlier, Ms. Niedner had filed her daughter's lawsuit in Massachusetts State court, and it seemed clear that Massachusetts substantive law would govern the case's claims. Massachusetts products liability law requires that design-defect claimants "prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm."¹² In other words, to assert a cognizable defective design claim under the Commonwealth of Massachusetts' substantive law, plaintiffs are obliged to offer a replacement, substitute design for the offending product that would be "technologically feasible," "practical," and effective in containing or abating the harm they claim to have suffered.

Proposing such a "technologically feasible and practical" re-design of a widely-marketed consumer product is often a formidable, expensive, and technologically daunting proposition. It forces a plaintiff to conjure up a better mousetrap than had the mousetrap-builder itself (with all its product-specific and market-specific knowledge, skill, and expertise). Truly, no small feat. And, quite understandably, Ms. Niedner did not fancy undertaking such an elaborate product reconfiguration effort. Instead, she proposed a shortcut route to the proof requirement Massachusetts law required of her: the "technologically feasible and practical alternative design" she offered as a substitute for the transdermal contraceptive patch her daughter used was an oral birth control pill.

In other words, Ms. Niedner posited that the feature that made the Ortho Evra patch's defective in design was that it was a patch and not a pill.

Ms. Niedner's creativity posed a perplexing analytical puzzle for the court. Could a design-defect plaintiff discharge her state law evidentiary obligation of showing a "technologically feasible and practical alternative design" by pointing to a different product entirely, and then claiming that the contested, injury-causing product was defective in design because it wasn't that other product?

The Massachusetts Appeal Court rejected Ms. Niedner's contention. The court crisply recounted Ms. Niedner's claim, namely, "that oral contraceptives, which are taken daily, are a feasible and safer alternative design to the patch, which is applied once per week for three weeks, with the fourth week being patch-free."¹³ But the two products, reasoned the court, were importantly distinctive: "While both products are hormonal contraceptives that prevent pregnancy, the difference in the drug delivery method, each of which has its own advantages and disadvantages, makes the pill

who used [certain] oral contraceptives . . . ranged from 1.2 to 2.2," and that "one of the studies found a statistically significant increased risk . . . for current users of Ortho Evra." FDA, *Ortho Evra (norelgestromin/ ethinyl estradiol) transdermal system* <https://www.fda.gov/safety/medwatch/safetyinformation/ucm211821.htm>.

¹² *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1014 (Mass. 2013) (QUOTING RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, comment f, at 24 (1998).

¹³ *Niedner*, 58 N.E.3d at 1087.

fundamentally different from the patch.”¹⁴ For this reason, because the two products were different, the court concluded: “one cannot serve as a safer alternative for the other.”¹⁵

IMPACT

Today, in many, and likely most, American jurisdictions, the reasonable-alternative-design (sometimes worded as “feasible”-alternative-design) requirement is an irreducible proof obligation in design defect product liability claims.¹⁶ The requirement was enshrined by the American Law Institute in its influential *Third Restatement of Torts: Products Liability*, published in 1998.¹⁷ As recast by one of the Nation’s most accomplished products liability scholars, this requirement compels a design defect litigant to come forward with “proof of some practicable, cost-effective, untaken design precaution” that would have saved the plaintiff from injury.¹⁸ Ordinarily, courts will not require the plaintiff to build an actual prototype of the proffered re-design,¹⁹ but plaintiff’s redesigning task is quite monumental nonetheless.²⁰

The dispositive analytical value of this reasonable-alternative-design (RAD) requirement is, however, easy to see. The requirement reliably positions the factfinder to perform, in some sensibly grounded manner, the risk/benefit calculus essential to a finding of strict products liability. At its core, design defect theory invites the factfinder to answer whether the product maker’s “failure to adopt a particular design feature proposed by the plaintiff was, on balance, right or wrong,” which, in turn, requires an examination of “what, in particular, allegedly was wrong with the manufacturer’s design decision.”²¹ When the design defect plaintiff is tasked to come forward with some substitute product design, the factfinder’s risk/benefit assessment

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ See DAVID G. OWEN, *PRODUCTS LIABILITY LAW* 505 (3d ed. 2015) (“Recognizing the central role of alternative design to design defectiveness, many jurisdictions, probably most, now require proof of a feasible design alternative in most design defect cases . . .”) (footnote omitted). See generally Aaron D. Twerski & James A. Henderson, Jr., *Manufacturers’ Liability for Defective Product Designs: The Triumph of Risk-Utility*, 74 *BROOK. L. REV.* 1061, 1079 (2009) (pronouncing the reasonable-alternative-design requirement “the Strong Majority Rule” in classic defective design cases).

¹⁷ See *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 2(b) (1998).

¹⁸ See OWEN, *supra* note 16, at 503.

¹⁹ See *id.* at 511-12. See generally *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 2(b) comment f (1998) (plaintiffs are not required “to produce a prototype in order to make out a prima facie case,” and “qualified expert testimony on the issue suffices, even though the expert has produced no prototype, if it reasonably supports the conclusion that a reasonable alternative design could have been practically adopted at the time of sale”).

²⁰ See Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 *CHI.-KENT L. REV.* 129, 148 (1996) (opining that RAD requirement “imposes an especially onerous burden on the plaintiff, a burden that she may often be unable to meet”).

²¹ *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 16 (S.C. 2010) (judicially adopting the RAD requirement for the State of South Carolina, quoting approvingly and relying upon David G. Owen, *Toward a Proper Test for Design Defectiveness: “Micro-Balancing” Costs and Benefits*, 75 *TEX. L. REV.* 1661, 1687 (1997)).

chore is readily performed—the factfinder will simply compare the manufacturer’s incumbent design (the one alleged to have injured the plaintiff) with the alternative design plaintiff has proposed, and then ask “whether the increased costs (lost dollars, lost utility, and lost safety) of altering the design—in the particular manner the plaintiff claims was reasonably necessary to the product’s safety—would have been worth the resulting safety benefits.”²² Without a proposed plaintiff alternative for comparison, the risk/benefit inspection is left unanchored, adrift in an unpredictable sea of undirected factfinder discretion. “[O]ne simply cannot talk meaningfully about a risk-benefit defect in a product design until and unless one has identified some design alternative (including any design omission) that can serve as the basis for a risk-benefit analysis.”²³

Thus, the RAD requirement represents a pivotal building block for design defect product claims in most jurisdictions, Massachusetts included. Ms. Niedner was accordingly obliged to meet that proof obligation in order to press a viable design defect claim.²⁴ Her proposed redesign for the Ortho Evra patch invited the factfinder to render a risk/benefit assessment by comparing the weekly-applied Ortho Evra patch to a daily, orally ingested birth control pill. With a dismissive brush-aside, the Massachusetts appeals court forbade such a comparison since the exercise would have compared two “fundamentally different” products. The court’s decision aligned with earlier, though still recent, Massachusetts precedent exploring a similar argument, albeit outside the drug and device environment. In 2013, the Supreme Judicial Court of Massachusetts had pronounced that, “in a case where the allegedly defective product is a cigarette, the reasonable alternative design must also be a cigarette.”²⁵

The intriguing question of whether different products can qualify as reasonable alternative designs for one another has visited the Nation’s courts before. Indeed, just a month before the *Niedner* decision was released, the Alabama Supreme Court weighed whether a dual-sensor smoke alarm (incorporating both ionization and photoelectric technology) could constitute a reasonable alternative design for a less expensive ionization-only smoke alarm. The court ruled that it could not: the proffer the Alabama plaintiff had made was “not, in fact, a safer, practical, alternative design to an ionization smoke alarm; rather, it [was] a design for a different product altogether.”²⁶ The court reached this result notwithstanding the plaintiff’s plea that the fundamental objective of *all* smoke alarms was the same—to detect smoke and alert occupants of the need to evacuate—and, thus, a superior smoke alarm design (regardless of its technology) ought to be an eligible RAD for any less-effective smoke alarm.²⁷ This logic did not persuade the Alabama court, however. In that case, the Alabama plaintiffs had been awakened by their ionization-only smoke alarm, and two adults and an infant child had successfully fled to safety; tragically, a second child, a

²² *Id.*

²³ Gary T. Schwartz, *Foreword: Understanding Products Liability*, 67 CAL. L. REV. 435, 468 (1979).

²⁴ See *Evans*, 990 N.E.2d at 1014 (“To establish a prima facie case of defect, the plaintiff must prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff’s harm.”) (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, comment f, at 24 (1998)).

²⁵ *Evans*, 990 N.E.2d at 1016.

²⁶ *Hosford v. BRK Brands, Inc.*, 2016 WL 4417256, at *6 (Ala. Aug. 19, 2016).

²⁷ *Id.* at *4.

toddler, had perished in the ensuing fire. The Alabama Supreme Court reasoned that had there been no market for less-expensive smoke alarm models, the plaintiff-family could well have lacked the means to have installed any smoke alarm whatsoever in their home, and that situation might have cost the lives of the remaining three family members.²⁸ To confirm the soundness of its rejection of the plaintiff-family's alternative design argument, the Alabama court cited from an earlier Texas Supreme Court decision that made the point with a flourish:

A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle. A convertible can be made safer by fully enclosing the cab, but then it is just an ordinary car. The law of products liability demands that manufacturers and distributors take feasible steps to make their products reasonably safe. It is not rational, however, to impose liability in such a way as to eliminate whole categories of useful products from the market.²⁹

Alabama was not alone. A quarter-century earlier, the U.S. Court of Appeals for the Eighth Circuit had reversed a jury's verdict in favor of the family of a state trooper who had died in the line of duty when an assailant's bullet penetrated through a gap in his protective vest.³⁰ The family offered, as a reasonable alternative design, a more expensive, wrap-around vest that would have offered their decedent more protective coverage. The court rejected that proffer, reasoning that the trooper's employer *could* have chosen to buy its officers vests with more protection, but had deliberately *elected* not to. Perhaps that purchase election was motivated by price; perhaps it was motivated by other functional trade-offs.³¹ In either event, the court ruled that vest manufacturers were "not obligated to market only one version of a product, that being the very safest design possible."³²

The *Niedner* case didn't involve cigarettes or smoke alarms or bullet-proof vests or motorcycles. Whether the "different-products" constraint on an eligible RAD applied in a food, drug, and device context remained an open question in Massachusetts. But not everywhere else. The "different-products" constraint had been litigated vigorously elsewhere in the drug and device context in the late 1990s and early 2000s in connection with pedicle screws. Back then, courts seemed to summarily reject the argument that, for example, a hook-and-wire anchor or other alternative surgical strategy could qualify as a RAD for pedicle screws.³³ Nationally, this view seemed to be shared broadly: "courts throughout the country have held that a party may not show

²⁸ See *id.* at *7.

²⁹ *Id.* at *6 (quoting *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995)).

³⁰ *Linegar v. Armour of Am., Inc.*, 909 F.2d 1150 (8th Cir. 1990).

³¹ *Id.* at 1154-55 (noting that the "best" coverage vest was also more confining, offering less flexibility, less mobility, worse heat dissipation, and worse sweat evaporation, all of which could prompt troopers to either "wear it at risk to their mobility or opt not to wear it at all").

³² *Id.* at 1154.

³³ See, e.g., *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (rejecting argument that other biomechanical stabilizing devices should be used instead of pedicle screws: "The problem with this argument is that it really takes issue with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek."). See also *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting argument that spinal fixation devices are defective because fusion procedures could be performed without them).

a reasonable alternative design by pointing to the availability of a different drug available for the same purpose.”³⁴

Although the practice fell into disuse for a time, the pitching of different products as drug or device RADs seems to have become resurgent of late. Over the course of the last decade, this type of argument has been pressed often across the Nation by design defect claimants, but rarely with much success.³⁵

Where such claims have found some resonance is when they posit different formulations or different constituent ingredients for a pharmaceutical. Since such “re-designs” fall far closer to the mark of a traditional RAD, courts have been more likely to find that such claims create triable issues of fact reserved for the province of the jury.³⁶ Of course, in those minority jurisdictions that have not adopted a mandatory RAD proof burden for some or all design defect claims, this different-product distinction has far less (if any) analytical relevance.³⁷

Which brings this discussion back to *Niedner*. The appellate court of Massachusetts was asked in *Niedner* to cast its lot afresh into this debate—could a viable design defect claim rest on a showing that some product design, entirely different from the one that allegedly caused injury to the claimant, was either available on the market or feasible to produce, and that such a product’s even theoretical existence was enough to establish defectiveness of the incumbent’s design? Or, conversely, was that other product one of those things that was “not like the other” and “just didn’t belong”? Massachusetts’ answer was concise and unequivocal: no. To qualify as an eligible RAD in Massachusetts, the court concluded, the substituted product had to be a true “re-design,” and not something else.

³⁴ Young v. Bristol-Myers Squibb Co., 2017 WL 706320, at *10 (N.D. Miss. Feb. 22, 2017).

³⁵ See, e.g., Mullins v. Johnson & Johnson, 2017 WL 711766, at *2-3 (S.D. W. Va. Feb. 23, 2017) (rejecting polypropylene sutures as RAD for TVT); Young v. Bristol-Myers Squibb Co., 2017 WL 706320, at *10-11 (N.D. Miss. Feb. 22, 2017) (rejecting “a different class of drugs” as a RAD for type-2 diabetes drug Farxiga); Brown v. Johnson & Johnson, 64 F. Supp. 3d 717, 722 (E.D. Pa. 2014) (rejecting acetaminophen as a RAD for ibuprofen, since each is “an entirely different product”); Massa v. Genentech Inc., 2012 WL 956192, at *7 (S.D. Tex. 2012) (rejecting alternative psoriasis treatments as a RAD for Raptiva because it was “not an argument that Raptiva should have been *safer* . . . [but was instead] an argument that Raptiva should have been *a different product*”); Brockert v. Wyeth Pharma., Inc., 287 S.W.3d 760, 771 (Tex. Ct. App. 2009) (rejecting argument that “Prempro should have been a different product: its predecessor Premarin”).

³⁶ See, e.g., Romero v. Wyeth LLC, 2012 WL 12547105, at *9 (E.D. Tex. May 30, 2012) (proposing a lowered dosage to replace Prempro “is sufficient to raise a fact issue”); Hines v. Wyeth, 2011 WL 1990496, at *8-9 (S.D. W. Va. May 23, 2011) (although RAD cannot be “an altogether essentially different product,” proposing to replace Prempro’s synthetic progesterin with non-synthetic oral micronized progesterone created “a question for the jury”); Torkie-Tork v. Wyeth, 739 F. Supp. 2d 895, 900-01 (E.D. Va. 2010) (proposing both to lower dose and to swap out synthetic progesterin to replace Prempro “presents a genuine issue of fact for trial”).

³⁷ Cf. Mullins v. Johnson & Johnson, 2017 WL 711766, at * (S.D. W. Va. Feb. 23, 2017) (proof of RAD not required under West Virginia law in negligence claim or malfunction theory claim); Newman v. Newman v. McNeil Consumer Healthcare, 2013 WL 7217197, at * (N.D. Ill. Mar. 29, 2013) (permitting plaintiffs to posit that acetaminophen is a safer alternative to ibuprofen products because it was not clear that Illinois would embrace the different-product RAD bar); Fraser v. Wyeth, Inc., 857 F. Supp. 2d 244, 256-57 (D. Conn. 2012) (denying summary judgment on “different-product” defense because local precedent “makes clear” that obliging design defect plaintiffs to propose a RAD “is not the case under Connecticut law”).

Ferring v. Burwell

MICHAEL H. HINCKLE* AND SNEHAL TRIVEDI**

WHY IT MADE THE LIST

*Ferring v. Burwell*¹ is notable because it is a rarity among Food and Drug cases. First, it is a case involving a challenge of the Food and Drug Administration’s (FDA) interpretation of the five-year exclusivity provision for New Drug Applications (NDAs) containing “new chemical entities.” Although court challenges involving the 180-day exclusivity for generic drugs have been fairly common over the years, cases involving five-year exclusivity come along less frequently. But, what really qualifies *Ferring* for the list is that it represents the rare instance where a District Court judge determined that, although FDA’s interpretation was permissible and reasonable, it nevertheless was “arbitrary and capricious” because it resulted in similar persons being treated differently depending on the timing of their applications. If the District Court’s decision is upheld by the Court of Appeals, it will likely be cited by numerous members of the FDA bar in future federal court pleadings and petitions before FDA.

DISCUSSION

Facts of the Case

Regulatory and Factual Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) amended the Federal Food, Drug, and Cosmetic Act (FDCA) creating a balance between expediting generic drug applications and protecting the interests of brand drug manufacturers.² The Hatch-Waxman Act created the modern “Abbreviated New Drug Application,” or ANDA for generic drugs. As part of the balance in exchange for the ANDA pathway, the Hatch-Waxman Act provided the brand drug industry with five years of market exclusivity against generic competition for NDAs that contain new active ingredients. Additionally, NDAs that are not eligible for the five years of exclusivity may be eligible for three years of exclusivity.³

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¹ *Ferring Pharm. Inc. v. Burwell*, No. 15-0802 (RC), 2016 WL 4734333, at *1 (D.D.C. Sept. 9, 2016).

² See the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (Sept. 24, 1984).

³ 21 U.S.C. § 355(j)(5)(F)(ii) (emphasis added); see also 21 U.S.C. § 355(c)(3)(E)(ii) (applicable to 505(b)(2) NDAs).

The five-year exclusivity provision states,

If an application submitted under [21 U.S.C. § 355(b)] for *a drug*, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application . . . [then] no application may be submitted under this subsection [i.e., an ANDA] . . . which *refers to the drug* for which the subsection (b) application was submitted before the expiration of five years from the date of approval . . .⁴

The abovementioned five-year exclusivity (NCE exclusivity or 5-year exclusivity) provision includes clauses describing how a drug may be eligible for the exclusivity (eligibility clause) and the parameters of exclusivity once it attaches (bar clause).⁵ Under the eligibility clause, a drug is eligible for exclusivity if it is “a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application.” The bar clause prevents the submission of an ANDA that references the “drug” that is the subject of the applicable NDA.⁶

Before FDA promulgated regulations for NCE exclusivity, it was unclear whether the word “drug” in both the eligibility and bar clauses referred to “drug product” or “drug substance.”⁷ FDA subsequently promulgated regulations stating that “drug” meant “drug product” in the eligibility clause and “active moiety” in the bar clause.⁸ FDA also interpreted the exclusivity as attaching to a “drug product” that contained “no active moiety that has been approved by FDA in any other application,” and barred the submission of any ANDAs containing the same active moiety as the drug product that received exclusivity. This interpretation of the bar clause is referred to as the “umbrella policy” because the exclusivity covers all of an exclusivity holder’s subsequently approved drug products that contain the same active moiety.

With regard to fixed-dose combination (FDC) products, i.e., drugs containing two or more active ingredients (and therefore active moieties) in a single dosage form, FDA’s policy meant that a FDC product was ineligible for five-year exclusivity if any one of its active moieties had been previously approved in another drug product.

Ferring Pharmaceuticals, Inc. (Ferring) is the manufacturer of the drug Prepopik[®], a FDC product intended for use in cleansing the colon in preparation for colonoscopy that contains three active ingredients, sodium picosulfate, magnesium oxide, anhydrous citric acid. While magnesium oxide and anhydrous citric acid had been previously approved, sodium picosulfate was a new active moiety. Despite FDA’s NCE exclusivity regulations, Ferring requested five-year market exclusivity because the combination product contained a new active moiety. In accordance with its

⁴ See 21 U.S.C. § 355(j)(5)(F)(ii) (for ANDA applications) and 21 U.S.C. § 355(c)(3)(E)(ii) (for 505(b)(2) applications) (emphasis added).

⁵ See Guidance for Industry: New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products, at *6 (October 2014).

⁶ For simplicity, this article refers to NCE exclusivity barring the submission of ANDAs. However, the exclusivity also bars the submission of certain 505(b)(2) NDAs.

⁷ A “drug substance” is defined in relevant part as an active ingredient that is intended to furnish the pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body. 21 C.F.R. § 314.3(b).

⁸ See 21 C.F.R. § 314.108. See also 21 C.F.R. § 314.3(b) (defining “active moiety” to mean “the molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance.”).

regulations and policy, FDA approved Prepopik on July 16, 2012 with three-year exclusivity instead of the requested NCE exclusivity.

Procedural History

On January 29, 2013, Ferring filed a Citizen Petition requesting FDA to alter its exclusivity determination for Prepopik, arguing that the statutory term “drug” in the eligibility clause referred to “drug substance” and not “drug product.” Under Ferring’s proposed interpretation, each drug substance in a FDC product would be independently evaluated under the eligibility clause. If any one of the drug substances met the criteria (i.e., not previously approved), the entire FDC product would receive NCE exclusivity.

On February 21, 2014, FDA issued a response to the Citizen Petition acknowledging that the statutory term “drug” was ambiguous and Ferring’s alternative interpretation as “drug substance” was reasonable. The agency also admitted that its then-existing interpretation of the NCE exclusivity provision could result in placing undue importance on the order in which applications were approved. Consequently, FDA issued a NCE Exclusivity Draft Guidance proposing to adopt an interpretation that would recognize NCE exclusivity for FDC products that contain a mixture of approved and unapproved active ingredients. However, FDA declined to retroactively apply the new policy to Prepopik.

On March 21, 2014, Ferring filed a Petition for Reconsideration and Petition for Stay, requesting FDA to review and reverse its February 21, 2014 determination that Prepopik was not eligible for the NCE exclusivity. Ferring also requested that FDA stay the application of its new interpretation in the Draft Guidance document until it resolved Ferring’s matters affecting Prepopik’s exclusivity.

In October 2014, FDA finalized its Draft Guidance, retaining the policy of granting NCE exclusivity to FDC products that contain at least one new active moiety, but continued to take the position that the new policy was not retroactive. Thus, despite acknowledging a revision of its current policy, FDA again declined to grant NCE exclusivity to Prepopik.

Ferring brought an action against FDA under the Administrative Procedure Act (APA) in the United States District Court for the District of Columbia challenging in part: (1) whether FDA’s prior interpretation of the statutory term “drug” in the eligibility clause should mean “drug product” or “drug substance”; (2) whether FDA’s umbrella policy resulted in disparate grant of NCE exclusivity based on the order in which NDAs were approved and was thus, arbitrary and capricious; and (3) whether FDA’s refusal to retroactively apply its new interpretation of its guidance document to Prepopik was arbitrary and capricious.

Both parties moved for summary judgment and the Court initially ruled in FDA’s favor on the statutory interpretation and “arbitrary and capricious” issues, but requested additional briefing on the retroactivity issue. Upon Ferring’s Motion for Reconsideration, the Court reversed its earlier ruling and found that FDA’s former interpretation was arbitrary and capricious. FDA has filed a Notice of Appeal with the U.S. Court of Appeals for the District of Columbia.

Rationale for Decision

In its initial summary judgment ruling, the District Court applied the familiar framework from *Chevron v. Natural Resources Defense Council, Inc.* and found that

the meaning of the word “drug” in the NCE exclusivity provision was ambiguous and could mean either “drug product” or “drug substance.” Not surprisingly, the Court then determined that both the former and current FDA interpretations of the statutory language were reasonable and therefore ruled in FDA’s favor on the statutory interpretation issue. The Court also held that FDA’s prior interpretation of the statute in combination with the umbrella policy was not arbitrary and capricious.

In its first Motion for Summary Judgment, Ferring argued that FDA’s prior interpretation of the exclusivity provision was arbitrary and capricious because, when combined with the umbrella policy, it created circumstances in which the eligibility for exclusivity turned arbitrarily on the order in which NDAs were approved. Ferring hypothesized that if a new drug substance was approved in a FDC product with a previously approved drug substance and then as a single-entity drug, neither the FDC nor the single-entity drug would be awarded NCE exclusivity. On the other hand, if the single entity was approved before the FDC, both products would be covered by NCE exclusivity under the umbrella policy. However, Ferring did not provide any specific examples of situations where the FDC was approved before the single entity. Rather, it only provided examples where single-entity drugs were approved first.

As a result, the Court found that Ferring’s examples were a “necessary outgrowth of [] FDA’s umbrella policy.”⁹ The Court determined that because the Hatch-Waxman Act encouraged brand manufacturers to make improvements in their drug products, the umbrella policy protected later drug products, which incorporated the novel active ingredient with other previously approved ingredients. The Court further reasoned that the sequence of NDA approvals between the single-entity and FDC products was nevertheless inapplicable to Prepopik because Prepopik contained sodium picosulfate, a unique substance that was incapable of conferring therapeutic benefit as a single-entity drug. Sodium picosulfate’s therapeutic effect could only be recognized in combination with other active ingredients. Therefore, because Prepopik’s two remaining ingredients, magnesium oxide and anhydrous citric acid, were approved, the Court determined that FDA’s grant of the five-year exclusivity towards the “most innovative drugs” was not arbitrary and capricious. However, the Court conceded that “[i]f there were, in fact, situations in which a drug was eligible for five-year exclusivity under FDA’s prevailing interpretation but failed to receive it because of the order in which it was approved, those circumstances might render the FDA’s policy arbitrary and capricious.”¹⁰ Ferring seized the opportunity afforded by the Court’s comment.

In its Motion for Reconsideration, Ferring provided three examples demonstrating that FDA’s interpretation produced circumstances that failed to treat “similar cases in a similar manner” and therefore constituted “arbitrary and capricious action” under the APA. In one example, a FDC product containing four active ingredients was approved in August 2012. Two of the four active ingredients were never approved by FDA and thus, were novel ingredients. Subsequently, in September 2014, both novel ingredients were approved in single-entity drugs; however, because they had already been approved as part of the FDC product in August 2012, they did not receive NCE exclusivity.

The District Court ultimately acknowledged and concluded that FDA’s original interpretation of “drug” to mean “drug product” in the eligibility clause, in conjunction

⁹ Ferring v. Burwell, 2016 WL 4734333, at *8.

¹⁰ *Id.*

with the umbrella policy, created a circumstance where FDC products could only receive the NCE exclusivity if the constituent single-entity products were approved first. The policy therefore unreasonably led to the denial of NCE exclusivity based on the order of NDA submissions. Determining that the umbrella policy resulted in an arbitrary and capricious interpretation of the exclusivity provision and denial of NCE exclusivity for Prepopik, the Court remanded the case to FDA for further proceedings. Finally, because the Court determined that FDA's prevailing interpretation of the NCE exclusivity provision was arbitrary and capricious at the time it denied Ferring's request for exclusivity, it did not consider Ferring's arguments related to FDA's refusal to retroactively apply its new interpretation to Prepopik.

IMPACT OF THE DECISION

If the District Court's decision is upheld on appeal, *Ferring* will have a significant impact both in the short and long term. In the short term, several approved FDC products were denied NCE exclusivity under a statutory interpretation that the court has struck down. FDA will have to develop a policy to address those NDAs, as well as ANDAs that may be pending for generic versions of those drugs. In the long term, a Court of Appeals decision upholding *Ferring* would likely be cited by numerous members of the FDA bar in support of assertions that the agency has violated the APA by treating similarly situated parties differently. Such assertions are commonly made in Citizen Petitions and other administrative submissions, but seldom dispositive. In a post-*Ferring* world, FDA may be compelled to take those types of assertions more seriously.

Philip Morris USA Inc. v. FDA

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WHY IT MADE THE LIST

*Philip Morris v. FDA*¹ represents the latest in a string of (generally successful) 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). The challenge yielded an order halting the agency's plans to require premarket authorization for changes to the label of a tobacco product. The U.S. District Court for the District of Columbia's decision avoided the First Amendment questions implicated by the now-vacated label policy. However, the court's interpretation of the operative statutory language raised new questions about FDA's administration of its authorities for premarket review of "new tobacco products."

DISCUSSION

Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the TCA, a "new tobacco product" must undergo premarket (or, in some cases, retroactive) review by FDA. The law defines a "new tobacco product" as "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007," as well as "any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." 21 U.S.C. § 387j(a)(1).

The law created three premarket review pathways, including the so-called "substantial equivalence" (SE) process. To obtain a marketing authorization via the SE pathway, a sponsor must demonstrate that a new tobacco product is "substantially equivalent" to an appropriate "predicate" product (i.e., a grandfathered product that does not qualify as a "new tobacco product" or a product that has previously been

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¹ No. 15-cv-1590 (D.D.C. Aug. 16, 2016).

found to be substantially equivalent to a grandfathered product).² Section 910(a)(3)(A) of the FDCA provides that a new tobacco product is substantially equivalent to a predicate if it “has the same characteristics as the predicate tobacco product” or “has different characteristics and the information submitted contains information . . . that demonstrates that . . . the product does not raise different questions of public health.” 21 U.S.C. § 387j(a)(3)(A).

FDA’s Substantial Equivalence Guidance

In September 2011, FDA issued a “Draft Guidance for Industry and FDA Staff: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions” (Draft Guidance). In the Draft Guidance, FDA stated that “[a] change to any part of a tobacco product after February 15, 2007[,] makes that product a ‘new tobacco product’” and “[t]he label and packaging of a tobacco product is considered a ‘part’ of that product.” The Draft Guidance indicated that FDA would exercise discretion not to enforce the premarket review requirements for certain categories of label and packaging changes made to grandfathered products (e.g., label changes necessary to comply with new requirements under the TCA, changing a cigarette product’s package from a hard pack to a soft pack or vice versa). Several industry members submitted comments to the Draft Guidance’s docket taking issue with the position that a change to a product’s label or packaging creates a new tobacco product as contrary to the language of the FDCA.

Three and a half years after issuing the Draft Guidance, FDA issued a new version entitled, “Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions” (First SE Guidance) (March 4, 2015). The First SE Guidance departed from the Draft Guidance in two significant ways.

First, while the Draft Guidance stated that the label was part of the tobacco product, the First SE Guidance concluded that it was not. However, the latter stated that, “if a product’s label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, the modified product is a new product . . . because that product was not commercially marketed in the United States as of February 15, 2007.” With respect to the “distinctness” analysis, the First SE Guidance stated that “[w]hether a product with a label change results in a distinct product depends on the circumstances.” It provided examples of modifications that might result in a distinct new tobacco product, such as “changes to logo, identifiable patterns of color, product descriptors, or any combination thereof” that “would lead consumers to believe that the product is different from the predicate.”

Thus, the First SE Guidance advised industry to evaluate whether consumers would perceive a product with a modified label as distinct from its predicate, and provided a chart with examples of changes that “may” or “may not” render a predicate product with a modified label “distinct” and therefore a “new tobacco product.” For example, the chart indicated that changing the label’s background color from green to red “might” make a product distinct, but changing it from white to cream “might not.” Likewise, the chart indicated that changing the object depicted in a logo (e.g., a star to a lion) “may” make the product distinct, but reducing the size of the same object on the new label “may not.”

² A “grandfathered” product is one that was commercially marketed in the United States as of February 15, 2007. *See* 21 U.S.C. § 387j(a)(1).

Under the First SE Guidance, a “distinct” label change would transform a predicate product into a new tobacco product requiring premarket review. As ostensible consolation, the First SE Guidance announced a policy permitting submission of a streamlined “Same Characteristics SE Report” to facilitate label changes that would render a product “distinct.” The Same Characteristics SE Report would include full identification information for both the new and predicate products, a statement regarding the manufacturer’s intent to commercially market both the new and predicate products (or only the new product) after receiving an SE order, a health information summary, an environmental assessment, and a specified certification statement confirming that the only modification involved a change to the label and describing that change. The Same Characteristics SE Report would need to include neither detailed information about the (shared) physical characteristics of the new or predicate products nor copies of either product’s label.

Second, the First SE Guidance expressly addressed product quantity changes. The guidance stated that a change in the per-package quantity of a predicate product qualified as a modification that would create a new tobacco product. As it did for label changes with the Same Characteristics SE Report, the First SE Guidance offered ostensible consolation in announcing a streamlined “Product Quantity Change SE Report” option. A sponsor could submit a Product Quantity Change SE Report when the “product quantity has changed, but the per weight composition, design features, heating source, and all other features are otherwise identical to the predicate product.”³ The prescribed contents of a Product Quantity Change SE Report mirrored those of the Same Characteristics SE Report, except that the former also would have to include “[s]cientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product as compared to the predicate product.”

Approximately one month after issuance of the First SE Guidance, Philip Morris USA Inc., R.J. Reynolds Tobacco Co., U.S. Smokeless Tobacco Co. LLC and others filed suit in the United States District Court for the District of Columbia challenging the First SE Guidance, specifically its positions that label changes and per-package product quantity changes trigger premarket review requirements, on statutory and constitutional grounds. Shortly thereafter, in response to FDA’s announcement that it would not enforce the First SE Guidance until it either had issued a revised guidance or announced that it would not make revisions, the companies agreed to a voluntarily dismissal without prejudice.

On September 8, 2015, FDA issued a revised “Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)” (Second SE Guidance), in which the agency doubled-down on its assertions that product quantity changes and product label changes that render a product “distinct” require premarket authorization. FDA included additional discussions of its rationales for these positions and left in place the policies permitting submission of Same Characteristics and Product Quantity Change SE Reports.

³ For example, the First SE Guidance offered that a sponsor could submit a Product Quantity Change SE Report to obtain authorization to increase the number of cigarettes in a predicate product’s package from 20 to 24 or to decrease the quantity of smokeless tobacco in a predicate product’s package from 24 grams to 5 grams.

The Second SE Guidance provided further explanation of FDA’s legal rationale for asserting that certain label changes may render a product “a new tobacco product” subject to the premarket review provisions of the FDCA. It first described Section 910(a)(3)(A) of the FDCA, which provides that a new tobacco product is substantially equivalent to a predicate if it “has the same characteristics as the predicate tobacco product” or “has different characteristics and the information submitted contains information . . . that demonstrates that . . . the product does not raise different questions of public health.” It then observed that the FDCA defines “characteristics” in terms of the physical attributes of a product, i.e., “the materials, ingredients, design, composition, heating source, or other features of a tobacco product.” Accordingly, the Second SE Guidance explained, the “same characteristics” prong of the substantially equivalent standard (in contrast to the second “different characteristics” prong) relates to a product that is physically identical to the cited predicate product. In FDA’s view, that the statute permits a finding of substantial equivalence under the “same characteristics” prong meant Congress must have contemplated that there would be new tobacco products that are physically identical to predicate products. FDA reasoned that a product with a label distinct from the predicate product but with identical physical characteristics would fall into this category.

FDA’s position on product quantity changes remained unchanged in the Second SE Guidance, which reiterated the agency’s claimed need to fully evaluate such changes due to their potential to affect initiation and cessation of product use. The Second SE Guidance also claimed that “another important purpose of requiring these SE Reports is to help FDA keep abreast of products in the marketplace so that it can properly evaluate whether products are in compliance with the [FDCA].” Consistent with the terms of the “same characteristics” prong of the definition of “substantial equivalence” in Section 910, which requires no scientific showing on the part of the applicant, the Second SE Guidance contemplated no substantive review of the label changes triggering the submission of Same Characteristics SE Reports (or even submission of the labels in question). Therefore, FDA could cite “keep[ing] abreast of products in the marketplace” as the lone practical justification for requiring submission of such reports.

The Court’s Ruling

On September 30, 2015, three weeks after FDA issued the Second SE Guidance, the plaintiffs filed a new complaint in the U.S. District Court for the District of Columbia. The complaint alleged that the Second SE Guidance was inconsistent with the FDCA, violated the Administrative Procedure Act (APA), and infringed the First Amendment. The plaintiffs filed a motion for summary judgment, and FDA filed a competing motion to dismiss or, in the alternative, for summary judgment in its favor.

Ripeness

The court was able to reach the merits of the case because it rejected FDA’s (common) defense that the issues raised were not “ripe” for judicial resolution. FDA argued that, since the Second SE Guidance merely represented the agency’s “current thinking,” and since the agency had not yet attempted to enforce the challenged legal interpretations described in the guidance, the court should defer review. While acknowledging that “[n]on-legislative agency statements of the type at issue here generally do not qualify as [reviewable] final agency action,” the court rejected FDA’s

reasoning, finding the reviewability standard met because: (1) FDA had taken a “definitive legal position” regarding its statutory authority in the guidance (and admitted it had no plans to change it); (2) the challenge presented a purely legal question of statutory interpretation (i.e., the court would not have benefitted from additional factual development in the context of a specific enforcement action); and (3) the guidance imposed an immediate and significant practical burden on industry (e.g., by the terms of the guidance, failure to file a streamlined SE report for covered label and quantity changes by the compliance dates would expose products to enforcement action). That this burden involved commercial speech restrictions apparently also helped the plaintiffs’ case for reviewability.

Label Changes

The court agreed with the plaintiffs that, based on the text, context, and structure of the TCA, Congress did not intend for FDA to require premarket review of label changes under Section 910 of the FDCA, which governs review of “new tobacco products.” For example, the court found FDA’s interpretation of Section 910, which references only physical characteristics of tobacco products, to be inconsistent with other provisions that permit or require premarket review of label statements in certain situations, discussed below.

In evaluating the arguments, the court rejected FDA’s position that the fact that the definition of “substantially equivalent” applies to products with the “same characteristics” means that Congress envisioned premarket review of products with identical physical characteristics but different labels. The court instead interpreted the “same characteristics” prong of the definition of “substantially equivalent” as “seemingly . . . intended for physical changes that were more than ‘minor,’ [and thus not eligible for an SE exemption,] but yet not so significant so as to require a showing, through clinical data if demanded, that ‘the product does not raise different questions of public health.’”

The court based this reading, in part, on Congress’s intention that FDA implement the SE requirements consistent with FDA’s preexisting SE pathway for medical devices.⁴ In the medical device context, as in the tobacco product context, the FDCA creates two tiers of substantial equivalence review, one for products with the “same technological characteristics” and the other for products with “different technological characteristics.” The court observed that the term “different technological characteristics” was defined to mean “a *significant change* in the materials, design, energy source, or other features of the device from those of the predicate device.” The court found it “reasonable to conclude” that Congress intended for “different characteristics” as used in the TCA “likewise to mean a ‘significant’ change in characteristics.”

The court also noted that “Congress clearly delegated to the FDA the authority to regulate label changes in other Sections of the Act.” *See, e.g.*, Section 903(b) of the FDCA, 21 U.S.C. 387c(b) (permitting FDA to “by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate [the FDCA]”); Section 911 of the FDCA, 21 U.S.C. § 387k (requiring premarket FDA review of “modified risk” label claims). In contrast, Section 910 is silent regarding FDA’s ability to require review of labeling changes generally. The

⁴ *See* Section 510(k) of the FDCA, 21 U.S.C. § 360(k).

court explained, “It is simply too far-fetched to believe . . . that the same Congress that expressly made labeling changes trigger FDA review in some Sections of the TCA, at the same time intended to provide the same or similar authority through an unintuitive, creative reading of Section 910.”

Last, the court dismissed the agency’s argument that “same characteristics” in Section 910 means “identical characteristics” in light of the existence of the SE exemption provision in Section 905(j)(3), 21 U.S.C. § 387e(j)(3). Under this section, FDA may exempt a product from the need to make a full demonstration of substantial equivalence if the product is “modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive,” and FDA determines that:

(i) such modification would be a minor modification of a tobacco product that can be sold under [the TCA];

(ii) [an SE] report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the public health; and

(iii) an exemption is otherwise appropriate.

Here, Congress explicitly excluded from the need to show substantial equivalence certain new products that, although physically different from the predicate, do not raise sufficient health risks to warrant FDA review. The court therefore concluded that “Congress surely did not intend . . . for products with *identical* physical characteristics, and thus with previously known effects, to be subject to a more intensive substantial equivalency showing under the ‘same characteristics’ prong” than certain products with *different* physical characteristics that qualify for an SE exemption.

Having found that the position unlawfully conflicted with the TCA under step one of the familiar *Chevron* analysis, the court declined to address the plaintiffs’ APA and First Amendment arguments.

Quantity Changes

The court rejected the plaintiffs’ challenge to FDA’s interpretation that changes in product quantity trigger premarket review requirements. The court easily found that a change in the quantity of a product contained in a package qualifies as a modification to the content or design of the product by looking to the plain text of Section 910’s definition of “new tobacco product.” It stated, “Congress’ use of the word ‘any’ suggests that even the slightest change to the physical components of an existing tobacco product would create a new tobacco product.” In so doing, the court rejected the plaintiffs’ arguments, including their assertion that the definition’s reference to “any modification” applies only to the per-weight or per-portion characteristics of a product. The court also found FDA’s position that quantity changes can affect the initiation and cessation behaviors of youth supported by the overall purpose of the TCA.

Procedural Issues

Last, the court rejected the plaintiffs’ procedural APA objections to use of the guidance process over notice-and-comment rulemaking for announcing the Same Characteristics and Product Quantity Change SE Report pathways. The court reasoned that, in that FDA’s position on product quantity changes was consistent with the text and structure of the statute, the guidance was an “interpretive” rule that did not require such rulemaking.

The court also concluded that it could sever the guidance document's treatment of label changes versus quantity changes. It therefore vacated the guidance's treatment of label changes and affirmed its treatment of quantity changes.

IMPACT

Following the court's decision, in October 2016, FDA reposted the Second SE Guidance with a cover sheet disclaimer acknowledging the court's decision that "a modification to an existing [tobacco] product's label does not result in a 'new tobacco product'" and the fact that the court vacated the Second SE Guidance "insofar as it interprets a labeling change as creating a 'new tobacco product' under the [TCA]." In December 2016, FDA issued a third edition of the SE Guidance, which states that, in light of the court's decision, "manufacturers need not receive premarket authorization for existing products that are the subject of a label change only (e.g., a product that has a new name but is otherwise identical to the predicate)." The third edition continues to include the prior version's discussions regarding quantity changes and the streamlined Product Quantity SE Report option.

While clearly addressing label and product quantity changes, the *Philip Morris* decision's rationale raised—but did not answer—new questions about the "same characteristics" prong of Section 910's definition of "substantially equivalent." How will FDA determine when an SE report involves a product, as described by the court, with the "same characteristics" as the cited predicate product (i.e., differences that do not qualify as minor modifications to tobacco additives but that are not "significant" enough to qualify the products' characteristics as "different" and therefore trigger a showing that the new product does not raise "different questions of public health")? What review standard applies? What data must the sponsor submit?

In implementing the TCA thus far, it appears that FDA has taken the position that any physical difference between the compared products means the products have "different characteristics" requiring a showing that the new product does not raise different questions of public health. This decision appears to gut that approach and create a new category of non-significant physical changes for SE purposes: those that do not render the products' characteristics "different" and instead permit a finding that they remain the "same." Seemingly, in such cases, the statute does not permit substantive review at all (as with the now-moot Same Characteristics SE report for label changes). The impacts of this decision, therefore, could reach well beyond the issue of label changes and significantly alter (and expose to challenge) FDA's implementation of the SE pathway to date.

The opinion also contains language that potentially undermines FDA's longstanding interpretation that "*as of* February 15, 2007," in the statute's definition of "new tobacco product" means "*on* February 15, 2007," thereby meaning that products commercially marketed before—but not on—the date do not have grandfathered status under Section 910. In reciting the legal framework at issue in the case, the court stated, "Thus, Congress placed beyond the FDA's premarket approval authority any tobacco product that was commercially marketed *before* February 15, 2007" (emphasis added). While FDA would likely argue that this language qualifies as "*dicta*," a challenger to FDA's questionable position could certainly cite it as supportive.

Last, the opinion’s analysis and language arguably undermine FDA’s recent preamble statements that certain forms of packaging (e.g., cellophane used to wrap cigars, e-liquid vials) qualify as components or parts of tobacco products, the modification of which could trigger premarket review requirements. *See* 81 Fed. Reg. 28,974, 29,015-29,016 (May 10, 2016). The court stated, “Finally, it is important that none of the actual terms that Congress used to define the term ‘new tobacco product’—and thus to initiate substantial equivalence review—can be read to encompass anything other than the physical attributes of the product itself, as distinct from its label or the *package* in which it is contained” (emphasis added). It further added, “The term ‘modification’ is described parenthetically to ‘include[e] a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient.’ . . . Again, all of those terms refer only to the physical attributes of a tobacco product—not its labeling or *packaging*” (emphasis added).

It appears that FDA has in fact treated this language as non-binding “dicta.” In a January 2017 decision overturning an internally appealed “Not Substantially Equivalent” order, the Deputy Director of FDA’s Center for Tobacco Products wrote, “. . . [P]ackaging is a component or part where it is intended or reasonably expected to alter or affect the tobacco product’s performance, composition, constituents, or characteristics. . . . FDA refers to this subset of packaging as the ‘container closure system.’ As a result, where packaging is a component or part of a tobacco product, evaluation of changes to the packaging is within the scope of the SE review process.”⁵ This determination provides some clarity on the question of how the agency will approach packaging changes following the *Philip Morris* decision.

However, questions remain, including precisely which types of packaging FDA will consider “components” or “parts” under this standard. Note that FDA’s pre-*Philip Morris* preamble language included some examples but promised an opportunity for public comment and guidance or regulations on the subject. One also could reasonably question whether FDA’s approach will withstand a legal challenge under *Philip Morris*, especially FDA’s preamble assertion that packaging materials that are generally intended to prevent unintended changes to the characteristics of the tobacco product, but that can impact the moisture level or shelf life of the product, meet the definition of “component” or “part,” the modification of which triggers premarket review under Section 910.

⁵ Letter to Gerard J. Roerty, Jr., Swedish Match North America, Inc., re FDA Submission Tracking Number AP0000017 (Jan. 13, 2017), <https://www.fda.gov/downloads/TobaccoProductsLabeling/MarketingandAdvertising/UCM540974.pdf>.

Morales v. Kraft Foods Group

GIANNA ARNOLD* AND MEGAN JULIAN

WHY IT MADE THE LIST

United States District Judge John A. Ronstadt for the Central District of California denied a motion to stay a class action alleging violations of the Unfair Competition Law, False Advertising Laws, and California Consumers Legal Remedies Act against Kraft Foods Group, Inc. based on the term “natural cheese” on the packaging of its shredded cheddar cheese product, which allegedly contain artificial coloring.¹ Even though many other courts have issued stays pending completion of the U.S. Food and Drug Administration’s (FDA) rulemaking, this court distinguished the other cases as involving the question of whether FDA regulations were violated. Here, the court framed the question as not whether Kraft has violated FDA standards for what can be called natural, but rather, whether the “natural cheese” label is deceptive to the reasonable consumer.²

DISCUSSION

Facts of the Case

The plaintiffs in the class action contended that Kraft’s use of the term “natural cheese” to market and sell a product that contains artificial coloring is misleading. Causes of action advanced included:

1. false and misleading advertising in violation of Cal. Bus. & Prof. Code §§ 17200 et seq. (Unfair Competition Law (UCL));
2. false and misleading advertising in violation of Cal. Bus. & Prof. Code §§ 17500 et seq. (False Advertising Law (FAL)); and
3. violation of the Consumers Legal Remedies Act (CLRA), Cal. Civ. Code §§ 1750 et seq. SAC, Dkt. 40.

Plaintiffs further alleged that they were misled by the use of the term “natural cheese” in connection with their purchase of Kraft’s “Natural Cheese Fat Free Shredded Fat Free Cheddar Cheese” (the Product) and that they would not have made

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¹ Claudia Morales, et al. v. Kraft Foods Group, Inc., et al., No. 2:14-cv-04387.

² Also of interest is that while there is no private right of action for violations of the Federal Food, Drug, and Cosmetic Act (FDCA), California’s Sherman Food, Drug, and Cosmetic Act, which has adopted requirements similar, if not identical, to FDA regulations, gives consumers a private right of action. See Cal. Health & Safety Code § 109875 et seq.; see also Brazil v. Dole Food Co. Inc., No. 12-CV-01831-LHK, at *27 (N.D. Cal. Mar. 25, 2013). This may be one reason why California is such an attractive forum for food and beverage lawsuits.

such purchases had they known the Product contained artificial coloring. In addition, the action alleged the artificial coloring poses health concerns for certain consumers, as it could cause hyperactivity in children or allergic reactions.

Coloring is added to cheese to turn it from white to orange. Kraft argued that the label natural cheese, as commonly used in the relevant industry, indicates that the cheese is made directly from cow's milk. Thus, as used in the industry, the term "natural cheese" refers to cheese that is made directly from milk, while processed cheese is made using natural cheese plus other ingredients that are cooked together to change the textural and/or melting properties and increase shelf life. Kraft further argued that even if the standard industry definition is not used, the addition of coloring does not on its own prevent a cheese from being a "natural cheese," stating that coloring added to a product can be via an artificial ingredient or a natural ingredient. The coloring within the cheese in question is provided by titanium dioxide, a mineral, and annatto, a substance derived from a seed. Kraft argued that these coloring additives are also natural. Given that the cheese is a natural cheese as that term is defined in the industry, and given that the color additives are natural, Kraft argued that the natural labeling is not misleading.

Questions to Consider

This case illustrates the type of guidance needed for the definition of natural:

- What constitutes natural?
- Can a product be labeled natural, where the product includes color additives, and where the color additives themselves are within the "natural" definition? For example, if beet juice is used to color lemonade, is the product natural?
- Is there any way to separate "natural" and "natural cheese"?
- Do consumers understand a difference between a product labeled "natural" and a product labeled "natural cheese."

Agency Guidance

FDA has not yet developed a definition for use of the term "natural" or its derivatives. Indeed, FDA has noted: "[f]rom a food science perspective, it is difficult to define a food product that is 'natural' because the food has probably been processed and is no longer the product of the earth."³ A regulatory review of the use of the term "natural" on food product labels was announced on November 12 (80 FR 69905-01), and FDA requested public comment on the use of the term in food labeling. The agency received more than 7,000 comments by the May 10, 2016 deadline. These submissions included comments from the dairy industry noting that "natural cheese" is a term of art.

The US Department of Agriculture (USDA) has defined this term for use with meat and poultry labeling as: "[a] product containing no artificial ingredient or added color

³ U.S. FOOD AND DRUG ADMIN, What Is the Meaning of 'Natural' on the Label of Food? <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm>.

and is only minimally processed. Minimal processing means that the product was processed in a manner that does not fundamentally alter the product.”⁴

An analogous labeling problem, the legal definition of the term “organic,” was addressed with the Organic Foods Protection Act of 1990⁵ (OFPA). Under OFPA, the National Organic Standards Board (NOSB) was established and authorized “to assist in the development of standards for substances to be used in organic production.” It is interesting that this was tasked to the USDA given that the Food Safety and Inspection Service (FSIS) of the USDA is responsible for inspections and quality standards for meat and poultry consumables, whereas food safety and labeling requirements are regulated by the Federal Food, Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act.

The Stay

Kraft filed a motion to stay on December 18, 2015, pending a decision by FDA as to the definition of “natural” in food labeling. The court denied the motion without prejudice. Kraft then renewed this motion on October 27, 2016, in view of anticipated rulemaking by FDA. Again, the court denied the motion without prejudice.

Because FDA is considering the definition of “natural,” multiple courts⁶ have stayed cases in deference to FDA’s expertise and specialized knowledge to define this term as it applies to food. This approach adheres to the doctrine of primary jurisdiction, allowing the federal agency to regulate, and avoiding the potential for inconsistent labeling requirements in different parts of the country. However, the judge in the *Morales* case departed from this general trend, determining that the relevant question was whether “natural cheese” is deceptive to the reasonable consumer under the UCL, FAL, and CLRA. The court reasoned that FDA standards are not determinative of questions based on California law. The court therefore declined to stay the case under the doctrine of primary jurisdiction, stating that any FDA regulation on the term “natural” would not be determinative of whether consumers were misled by the term “natural cheese.”

CONCLUSION

Consumer surveys indicate that consumers express a preference for products labeled “natural.” However, federal agencies charged with regulating food labeling, such as FDA and USDA, have provided minimal guidance on what constitutes “natural.” Therefore, the increasing number of “all natural” cases over the past decade

⁴ U.S. DEP’T. OF AGRICULTURE, Meat and Poultry Labeling Terms, https://www.fsis.usda.gov/wps/portal/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labelingterms!/ut/p/a1/jZHfT4MwEMf_Fh94LC0yI803QmIEHWQhateXU7ZrISktaTsJ_vUyjSYzm-7u6e4-39wvzDDFTPO3VnLfGs3VIWbzV7Im82iZkrxcRnckK57X5UOakKv1MwGbP4AivlB_xhLynz6_oMG1XaUriVnPFYNaLQymEjzi2g1gHabCmB1yXIAfkeBbj1wD4L8LitegWi0x7YAfVDvUm73ydwvplIQ-2c_gFs-NpSDR5VsTV7D4vYILOfgMnzvUFnL_HtLBUpv78zSbRdbyYNrMgwiIN93ZKN9737jYgARmGIZTGSAXhlnQBOSVpjPOYHpO4757o-2MiqgyxehyuPgCERj8l/#14.

⁵ Title 21 of Food, Agriculture, Conservation, and Trade Act of 1990, codified at 7 U.S.C. Ch. 94, 7 U.S.C. § 6501 et seq.

⁶ This has included *inter alia*, the Ninth Circuit and district courts in California, Missouri, New Jersey, and New York.

is not surprising. We now face regulation by litigation; food labeling issues have been turned over to the courts given the regulatory system's silence.⁷ Defendants may respond to class action claims based on labeling, including the presence of artificial, synthetic, or genetically engineered ingredients, by requesting a stay under the doctrine of primary jurisdiction. However, the *Morales* case indicates that state courts may not always recognize the issues to be relevant to federal agency rulemaking. *Morales v. Kraft Foods Group* is currently set to go to trial this summer.

⁷ Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, Governance Studies at Brookings, June 2014.

Universal Health Services, Inc. v. Escobar

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

WHY IT MADE THE LIST

*Escobar*¹ made this year's list because it addressed the reach of one of the government's most powerful enforcement tools, the federal False Claims Act (FCA). The FCA imposes civil penalties and treble damages for knowingly presenting "false" claims for payment to federal government programs, including Medicare and Medicaid. Because the statute is not explicit about what constitutes a false claim, courts have long struggled to articulate the limits of liability under the FCA.

The Supreme Court granted certiorari in *Escobar* to resolve conflict in the lower courts about the implied false certification theory of FCA liability. According to that theory, a defendant violates the FCA if it submits a claim that implicitly certifies compliance with a statutory, regulatory, or contractual requirement that the defendant has failed to satisfy. In a unanimous decision, *Escobar* held that the implied false certification theory is a valid basis for FCA liability, at least in some circumstances, provided that the requirement at issue was material to the government's payment decision.

Escobar's approval of the implied false certification theory was a victory for whistleblowers and the Department of Justice but not a complete one. The Supreme Court cautioned that the materiality requirement must be applied rigorously by the lower courts and may bar FCA claims even at the pleading stage.

Already, courts are wrestling with how to apply the standards that *Escobar* announced. The decision is sure to have a profound impact on implied false certification cases in 2017 and beyond.

DISCUSSION

Background

Julio Escobar and Carmen Correa were the parents of Yarushka Rivera, a teenager who received mental health care from Arbor Counseling Services through the Massachusetts Medicaid program. *Escobar*, 136 S. Ct. at 1997. Arbor is owned and operated by a subsidiary of Universal Health Services. After five years of intermittent

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¹ Universal Health Services, Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016).

counseling, providers at Arbor diagnosed Rivera with bipolar disorder and prescribed medication for her treatment. She experienced an adverse reaction to the medication, suffered multiple seizures, and died. *Id.*

Soon after Rivera's death, her parents learned that many of Arbor's providers, including those who had diagnosed Rivera and prescribed her medication, were not licensed doctors and did not have the authority to counsel patients or write prescriptions. *Id.* They were also largely unsupervised despite state regulations detailing supervision requirements for unlicensed staff. *Id.* at 1198.

Rivera's parents filed a qui tam action against Universal Health Services based on an implied false certification theory. They alleged that Universal Health Services, acting through Arbor, submitted claims to Medicaid that were false because they included payment and provider codes that implicitly certified that Arbor's staff had qualifications they lacked. The complaint alleged that Medicaid would not have reimbursed the claims had it been aware that the providers were unlicensed, unqualified, and unsupervised staff members who were counseling patients and prescribing medication in violation of Medicaid regulations. *Id.* at 1997-98.

The district court dismissed the complaint. It construed First Circuit precedent as holding that a defendant can be liable under the FCA only for misrepresenting its compliance with an express condition of payment under the relevant government program. It held that Escobar failed to state a claim because the regulations that Arbor allegedly violated were conditions of participation in the state Medicaid program but not conditions of payment. *Id.*

The First Circuit reversed. It held that the submission of any claim implicitly certifies that the billing party complies with all relevant program requirements. It determined that a defendant can violate the FCA by falsely certifying compliance with a requirement that is not expressly designated as a condition of payment. Based on its interpretation of the state Medicaid regulations, the First Circuit held that compliance with the regulations was a condition of payment and could support the FCA claims alleged. *Id.*

The Circuit Split

Just months after the First Circuit issued its decision in *Escobar*, the Seventh Circuit issued a decision that flatly rejected the First Circuit's view. In *United States v. Sanford Brown Ltd.*, the Seventh Circuit held that the FCA "is simply not the proper mechanism" to enforce compliance with statutes, regulations, or contractual provisions that may apply to participation in an agency's programs because the agency itself is in the best position to assess and adjudicate compliance. 788 F.3d 696, 712 (7th Cir. 2015). The Seventh Circuit's opinion not only conflicted with the First Circuit's decision in *Escobar* but also the views expressed by most other circuit courts.

Among the circuits that recognized implied false certification, there was disagreement about the scope of liability. The Second and Sixth circuits imposed liability only if the government expressly conditioned payment on the defendant's compliance with the requirement at issue. *Escobar*, 136 S.Ct. at 1998. But like the First Circuit, the Fourth Circuit and the D.C. Circuit were willing to extend liability beyond expressly designated conditions of payment. *Id.*

The Supreme Court granted certiorari in *Escobar* to clarify both the viability and the scope of the implied false certification theory of FCA liability.

The Supreme Court's Opinion

The Supreme Court began by holding that, “at least in certain circumstances, the implied false certification theory can be a basis for liability” under the FCA. *Id.* at 1995. The Court reached its conclusion by determining that the FCA incorporates the common-law understanding of fraud, which encompasses misrepresentations by omissions and misleading half-truths. It explained that Arbor submitted claims that included codes corresponding with certain counseling services and job titles; those codes constituted specific representations that were misleading in context because they implied that the providers had qualifications they lacked. *Id.* at 1999-2000.

The Court declined to reach the broader question of whether every claim for payment implicitly represents compliance with legal requirements even absent a specific misrepresentation. It held that the implied false certification theory is viable “at least” in cases where two conditions are met: “[1] first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and [2] second, the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements make those representations misleading half-truths.” *Id.* at 2001.

The Court went on to hold that defendants can be liable under the FCA for failing to disclose their noncompliance with a legal requirement regardless of whether that requirement is an express condition of payment. But the FCA is not “an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Id.* (quotation and citation omitted). The essential question is whether compliance is material to the government’s decision to pay the claim. *Id.* at 2001-02.

The materiality requirement is “rigorous” and “demanding,” the Court explained. *Id.* at 2002-03. Whether compliance is an express condition of payment is relevant to materiality but not dispositive. The government’s payment practices are also relevant. If the defendant knows that the government “consistently refuses” to pay claims based on noncompliance with a particular requirement, that is evidence of materiality. *Id.* at 2003-04. Conversely, if the government pays a claim knowing that the billing party is not complying with a particular requirement, or routinely pays a type of claim knowing that particular requirements have not been met, that is “very strong evidence” against materiality. *Id.*

With this guidance, the Court vacated the First Circuit’s opinion and remanded it for further consideration consistent with its holdings.

IMPACT OF THE CASE

Escobar had an immediate impact in the lower courts. The decision ended debate about the viability of the implied false certification theory but sparked new debates that are likely to continue for years to come.

Courts are already struggling with whether the two conditions for liability articulated in *Escobar* are absolute and exclusive requirements for an implied false certification claim. Some courts have suggested that *Escobar* established a mandatory two-part test; the defendant must have (1) made a specific representation about the goods or services provided, and (2) failed to disclose noncompliance with material

requirements such that the representation was misleading.² Other courts have held that *Escobar*'s conditions are sufficient but not necessary to state a claim.³ Recognizing the difficulty of the issue, a federal district court in California has certified the question to the Ninth Circuit for interlocutory consideration. *See* *Rose v. Stephens Institute*, No. 16-8-167 (9th Cir. Nov. 7, 2016). On the other side of the country, a magistrate judge in New York has recommended certification of the question to the Second Circuit. *United States ex rel. Panarello v. Kaplan Early Learning Co.*, No. 11-cv-00353 (W.D.N.Y. Nov. 14, 2016). Meanwhile, litigants face considerable uncertainty in implied false certification cases that do not satisfy *Escobar*'s conditions.

Escobar has also created uncertainty about how courts should weigh the government's payment practices in the materiality analysis. Evidence that the government paid claims despite actual knowledge of the defendant's non-compliance has proven important in several appellate cases affirming summary judgment for defendants in implied false certification decisions since *Escobar*.⁴ For example, in *United States ex rel. McBride et al. v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017), the court affirmed summary judgment for defendants and explained that it could not "ignore what actually occurred" in that case, which was that the government had investigated the allegations against the defendant and continued to pay claims. *Id.* The court's analysis reflects that *Escobar* reinforced a strong defense based on government inaction in the face of actual knowledge of non-compliance.

That said, the First Circuit gave little attention to the government's payment practices when it considered *Escobar* on remand. The First Circuit focused instead on state regulations indicating that licensing and supervision requirements were conditions of payment. The court concluded that those regulations were "central[]" to the state's contractual relationships with providers. *United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 110 (1st Cir. Mass. 2016). Because it considered the regulations at issue essential to the regulatory framework, the court

² *See, e.g.*, *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) (affirming summary judgment for the defendant after concluding that neither of *Escobar*'s conditions were satisfied); *United States ex rel. Kelly v. Serco*, 846 F.3d 325 (9th Cir. 2016) (same); *United States ex rel. Tessler v. City of N.Y.*, 2016 U.S. Dist. LEXIS 174013, at *12 (S.D.N.Y. Dec. 16, 2016) (concluding that relators "must show" that the alleged false claim makes specific representations); *United States ex rel. Handal v. Cent. for Empl. Training*, 2016 U.S. Dist. LEXIS 105158, at *12 (E.D. Cal. Aug. 8, 2016) ("To establish implied false certification, a plaintiff must show [*Escobar*'s two conditions] . . ."); *United States ex rel. Doe v. Health First, Inc.*, 2016 U.S. Dist. LEXIS 95987, at *8 (M.D. Fla. July 22, 2016) ("[*Escobar*'s] two conditions must exist to impose liability . . ."); *United States ex rel. Creighton v. Beauty Basics Inc.*, No. 2:13-CV-1989-VEH, 2016 U.S. Dist. LEXIS 83573, at *9 (N.D. Ala. June 28, 2016) ("[T]he plaintiff must allege [*Escobar*'s two conditions].").

³ *See, e.g.*, *United States ex rel. Panarello v. Kaplan Early Learning Co.*, No. 11-cv-00353, 2016 U.S. Dist. LEXIS 158193, at *13 (W.D.N.Y. Nov. 14, 2016) ("The fact that *Escobar* clarified 'some' of the circumstances creating implied false certification liability suggests that compliance with the conditions it discussed is not necessarily a prerequisite to implied false certification liability in every case."); *Rose v. Stephens Institute*, 2016 U.S. Dist. LEXIS 128269, at *13 (N.D. Cal. Sept. 20, 2016) ("[Defendant] is incorrect as a matter of law that *Escobar* established a rigid 'two-part test' for falsity that applies to every single implied false certification claim."); *United States ex rel. Landis v. Tailwind Sports Corp.*, 2017 U.S. Dist. LEXIS 19623, at **36-37 (D.D.C. Feb. 3, 2017) (concluding that a request for payment can be the basis of an implied false certification claim even absent a specific misrepresentation).

⁴ *See also* *United States ex rel. Searle v. DRS C3 & Aviation Co.*, No. 15-2442 (4th Cir. Feb 23, 2017) (unpublished) (affirming summary judgment for defendants based in part on declarations from government officials that undercut allegations of materiality); *U.S. ex rel. Kelly v. Serco, Inc.*, 856 F.3d 325 (9th Cir. 2016) (affirming summary judgment for defendants based partly on evidence that the government knew of alleged violations and did not require the defendant to change its conduct).

held that the complaint alleged material misrepresentations. In so holding, the court gave little weight to the defendant’s argument that the misrepresentations could not have been material because the government continued to pay claims even after it became aware of non-compliance. In the First Circuit’s view, the allegations showed only that the government had notice of complaints against the defendant, not knowledge of actual non-compliance. *Id.* at 112.

The First Circuit’s decision on remand raises the question of how courts will evaluate implied false certification cases at the pleading stage. At a minimum, bare-bones allegations of materiality should not suffice. For example, in *United States ex rel. Dresser v. Qualium Corp.*, 2016 U.S. Dist. LEXIS 93248 (N.D. Cal. July 18, 2016), the court held that a complaint must not only allege that misrepresentations were material but also explain why. *Id.* at *20. That said, courts have accepted allegations of materiality based on a requirement’s centrality to the regulatory framework rather than the government’s actual payment practices. *See, e.g.*, *United States v. Planned Parenthood of the Heartland, Inc.*, 2016 U.S. Dist. LEXIS 181100, at *32 (S.D. Iowa, June 21, 2016) (citing *Escobar* and concluding that compliance with licensing and prescribing requirements was material largely because the requirements were at “the heart” of the prescription medication regulation).

Direct allegations that the government continued to pay claims after becoming aware of the defendant’s non-compliance may support dismissal at the pleading stage. For example, in *City of Chicago v. Purdue Pharma*, 2016 U.S. Dist. LEXIS 134752 (N.D. Ill. Sept. 29, 2016), the City of Chicago alleged that the pharmaceutical company defendants engaged in deceptive marketing practices that caused doctors to submit claims that were allegedly false because they represented that opioids were medically necessary to treat chronic pain. But the City further alleged that it “continues to pay the claims that would not be paid but for defendants’ illegal business practices.” *Id.* at *52. Citing *Escobar*, the court held that the City’s allegation of continued payment was inconsistent with its assertion that the alleged misrepresentations were material.

Like *Dresser* and *City of Chicago*, many of the complaints dismissed based on *Escobar* were filed before the Supreme Court issued its decision. It seems likely that whistleblowers will learn from post-*Escobar* dismissals and soon become adept at alleging materiality with *Escobar*’s standards in mind.

Not surprisingly, the government has resisted the suggestion that payment of a claim despite actual knowledge of non-compliance indicates that an alleged misrepresentation is immaterial. The Department of Justice and U.S. Attorneys offices have expressed their views in many post-*Escobar* briefs and statements of interest. In general, they have argued that *Escobar* did not establish a heightened materiality standard; instead, determining materiality requires a multi-factor analysis; and although payment practices may be considered in the analysis, a decision to pay claims even with actual knowledge of non-compliance should not always undermine a finding of materiality.⁵

⁵ *See, e.g.*, Br. for the U.S. as Amicus Curiae Supporting Appellant, *United States ex rel. Escobar v. Universal Health Servs.*, No. 14-1423 (1st Cir. Aug. 22, 2016); Br. for the U.S. as Amicus Curiae Supporting Appellant, *United States ex rel. Miller v. Weston Educational d/b/a Heritage College*, No. 14-1760 (8th Cir. Sept. 14, 2016); Statement of Interest, *United States ex rel. Zayas v. AstraZeneca Biopharm, Inc.*, No. 14-cv-1718 (E.D.N.Y. Aug. 8, 2016); Statement of Interest, *United States ex rel., Herman v. Coloplast Corp.*, No. 11-cv-12131 (D. Mass. Aug. 19, 2016).

As courts and litigants wrestle with *Escobar*'s materiality standard, the decision's emphasis on the government's payment practices is bound to shape discovery strategy in implied false certification cases. The government may find it difficult to avoid having its agents testify in FCA cases because those who handle claims for payment may be the most qualified to speak to the government's practices. For example, in *United States ex rel. Ribik v. HC ManorCare, Inc.*, No. 09-cv-13 (E.D. Va. Feb. 3, 2017) a district court denied the Department of Justice's motion to quash subpoenas to Medicare Administrative Contractors because the court concluded that the defendant had the right to "explore whether the four contractors actually processed claims in the manner asserted as correct by the plaintiff." *Id.*

Escobar's focus on actual payment practices could also subject drug and medical device manufacturers to more non-party subpoenas from those in their industries facing FCA claims based on implied false certification allegations. Defendants may increasingly take the position that they are entitled to obtain discovery from their competitors to establish that the government routinely pays claims despite non-compliance with particular requirements within their industries.

Another potentially significant question is what impact *Escobar* will have in cases involving allegations of off-label promotion. One such case is currently unfolding in a California federal court. *United States ex rel. Brown v. Celgene Corp.*,⁶ involves allegations that Celgene violated the FCA by causing pharmacies to submit claims for medication prescribed off-label. 2016 U.S. Dist. LEXIS 180628 (C.D. Cal. 2016). The implied false certification theory is that claims for off-label uses of the drugs at issue were false because they were allegedly not reimbursable under Medicare. *Id.* at 10.

Relying in part on *Escobar*, Celgene moved for summary judgment. It argued that *Escobar* precluded liability because the allegedly false claims did not include specific representations; they were simply claims presented for payment. Celgene also offered robust evidence that the government knowingly reimburses off-label prescriptions; knowingly reimbursed off-label prescriptions for the particular drugs at issue; and continued to reimburse claims for off-label uses of those drugs after the case was filed. *Id.* at **37-41.

The district court largely rejected Celgene's arguments based on *Escobar*. It concluded that *Escobar* did not foreclose the possibility that an implied false certification case could proceed absent specific representations. The court also concluded that even if the government reimbursed some claims knowing that they were for off-label uses, it did not necessarily pay particular claims at issue with actual knowledge as to those claims. *See id.* Celgene has since moved for reconsideration and certification of questions for interlocutory consideration; its motion was still pending when this article went to print.

Celgene is one of several post-*Escobar* cases worth watching for those in the drug and medical device industries. Because the Supreme Court's opinion raised as many questions as it answered, *Escobar* will have a significant impact on implied false certification cases in 2017 and beyond.

⁶ Sidley Austin is counsel to Celgene in this matter.

Significant Settlements 2016

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 2016. 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 that imposes liability on persons and companies who defraud governmental programs and contracts. Between fiscal years 2009 and 2016, DOJ has recovered \$19.3 billion in health care fraud claims. After a small dip in recoveries in fiscal year 2015, fiscal year 2016 False Claims Act recoveries bounced back to nearly \$5 billion, which was the third highest annual recovery in False Claims Act history.¹ For healthcare fraud claims, the largest recoveries (\$1.2 billion) came from the drug and medical device industry, as discussed further below.

The 2016 settlements also illustrate DOJ's commitment to holding individuals accountable for corporate wrongdoing in line with the DOJ's memorandum issued in September 2015. Commonly referred to as the "Yates memorandum," the memorandum reinforced DOJ's "commitment to use the False Claims Act and other civil remedies to deter and redress fraud by individuals as well as corporations."²

Although uncertainty exists regarding the DOJ's enforcement direction with the change in administration, some believe that DOJ enforcement efforts related to healthcare and the food and drug industry will not wane. Accordingly, the below settlements may provide useful insight into DOJ's enforcement priorities and related civil and criminal penalties. The settlements discussed are categorized by regulatory category: food, medical devices, drugs, and dietary supplements and listed in alphabetical order.

FOOD

Food safety was at the forefront of DOJ's settlements with food companies in 2016, which included the largest fine ever paid in a food safety case with an \$8 million

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¹ Press Release, DOJ, Justice Department Recovers Over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016).

² *Id.*

criminal fine plus a \$3.2 million asset forfeiture.³ As stated by the Department of Justice’s then Principal Deputy Assistant Attorney General Benjamin Mizer, “Our food safety work is fundamental to our consumer protection mission, because no product plays a more vital role in the lives of every single American . . . food safety is a priority for the Justice Department. Our role in protecting consumer safety is at its apex when consumers can least protect themselves.”⁴ As FDA continues to implement the Food Safety Modernization Act, DOJ’s focus on food safety is likely to continue.

In line with the 2015 Yates memorandum, the 2016 settlements also highlight DOJ’s intention to bring actions against both companies and individuals. For example, DOJ settled a criminal fraud action against two cheese companies and a cheese company executive.⁵ The cheese companies pled guilty to conspiring to introduce misbranded and adulterated cheese products into interstate commerce and the executive pled guilty as a “responsible corporate officer” to a count of aiding and abetting the introduction of adulterated and misbranded cheese products into interstate commerce.

This section highlights some of the key settlements from the food industry.

ConAgra Grocery Products LLC—Largest Fine for Food Safety Case⁶

In December 2016, ConAgra Grocery Products LLC, a subsidiary of ConAgra Foods Inc., pled guilty to a criminal misdemeanor charge alleging the shipment of contaminated peanut butter linked to a 2006-2007 nationwide outbreak of salmonella poisoning. ConAgra Grocery Products was sentenced to pay an \$8 million criminal fine and forfeit an additional \$3.2 million in assets, which is the largest fine ever paid in a food safety case.

As background, in February 2007, FDA and the Centers for Disease Control and Prevention (CDC) announced that an ongoing outbreak of salmonellosis cases could be traced to Peter Pan and private label peanut butter produced and shipped from ConAgra Grocery Products’ peanut butter plant. CDC identified more than 700 cases of salmonellosis with no deaths linked to the outbreak with illness onset dates beginning in August 2006.

ConAgra Grocery Products voluntarily terminated production at the plant and recalled all peanut butter manufactured there since January 2004. ConAgra Grocery Products admitted in the plea agreement that samples obtained after the recall showed that peanut butter made at its plant on nine different dates between August 2006 and January 2007 were contaminated with salmonella. Environmental testing conducted after the recall identified the same strain of salmonella in at least nine locations throughout the plant. ConAgra Grocery Products also admitted that it had previously

³ Press Release, DOJ, Conagra Subsidiary Sentenced in Connection with Outbreak of Salmonella Poisoning Related to Peanut Butter (Dec. 13, 2016).

⁴ Press Release, DOJ, Principal Deputy Assistant Attorney General Benjamin C. Mizer Delivers Remarks at the Consumer Federation of America’s 39th Annual National Food Policy Conference (Apr. 6, 2016).

⁵ Press Release, FDA, FDA resolves criminal and civil actions against cheese manufacturer (March 3, 2016).

⁶ Press Release, DOJ, Conagra Subsidiary Sentenced in Connection with Outbreak of Salmonella Poisoning Related to Peanut Butter (Dec. 13, 2016).

been aware of some risk of salmonella contamination having found salmonella in samples of finished peanut butter on two occasions in October 2004. The company also admitted that employees charged with analyzing finished product tests failed to detect salmonella in the peanut butter and that it was unaware that some of the employees did not know how to properly interpret the results. The company made efforts to address risks related to salmonella contamination, but did not fully correct the conditions until after the 2006-2007 outbreak. After the 2007 recall, the company stated that it believed that moisture entered the production process, which enabled the growth of salmonella present in the raw peanuts or peanut dust.

According to DOJ, ConAgra Grocery Products has since made “significant upgrades” to the plant to address the conditions identified as potential factors that could contribute to salmonella contamination and instituted new and enhanced safety protocols and procedures.

*Roos Foods*⁷

Roos Foods, Inc., a Delaware-based cheese manufacturer, was the subject of both criminal and civil actions brought by FDA and DOJ. In January 2016, Roos Foods and its two co-owners entered into a civil consent decree of permanent injunction prohibiting the company and the owners from producing and distributing food unless FDA confirms that their operations comply with the Federal Food, Drug, and Cosmetic Act (FDCA) and all applicable food safety regulations. In March 2016, a federal judge accepted Roos Foods’ guilty plea to one criminal misdemeanor count of violating the FDCA by introducing adulterated food into interstate commerce and sentenced the company to pay a \$100,000 fine.

As background, in February 2014, CDC reported eight people (five adults and three newborns) were infected with *Listeria monocytogenes* (*L. mono*) after having eaten soft or semi-soft cheeses. The *L. mono* was isolated from cheese manufactured by Roos Foods. FDA subsequently inspected Roos Foods’ facility and established that the products were adulterated. FDA found numerous failures to implement effective monitoring and sanitation controls in accordance with cGMPs, including (1) leaks in the manufacturing area resulting in water leaking into the cheese processing equipment and storage tanks, (2) standing water on the floor throughout the cheese curd processing room in proximity to the cheese vats and in the storage rooms, (3) rust flakes on the manufacturing equipment precluding effective cleaning and sanitizing, (4) deteriorated and uncleanable surfaces on walls, floors, and ceilings, (5) openings to milk storage tanks and transfer piping were not capped to prevent contaminants from entering or contaminating food contact surfaces, and (6) product residue on equipment that had been purportedly cleaned. FDA collected environmental samples and found *L. mono* on 12 surfaces in the facility. In response, in March 2014, FDA suspended Roos Foods’ food facility registration, which halted Roos Foods’ manufacture and distribution of food.

The consent order places rigorous requirements on Roos Foods should it wish to resume its food operations. These requirements include: (1) retaining an independent laboratory to regularly collect samples and analyze them for the presence of *Listeria*,

⁷ Press Release, FDA, FDA resolves criminal and civil actions against cheese manufacturer (March 3, 2016); Press Release, DOJ, Delaware Cheese Company Pleads Guilty to Food Adulteration Charge (March 3, 2016); Press Release, DOJ, Delaware Cheese Company Agrees to Plead Guilty to Food Adulteration Charge, Signs Consent Decree (Jan. 22, 2016).

(2) retain an independent sanitation expert to inspect the facility and determine whether the controls conform with the FDCA, (3) work with the sanitation expert and laboratory to develop a written *Listeria* monitoring program including employee training program and environmental monitoring and testing, (4) provide reports to FDA regarding actions taken to bring the operations into compliance with the FDCA, and (5) destroy all in-process and finished articles of food.

*Universal Cheese & Drying, Inc. and International Packing, LLC*⁸

In a fraud criminal action, in February 2016, Universal Cheese & Drying, Inc. and International Packing, LLC pled guilty to one count each of conspiring to introduce misbranded and adulterated cheese products into interstate commerce and to commit money laundering. The companies also agreed to forfeit \$500,000 each to the United States and were sentenced to 36 months' probation. A Castle Cheese Company executive also pled guilty as a responsible corporate officer to one misdemeanor count of aiding and abetting the introduction of adulterated and misbranded cheese products into interstate commerce in violation of the FDCA. The executive was sentenced to three years' probation, a \$5,000 fine, and 200 hours of community service.

In conjunction with FDA's Office of Criminal Investigations and the Internal Revenue Service's Criminal Investigation, DOJ initiated the criminal action against the two cheese companies and the company executive. Unlike the food safety actions, DOJ did not find that the adulterated products posed a threat to the health or safety of consumers. Instead, the action was based in fraud. According to the criminal information, the corporate defendants had packaged and sold cheese under different labels at the Castle Cheese facility in Pennsylvania, which was then distributed through retail, food service, and wholesale customers. The defendants were aware that their cheese products did not conform to FDA standards of identity for real parmesan and romano cheese, but represented to customers that the products contained 100 percent real parmesan and romano cheese. The defendants were also aware that the cheese products were misbranded because they bore labels that did not accurately reflect the products' ingredients. The defendants also likely knew that the cheese products were adulterated because certain ingredients had been substituted or omitted and other ingredients added. The defendants then used proceeds from the sale of the cheese products to continue manufacturing and packaging cheese.

Representative Civil Settlements

In 2016, FDA and DOJ entered into several consent orders related to food safety allegations. The consent decrees of permanent injunction prohibited the companies and, in some cases, certain company personnel, from manufacturing and/or distributing food products until it demonstrated that its facilities and processing equipment were suitable to prevent contamination. The consent orders largely required the company to retain an independent expert to develop a pathogen control program, retain an independent laboratory to conduct analyses of both the environment and food products, provide employee training on sanitary food handling techniques, and provide

⁸ Press Release, DOJ, Slippery Rock Cheese Companies Sentenced for Selling Adulterated Products (Jan. 20, 2017); Press Release, DOJ, Castle Cheese Company Executive Michelle Myrter Sentenced in Adulterated Cheese Case (Oct. 11, 2016); Press Release, DOJ, Court Accepts Pleas in Adulterated and Misbranded Cheese Cases (Feb. 26, 2016)

FDA with advance notice of its intention to resume operations. Below are examples of the consent orders:

*Henry's Farms*⁹

A Virginia soybean and sprouts company entered in a consent decree of permanent injunction for multiple violations of the FDCA. FDA in conjunction with the Virginia Department of Agriculture and Consumer Services and Virginia Rapid Response Team conducted multiple inspections and collected environmental, in-process, and finished sprout product samples. Several of the samples testing positive for *Listeria monocytogenes*. The inspections also showed unsanitary conditions, including a persistent rodent infestation and dirty food processing equipment. No illnesses had been reported in connection to Henry's Farm.

*Kwong Tung Foods, Inc.*¹⁰

A Minnesota sprout and noodle company, its president, and vice president entered into a consent decree of permanent injunction for significant and ongoing violations of the FDCA related to unsanitary conditions. FDA inspections revealed repeated unsanitary conditions including rodent excreta pellets, improper cleaning, mold-like substances on equipment, failure to prevent cross-contamination from allergens, and improper employee sanitation practices. Prior to entering the consent order, Kwong Tung Foods received a FDA warning letter and worked with both FDA and the Minnesota Department of Agriculture to address these issues, but still failed to take adequate corrective actions. No illnesses had been reported in connection with Kwong Tung Foods.

*Native American Enterprises, LLC*¹¹

A Kansas food manufacturer, its part-owner, and its product manager entered into a consent decree of permanent injunction for repeated and ongoing violations of the FDCA related to unsanitary conditions. FDA inspections of the company's food processing facility found continued unsanitary conditions, including unsanitary employee practices and persistent strains of *Listeria Monocytogenes*. Despite having received a FDA warning letter, the company did not adequately change its practices. No illnesses had been reported in connection with Native American Enterprises.

MEDICAL DEVICES

In 2016, DOJ continued its focus on combating health care fraud and protecting the health and safety of patients through civil and criminal actions against medical device companies and those companies' executives. Several of these medical device

⁹ Press Release, FDA, FDA and DOJ take action against Virginia soybean business for selling contaminated sprouts (March 3, 2016).

¹⁰ Press Release, FDA, Federal court orders Minnesota sprout and noodle company to cease operations due to unsanitary conditions (July 19, 2016); Press Release, DOJ, District Court Enters Permanent Injunction Against Minnesota Food Manufacturer and Company's Managers to Prevent Distribution of Adulterated Food Products (July 15, 2016).

¹¹ Press Release, FDA, FDA takes action against Kansas food manufacturer for repeated food safety violations (June 1, 2016).

settlements were a direct result of the DOJ's Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, an initiative announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The HEAT partnership relies heavily on the False Claims Act as “[o]ne of the most powerful tools in this effort.”¹²

Other settlements related to the manufacturing, sale, and marketing of adulterated or misbranded devices:

*Acclarent Inc.*¹³

Acclarent Inc., a medical device manufacturer and subsidiary of Johnson & Johnson, agreed to pay \$18 million to settle False Claims Act allegations that it caused health care providers to submit false claims to federal health care programs by marketing and distributing its sinus spacer product for use as a drug-delivery device without FDA approval or clearance of that use. In 2006, Acclarent had received FDA clearance to market its Relieva Stratus MicroFlow Spacer device (Stratus) to be used with saline only to maintain sinus openings following surgery. Acclarent allegedly intended for Stratus to be used as a drug-delivery device for prescription corticosteroids and specially designed the device for this use. According to DOJ, Acclarent marketed Stratus as a drug-delivery device even after FDA denied Acclarent's request to expand its approved uses and after Acclarent added a warning to its label regarding use of active drug substances in the Stratus. In 2013, Acclarent discontinued all sales of Stratus and withdrew all FDA marketing clearances for the device.

Acclarent's \$18 million settlement resolved a civil lawsuit filed under the whistleblower provision of the False Claims Act. Separately, Acclarent's former CEO and former Vice President of Sales were convicted in a jury trial of 10 misdemeanor counts of introducing adulterated and misbranded medical devices into interstate commerce.

*Biocompatibles Inc.*¹⁴

Biocompatibles Inc., a subsidiary of BTG plc, pled guilty to misbranding its embolic device LC Bead and agreed to pay more than \$36 million to resolve criminal liability and False Claims Act allegations. FDA had cleared LC Bead as an embolization device to be placed in blood vessels to block or reduce blood flow to certain types of tumors and arteriovenous malformations. FDA had never cleared or approved LC Bead as a drug-device combination product or for use as a drug-delivery device. In 2004, at FDA's request, Biocompatibles provided FDA with assurances that it would not use the LC Bead embolization clearance to market the device for drug delivery. However, according to the statement of offense, Biocompatibles began marketing LC Bead for drug delivery two years later through a distribution company. The distribution company told its sales representatives that the LC Bead was a drug-delivery device and trained its sales representatives to “aggressively penetrate the

¹² Press Release, DOJ, Johnson & Johnson Subsidiary Acclarent Inc. Pays Government \$18 Million to Settle False Claims Act Allegations (July 22, 2016).

¹³ *Id.*

¹⁴ Press Release, DOJ, Medical Device Maker Biocompatibles Pleads Guilty to Misbranding and Agrees to Pay \$36 Million to Resolve Criminal Liability and False Claims Act Allegations (Nov. 7, 2016).

chemoembolization market.” Sales representatives also told healthcare providers that the device increased the level of chemotherapy delivered to a liver tumor, resulting in better tumor response rates. In 2009, Biocompatibles had filed an application with FDA for approval of LC Bead as a drug-eluting bead combination product, but FDA rejected the application because clinical studies did not provide adequate evidence of therapeutic benefit. Biocompatibles’ distributor continued to advise healthcare providers that LC Bead provided “better” or “superior” therapy for certain types of cancer.

DOJ further alleged that Biocompatibles caused false claims to be submitted to government healthcare programs for procedures where the LC Bead was used a drug-delivery device for chemotherapy drugs. By marketing and selling the LC Bead as a new combination drug-device product that had not been cleared or approved by FDA, Biocompatibles was selling a product that was not covered by Medicare and other federal healthcare programs.

To resolve criminal liability allegations, Biocompatibles agreed to pay \$8.75 million in criminal fines and \$2.25 million in criminal forfeitures. To resolve civil allegations under the False Claims Act, Biocompatibles agreed to pay \$25 million.

*B. Braun Medical, Inc.*¹⁵

B. Braun Medical Inc., a drug and medical device company, agreed to pay \$4.8 million in criminal penalties and forfeiture and up to \$3 million in restitution to resolve criminal liability for selling contaminated pre-filled saline flush syringes. Although the B. Braun saline syringes bore B. Braun labels, they were manufactured by another company, AM2PAT, Inc. Prior to purchasing syringes from AM2PAT, B. Braun had been aware of AM2PAT manufacturing problems. Through separate audits, FDA and B. Braun found AM2PAT had problems complying with current good manufacturing practices. AM2PAT addressed the initial problems, but problems persisted. AM2PAT notified B. Braun that it planned to move to a new manufacturing facility and start sterilizing the B. Braun saline syringes through a new radiation sterilization process. B. Braun began selling the saline syringes made at the new facility and sterilized with the new method before its quality department approved the changes. B. Braun subsequently approved the changes without having seen the new facility or operation and even after receiving complaints about the syringes changing colors, learning that AM2PAT made additional changes to the radiation process. Within two months of selling the new syringes, B. Braun recalled all the syringes because the radiation sterilization process caused dangerous particles to develop in the saline in the syringes. AM2PAT subsequently told B. Braun that it had provided B. Braun incorrect information about the radiation sterilization process and that it had moved to the new facility without validating the equipment. Despite this new information, B. Braun resumed buying the saline syringes from AM2PAT without going to the new facility. Within a month, AM2PAT manufactured syringes contaminated with *Serratia marcescens* bacteria, resulting in infected patients in four states.

In addition to paying criminal penalties, B. Braun entered into a non-prosecution agreement with DOJ. Under the agreement, B. Braun agreed to (1) increase oversight of its product suppliers including conducting on-site audits, (2) be monitored by an

¹⁵ Press Release, DOJ, B. Braun Medical Inc. Agrees to Resolve Criminal Liability Relating to its Sales of Contaminated Syringes (May 18, 2016).

independent compliance auditor, and (3) review and certify the company's compliance efforts on an annual basis.

The settlement follows DOJ's earlier prosecution of AM2PAT, AM2PAT's quality control director, plant manager, and former president. The quality control director and plant manager both pled guilty to conspiracy to commit felony violations of the FDCA and were sentenced to 54 months in prison. AM2PAT's former president was indicated on similar charges, but fled the country and is on FDA's Office of Criminal Investigations' "Most Wanted" list.

*Olympus Corporation of the Americas*¹⁶

Olympus Corporation of the Americas, the United States' largest distributor of endoscopes and related equipment, and an Olympus subsidiary paid \$646 million in a global settlement, including \$267.3 million in federal recoveries under the False Claims Act, \$43.5 million in recoveries for state Medicaid programs, and \$335.2 million in criminal penalties. Olympus also entered into a three-year deferred prosecution agreement (DPA) that would allow Olympus to avoid conviction if it complies with the reform and compliance requirements in the agreement.

The settlement resolved allegations that Olympus won new business and rewarded sales between 2006 to 2011 by giving doctors and hospitals kickbacks in violation of the Anti-Kickback Statute (AKS), including consulting payments, foreign travel, meals, millions of dollars in grants, and free endoscopes.¹⁷ The kickbacks helped Olympus obtain more than \$600 million in sales and realize gross profits of more than \$230 million. The improper payments occurred while Olympus lacked compliance programs. Olympus's civil and criminal penalties resulted in the largest total amount paid in U.S. history for violations involving the AKS by a medical device company.

Under the DPA, Olympus was required to adopt compliance measures including developing compliance training, maintaining an effective compliance program, maintaining a confidential hotline and website for employees and customers to report wrongdoing, and adopting an executive financial recoupment program requiring executives who engage in misconduct or fail to promote compliance to forfeit up to three years of performance pay.

Olympus also executed a corporate integrity agreement (CIA) with the Department of Health and Human Services-Office of Inspector General. The CIA outlines the compliance program Olympus must maintain, including (1) compliance responsibilities for Olympus management and the board of directors, (2) health care compliance code of conduct, (3) training and education, (4) requirements for consulting arrangements, grants and charitable contributions, management of field assets and review of travel expenses, (5) risk assessment and mitigation process, and (6) review procedures for testing the compliance program.

*Pharmaceutical Innovations Inc.*¹⁸

Pharmaceutical Innovations Inc. pled guilty to two misdemeanor counts of introducing adulterated medical devices into interstate commerce and was ordered to

¹⁶ Press Release, DOJ, Medical Equipment Company Will Pay \$646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America (March 1, 2016).

¹⁷ See *id.*; see also Olympus Deferred Prosecution Agreement.

¹⁸ Press Release, DOJ, New Jersey Medical Device Manufacturer Admits Selling Contaminated Ultrasound Gel; Court Orders Permanent Injunction (July 6, 2016).

pay a \$50,000 criminal fine and \$50,000 criminal forfeiture (the approximate value of the adulterated gel). In a related civil settlement filed against Pharmaceutical Innovations and its then president, Pharmaceutical Innovations agreed to the forfeiture and destruction of particular gel products that tested “exceptionally high” for infectious bacteria and agreed to a consent decree of permanent injunction.¹⁹ The civil action alleged that the company was selling medical devices that had not been approved or cleared by FDA, was violating current good manufacturing practices, and failed to take required actions after receiving reports of serious injuries associated with its products.

The criminal and civil actions arose from the company’s distribution of ultrasound gel contaminated with bacteria. In February 2012, a hospital reported that 16 surgical patients were infected with *Pseudomonas aeruginosa*, which was confirmed through testing to be tied to a lot of Pharmaceutical Innovations ultrasound gel. A second lot shipped later in 2012 was found to be contaminated with *Pseudomonas aeruginosa* and *Klebsiella oxytoca*.

DRUGS

As in past years, the 2016 significant settlements related to drug products arose from False Claims Act claims and related state claims. The claims included reporting false and fraudulent pricing, anti-kickback related issues, and misleading effectiveness claims.

*Forest Laboratories and Forest Pharmaceuticals*²⁰

Forest Laboratories, LLC and its subsidiary Forest Pharmaceuticals paid \$38 million to resolve allegations that they violated the False Claims Act by paying kickbacks to induce physicians to prescribe three of its drugs between 2008 and 2011. The government alleged that the companies provided payments and meals to certain physicians in connection with speaker programs even when the programs were cancelled, when no licensed health care professionals attended the programs, when the same attendees had attended multiple programs over a short period of time, or when the meals associated with the programs exceed Forest’s internal cost limitations. Under the settlement, the federal government would receive \$35.5 million and state Medicaid programs would receive \$2.5 million.

*Genentech Inc. and OSI Pharmaceuticals LLC*²¹

Genentech Inc. and OSI Pharmaceuticals LLC paid \$67 million to resolve False Claims Act allegations that they made misleading statements between 2006 and 2011 about the effectiveness of the drug Tarceva to treat non-small cell lung cancer. The copromoters of Tarceva allegedly made misleading representations to healthcare providers where there was little evidence to show that Tarceva was effective to treat

¹⁹ The then president was subsequently dropped from the case and his son who became company president was added to the case.

²⁰ Press Release, DOJ, Forest Laboratories and Forest Pharmaceuticals to Pay \$38 million to Resolve Kickback Allegations Under the False Claims Act (Dec. 15, 2016).

²¹ Press Release, DOJ, Pharmaceutical Companies to Pay \$67 Million to Resolve False Claims Act Allegations Relating to Tarceva (June 6, 2016).

patients with non-small cell lung cancer unless they also had never smoked or had a mutation in their epidermal growth factor receptor. Under the settlement, the federal government would receive \$62.6 million and state Medicaid programs would receive \$4.4 million.

*Wyeth and Pfizer Inc.*²²

Wyeth and Pfizer Inc. paid \$784.6 million to resolve federal False Claims Act claims and state claims that Wyeth knowingly reported false and fraudulent prices on Protonix Oral and Protonix IV, two proton pump inhibitor (PPI) drugs used to treat acid reflux. According to the complaint, Wyeth bundled these two products and sold the bundle at significant discounts to hospitals nationwide. Wyeth used this arrangement to induce hospitals to buy the Protonix Oral product. By inducing hospitals to prescribe the Protonix Oral product, discharged patients would be more likely to stay on the Protonix Oral product instead of switching to another PPI and would pay nearly full price for the drug. According to the government, Wyeth failed to report these best prices to the government and pay the hundreds of millions of dollars in rebates that it owed to Medicaid between 2001 and 2006. Under the settlement, Wyeth paid \$413.25 to the federal government and \$371.35 to state Medicaid programs.

DIETARY SUPPLEMENTS

In November 2015, DOJ announced the end of a yearlong effort to focus civil and criminal enforcement resources on dietary supplements. According to DOJ, it pursued more than 100 makers and marketers of dietary supplements in a nationwide sweep, alleging that the companies sold supplements containing ingredients other than those listed on the product label or the sale of products that made health or disease treatment claims that were unsupported by adequate scientific evidence.

As highlighted below, DOJ continued to pursue companies and individuals for the sale of unlawful dietary supplements in 2016. These companies and individuals allegedly sold “dietary supplements” as treatments for serious diseases such as herpes, cancer, Alzheimer’s, and AIDS without obtaining FDA approval to distribute the products as drugs.

*Clifford Woods and Clifford Woods LLC*²³

Clifford Woods and his company, Clifford Woods LLC, entered into a consent decree of permanent injunction prohibiting them from selling products as cures for a variety of diseases. The consent order resolved a civil complaint that alleged that defendants sold and promoted dietary supplement products as treatments for cancer, type 2 diabetes, Alzheimer’s disease, HIV infection, and AIDS. The complaint also alleged that the defendants defrauded consumers by promoting products as treatments of these diseases despite credible scientific substantiation.

²² Press Release, DOJ, Wyeth and Pfizer Agree to Pay \$784.6 Million to Resolve Lawsuit Alleging That Wyeth Underpaid Drug Rebates to Medicaid (April 27, 2016).

²³ Press Release, DOJ, Residents of Three States Charged with Unlawful Sale of Dietary Supplements (July 12, 2016).

Woods also pled guilty to a criminal charge for distribution of an unapproved new drug, specifically the promotion and distribution of the product Taheebo Life Tea as a treatment for cancer.

*GNC*²⁴

On the heels of the USPlabs LLC (USP Labs) indictment in November 2015, GNC entered in a non-prosecution agreement resolving GNC’s liability for selling certain dietary supplements produced by USP Labs in 2013. An investigation conducted by FDA, the U.S. Attorney’s Office for the Northern District of Texas, and the Consumer Protection Branch of DOJ’s Civil Division demonstrated that GNC’s “practices related to ensuring the legality of products on its shelves were lacking.”²⁵

The non-prosecution agreement required GNC “to reform its practices related to potentially unlawful dietary ingredients and dietary supplements,” including “embark[ing] on a series of voluntary initiatives designed to improve the quality and purity of dietary supplements” to “prevent unlawful dietary supplements from reaching its shelves.”²⁶ These initiatives included:

- GNC will take immediate action to suspend the sale of products after learning of FDA issuing a public written notice indicating that a purported dietary supplement or an ingredient contained in a purported dietary supplement is not legal and/or not safe.
- GNC will establish a “restricted list” (containing ingredients that are not to be used in dietary supplements) and a “positive list” (containing ingredients that are approved for sale). Products containing novel ingredients that do not appear on either list will require further internal action and approval before being offered for sale.
- GNC will substantially revise its internal operating procedures for dealing with vendors whose products GNC sells, including more explicit vendor guarantees that products do not contain ingredients on the “restricted list” and that their products comply with federal law.
- GNC will voluntarily work to develop an industry-wide quality seal program. GNC retail salespeople will not receive bonus commission or “promotional money” to direct customers to products not carrying the seal.
- GNC will update its adverse event reporting policy to ensure that its employees understand the proper procedures if a customer complains of injuries associated with a dietary supplement bought at GNC.

GNC also agreed to pay \$2.25 million and cooperate in dietary supplement investigations conducted by the government.

*Guy Lyman and Flor Nutraceuticals LLC*²⁷

Guy Lyman and his company, Flor Nutraceuticals LLC, entered into a consent decree of permanent injunction to settle a civil action. The civil action alleged that Lyman and Flor Nutraceuticals sold liquid and tablet drug and dietary supplement products named Herpaflor to treat herpes since at least 2011, but the products were not

²⁴ Press Release, DOJ, GNC Enters Into Agreement with Department of Justice to Improve its Practices and Keep Potentially Illegal Dietary Supplements Out of the Marketplace (Dec. 7, 2016).

²⁵ Press Release, DOJ, GNC Enters Into Agreement with Department of Justice to Improve its Practices and Keep Potentially Illegal Dietary Supplements Out of the Marketplace (Dec. 7, 2016).

²⁶ *Id.*

²⁷ Press Release, DOJ, Residents of Three States Charged with Unlawful Sale of Dietary Supplements (July 12, 2016).

approved by FDA. Under the consent decree, Lyman and Flor Nutraceuticals were prohibited from selling Herpaflor as a treatment for herpes.

On the same day, DOJ also filed a criminal information charging Lyman with one misdemeanor count of introduction of an unapproved drug (Herpaflor) into interstate commerce in violation of the FDCA. Lyman subsequently pled guilty, was sentenced to a \$275 fine and assessment, and was prohibited from marketing or selling dietary supplements.

*James Hill*²⁸

James Hill entered into a consent decree of permanent injunction to resolve a civil complaint filed against him. The civil action alleged that Hill marketed the product, Viruxo Immune Support, as a “natural herpes medicine” dietary supplement that could stop herpes outbreaks. The complaint contended that Viruxo qualified as an unapproved and misbranded drug because of product claims that it could treat the herpes virus without approval from FDA that it was safe and effective for such use. The complaint also alleged that Hill defrauded consumers by promoting the product to treat a disease despite the absence of well-controlled clinical studies or other credible scientific substantiation. Hill had previously received a warning letter from FDA and the Federal Trade Commission advising him that his product was an unapproved drug and was misbranded. Under the consent decree, Hill was prohibited from distributing Viruxo as a treatment for herpes.

DOJ also filed a criminal information charging Hill with one misdemeanor count of distributing an unapproved new drug in violation of the FDCA. Hill subsequently pled guilty and was sentenced to one year probation.

CONCLUSION

As these settlements illustrate, FDA and DOJ largely kept in step with their historic roles in pursuing enforcement actions against the food and drug industry, particularly with use of the False Claims Act. DOJ further demonstrated its commitment to holding individuals accountable for corporate misconduct in line with the 2015 Yates memorandum. The change of administration has already brought a change in leadership at FDA and DOJ. Although DOJ has been active in the healthcare and food and drug spaces already this year, it will be interesting to see whether FDA and DOJ continue to maintain their historic enforcement priorities and whether next year’s Significant Settlements chapter reads significantly different from this one.

²⁸ *Id.*

Significant Agency Enforcement Actions 2016:

Tobacco Products Deeming Rule, Food Labeling and Safety Rules, and Homeopathic Drug Products Enforcement Statement

JONATHAN A. HAVENS*

2016 was a busy regulatory year for the U.S. Food and Drug Administration (FDA) and its sister agencies, the U.S. Department of Agriculture (USDA) and the Federal Trade Commission (FTC), perhaps the last such one in a while. On January 30, 2017, President Trump signed a “one in, two out” executive order that aims to reduce federal regulations and control regulatory costs.¹ Pursuant to this executive order, whenever an executive department or agency proposes a new regulation, it must identify at least two existing regulations to be repealed. It is not clear whether an executive department or agency proposing a new regulation has to identify two of its own rules to repeal or whether it could target another agency’s or department’s rules. Since President Trump issued the order, there has been a noticeable but expected decline in federal agency regulatory actions.

Last year saw significant regulatory and enforcement developments affecting, among others, the food, drug, and tobacco industries. What follows is a discussion of a select few of these developments, namely: (1) FDA issuing its final tobacco products deeming rule; (2) the agency issuing its final rule to revise the Nutrition Facts and Supplement Facts labels for packaged foods and dietary supplements, respectively, and USDA issuing its proposed rule to update the Nutrition Facts label for meat and poultry products; (3) the agency issuing several final rules related to the FDA Food Safety Modernization Act (FSMA), both to implement FSMA and to delay and clarify compliance dates for previously-issued FSMA rules; and (4) FTC issuing an enforcement policy statement on certain homeopathic drug products.

TOBACCO PRODUCTS DEEMING RULE

In arguably one of the biggest regulatory developments of last calendar year, on May 5, 2016, more than two years after FDA proposed a regulation to deem e-cigarettes, cigars, hookah tobacco, and pipe tobacco, among others, to be subject to the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA), the

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¹ Exec. Order No. 13,771, 82 Fed. Reg. 9,339 (Feb. 3, 2017).

agency issued its final Deeming Rule.² But the process to deem such products to be subject to FDA's authority under the Act, in fact, took much longer than that.

On June 22, 2009, President Obama signed the Tobacco Control Act³ into law. In the TCA, cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FDCA (21 U.S.C. §§ 387 through 387u). In order to regulate other kinds of tobacco products, however, the TCA required that the agency first issue a regulation deeming such products to be subject to FDA's tobacco product authorities.

The Deeming Rule requires that all "new tobacco products" (as that term is defined in section 910(a)(1) of the Act) obtain premarket authorization from the agency via one of three pathways: (1) substantial equivalence (SE); (2) exemption from SE; or (3) premarket tobacco product application (PMTA) approval. Unless a product was on the market as of the Rule's "grandfather date" (i.e., February 15, 2007), or unless a sponsor is able to demonstrate substantial equivalence to a grandfathered product (i.e., there are no new public health questions when comparing the applicant product with the predicate product), the sponsor would have to submit a PMTA. The significant takeaway from the Rule is that, because many of the newly deemed products came on the market after the grandfather date (e.g., e-cigarettes and vapor products), most, if not all will have to go through the most onerous PMTA pathway in order to stay on the market. The likely result is that there will be major industry consolidation because of the cost involved in preparing and submitting a PMTA, which many estimate to exceed \$1 million per application (i.e., per product).

In response to concerns that the Deeming Rule, as written, would eliminate a large portion of the e-cigarette and vapor products industry, Representatives Tom Cole (R-Okla.) and Sanford Bishop (D-Ga.) introduced in February 2017 H.R. 1136, the FDA Deeming Authority Clarification Act of 2017.⁴ If enacted, the bill would change the "grandfather date" for FDA's tobacco products deeming rule from February 15, 2007 to the deeming rule's effective date (i.e., Aug. 8, 2016). Cole and Bishop introduced a similar bill (H.R. 2058) by the same name in the last congress.⁵ Beyond the grandfather date change, H.R. 1136 would, among other things, impose advertising restrictions for vapor products and direct FDA to establish product standards for vapor product batteries. Given that most, if not all e-cigarette and vapor products came on the market after the current grandfather date of February 15, 2007, H.R. 1136 would have a profound impact on this still fledgling industry. While H.R. 2058 stalled in the last congress, H.R. 1136 could fare differently. On March 8, 2017, four major vaping advocacy organizations, the Consumer Advocates for Smoke-free Alternatives Association (CASAA), the American Vaping Association (AVA), the Vapor Technology Association (VTA), and the Smoke-Free Alternatives Trade Association (SFATA), sent a joint letter to House Speaker Paul Ryan (R-Wis.) and Minority

² 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).

³ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1783 (2009) (codified at 21 U.S.C. § 301 et seq.).

⁴ FDA Deeming Authority Clarification Act of 2017, H.R. 1136, 115th Cong. (2017).

⁵ FDA Deeming Authority Clarification Act of 2015, H.R. 2058, 114th Cong. (2015).

Leader Nancy Pelosi (D-Calif.) urging support for the bill.⁶ Although President Trump's stance on e-cigarettes and vapor products is not yet known, he has called for reform of FDA, which indicates he could be receptive to signing H.R. 1136 into law, assuming congressional approval.

With regard to cigars, Senator Bill Nelson (D-Fla.) reintroduced S. 294 on February 2, 2017 to exempt traditional large and premium cigars from FDA regulation.⁷ The text of the bill is the same as S. 441,⁸ which Nelson introduced in the 114th Congress, and H.R. 564,⁹ which was introduced in the House of Representatives in January 2017. The proposed legislation in the Senate and House of Representatives would define large and premium cigars as:

- any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and—
- has a 100 percent leaf tobacco binder and is hand rolled;
- has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or
- has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and
- is not a cigarette or little cigar.

Beyond S. 294, the cigar industry is hopeful that a lawsuit against FDA currently before the United States District Court for the District of Columbia will be successful in thwarting the agency's regulation of cigars.¹⁰ The Cigar Association of America (CAA), Cigar Rights of America (CRA), and the International Premium Cigar & Pipe Retailers Association (IPCPR) filed a motion for summary judgment in the organizations' joint lawsuit against FDA in February 2017. CAA, CRA, and IPCPR allege in their suit that FDA's Deeming Rule is: (1) arbitrary, capricious, an abuse of discretion, and not in accordance with law; (2) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and (3) violates the Regulatory Flexibility Act. Also in February 2017, Arizona, Louisiana, Michigan, and Texas filed an amicus curiae brief opposing the agency's regulation of premium cigars as part of CAA's, CRA's, and IPCPR's suit against the agency.¹¹ The states make two main points in their brief:

⁶ CASAA, AVA, VTA, and SFATA Letter to House Speaker Paul Ryan and Minority Leader Nancy Pelosi, Mar. 8, 2017, <http://casaa.org/wp-content/uploads/HR-1136-Letter-to-Speaker-Ryan-and-Leader-Pelosi-3-8-17.pdf>.

⁷ Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2017, S. 294, 115th Cong. (2017).

⁸ Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2015, S. 441, 114th Cong. (2015).

⁹ Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2017, H.R. 564, 115th Cong. (2017).

¹⁰ Cigar Assoc. of America et al. v. U.S. Food and Drug Admin. et al., 1:16-cv-1460 (D.D.C July 15, 2016).

¹¹ See *id.*, Brief of the States of Arizona, Louisiana, Michigan, and Texas as Amici Curiae in Support of Plaintiffs. (D.D.C. Feb. 21, 2017).

1. FDA failed to provide an adequate cost-benefit analysis determining that the benefits of deeming premium cigars to be regulated tobacco products outweigh the undeniably severe costs, particularly to thousands of small businesses.

2. FDA failed to adequately address the way in which deeming cigars will undermine the public health programs funded by state excise taxes on non-cigarette tobacco products.

The United States District Court for the District of Columbia has scheduled a July 28, 2017 hearing in the case.

NEW NUTRITION FACTS AND SUPPLEMENT FACTS LABELS

Starting in July 2018, consumers might notice some differences on their food and dietary supplement packages. On May 27, 2016, FDA finalized rules to revise the Nutrition Facts label for foods and Supplement Facts label for dietary supplements (NFSF Rules or the Rules).¹² While the Rules' changes are supposed to make it easier for consumers to make better informed food choices, beyond simple label formatting modifications, the Rules contain other changes that will present significant compliance challenges for industry.

Nutrition Facts Label—Packaged Foods

The formatting changes to the Nutrition Facts label include increasing the type size for “Calories,” “servings per container,” and the “Serving size” declaration, and **bolding** the number of calories and the “Serving size” declaration to highlight this information. Per the NFSF Rules, manufacturers must declare the actual amount, in addition to percent Daily Value (DV) of vitamin D, calcium, iron, and potassium, whereas declaration of other vitamins and minerals like Vitamins A and C will be voluntary. In order to give consumers a better idea of what percent DV means, the Nutrition Facts label footnote is also changing to: “*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.” FDA has provided a side-by-side comparison of the old and new versions of the label.¹³

The agency is also requiring a number of changes to the Nutrition Facts label based on what it describes as “updated information regarding nutrition science.”¹⁴ These changes represent the more controversial aspects of the rule, as they not only present the greatest compliance challenges but it is also unclear whether the agency has adequate justification to require that certain of these changes be implemented. The inclusion of “Added sugars” on the new label is perhaps the most notable change, along with FDA’s establishment of a Daily Reference Value (DRV) of the same. Manufacturers will now need to identify such sugars in grams and as a percent DV.

¹² Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Final Rules, 81 Fed. Reg. 33,742 (May 27, 2016).

¹³<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM501646.pdf>.

¹⁴ FDA, Changes to the Nutrition Facts Label <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm> (last updated Mar. 15, 2017).

In response to comments to the NFSF proposed rules, and perhaps in anticipation of a legal challenge from industry, FDA discussed in the preamble of the NFSF final rules its justification for compelling disclosure of added sugars and its ability to compel speech under the First Amendment.¹⁵ The agency noted that “[t]he disclosure of added sugars is factually accurate nutrition information and industry’s interest in not disclosing such factual information is minimal” and that the required declaration “readily satisfies the *Zauderer [v. Office of Disciplinary Counsel of Supreme Court, 471 U.S. 626 (1985)]* test.”¹⁶ It remains to be seen whether or not the agency’s position on added sugars is defensible, but it is reasonable to expect a legal challenge to at least that portion of the rules.

With regard to serving sizes, the NFSF Rules have increased the number of “servings per container” and the “serving Size” declaration, and have made their type larger and/or bolder. The rule has also updated serving sizes to reflect what people actually eat and drink today (e.g., the serving size for ice cream was previously ½ cup and is now ¾ cup). The rule also contains new dual-column labeling requirements for packages that are between one and two servings or are larger than a single serving but could be consumed in one or multiple sittings.¹⁷

While the agency will continue to require declaration of “Total Fat,” “Saturated Fat,” and “Trans Fat” on the label, FDA is removing “Calories from Fat” because, according to the agency, research shows the *type* of fat is more important than the amount. One aspect of the Rules that will present a compliance challenge to industry is the updated DRVs and reference daily intakes (RDIs) for nutrients like sodium, dietary fiber and vitamin D, which FDA is updating based on newer scientific evidence.¹⁸ These changes will mean both recalculation of percentage DVs and also perhaps removal of certain nutrient content claims (e.g., if a product is no longer a “good source of fiber” in light of the updated DVs and/or serving sizes).

Speaking of fiber, the Rules contain a new definition of “dietary fiber” and recordkeeping requirements for foods that contain a mixture of dietary fiber and non-digestible carbohydrate(s) that do not meet the definition of dietary fiber. Packaged food companies will need to determine if the ingredients in their products can still be considered dietary fiber under the new definition.

¹⁵ 81 Fed. Reg. at 33,758.

¹⁶ *Id.*

¹⁷ See FDA, The New Nutrition Facts Label- Examples of Different Label Formats, <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labelling/Nutrition/UCM511964.pdf> (last visited Mar. 16, 2017).

¹⁸ Some of the rule’s updated DRVs and RDIs are as follows:

- Total Fat: 65 g to 78 g;
- Total Carbohydrate: 300 g to 275 g;
- Dietary Fiber: 25 g to 28 g;
- Sodium: 2,400 mg to 2,300 mg;
- Potassium: 3,500 mg to 4,700 mg;
- Calcium: 1,000 mg to 1,300 mg; and
- Vitamin D: 400 IUs (10 µg) to 20 µg.

Supplement Facts Label

While FDA's announcement and follow-on communications about the NFSF Rules focused almost exclusively on the changes to the Nutrition Facts label, the Rules also contain major changes to the Supplement Facts label, largely to make the Supplement Facts label consistent with the Nutrition Facts label. In addition to the changes made for label consistency, to enable manufacturers to know where to declare fluoride on the Supplement Facts label, FDA added it to the list of nutrients in 21 C.F.R. § 101.36(b)(2)(i)(B) such that, when it is declared, it should be placed below potassium on the label.

Effective and Compliance Dates

As is FDA's practice, the effective date and compliance dates of the NSFS Rules are staggered. The Rules became effective on July 26, 2016, but the new labels will not need to be implemented until the compliance date of July 26, 2018, or July 26, 2019 for companies with less than \$10 million in annual sales. In light of the staggered effective and compliance dates, many in industry wondered when the revised labels must appear on food and supplement packages. In its January 2017 Draft Guidance on the Rules,¹⁹ FDA stated that products labeled on or after the compliance dates must bear Nutrition Facts or Supplement Facts labels that comply with the new requirements. FDA will not consider the location of a food in the distribution chain when determining the compliance date for a particular food product (e.g., the product, whether labeled before or after the compliance date, may be at the manufacturing facility awaiting distribution, at a warehouse awaiting further distribution, in transit to the United States to be offered for import, or on the store shelf of a U.S. retail establishment). In other words, the agency will consider the date the food product was labeled for purposes of determining the compliance date. The position expressed in the Draft Guidance, when the document is finalized, will merely represent FDA's current thinking, and is not binding on the agency (i.e., it could change at any time).

Nutrition Facts Label—Meat and Poultry Products

In December 2016, USDA's Food Safety and Inspection Service (FSIS) issued a proposed rule to overhaul the Nutrition Facts label for meat and poultry products (Proposed Rule).²⁰ FSIS issued its proposal in part to parallel FDA's NFSF Rule. Like FDA's NFSF Rules, while the Proposed Rule's label changes are supposed to make it easier for consumers to make better informed food choices, it would, if finalized, pose significant compliance challenges for industry.

USDA's Proposed Rule would, among other things:

- revise the format of the Nutrition Facts label;
- update the list of nutrients that are required or permitted to be declared on the Nutrition Facts label;
- update certain DRVs and RDIs;

¹⁹ FDA, Draft Guidance, Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals, Jan. 2017, <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/UCM535372.pdf>.

²⁰ Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed; Proposed Rule, 82 Fed. Reg. 6,732 (Jan. 19, 2017).

- amend the labeling requirements for foods for children under the age of four years and pregnant women and lactating women;
- establish nutrient reference values for these populations;
- amend the definition of a single-serving container; and
- update and modify certain reference amounts customarily consumed (RACCs).

Consistent with FDA’s NFSF Rules, USDA is proposing to remove certain requirements from the Nutrition Facts label, such as “Calories from fat” while adding others, including required declarations of “Added sugars,” Vitamin D, and potassium, and voluntary declarations of Vitamins A and C. Also, like FDA, USDA is proposing to update the reference value for the declaration of percent DV for sodium from the current value of 2,400 mg to 2,300 mg, in light of current scientific evidence that supports limiting intake of sodium to less than 2,300 mg per day.

As with FDA’s final NFSF Rules, USDA’s Proposed Rule would pose significant compliance challenges. In addition to determining how much added sugars, Vitamin D, and potassium are present in their products, meat and poultry firms would also need to calculate the percentage DV based on the Proposed Rule’s updated DV values for certain nutrients. Beyond the percentage DV calculations, it is possible that meat and poultry marketers would need to remove nutrient content claims from their product labels or reformulate products in order to continue to make such claims. This results from the Proposed Rule’s changes in the RACC categories, changes in DV for certain vitamins and minerals, and modifications to the definition of dietary fiber.

Interestingly, and unlike FDA did in its NFSF Rules, USDA does not explain in its Proposed Rule why required declaration of “Added sugars” does not violate the First Amendment rights of covered firms. In contrast, and as discussed above, FDA discussed at length in the NFSF Rules why, in the agency’s opinion, FDA’s decision to compel food firms to disclose added sugars meets the three-part test set forth by the Supreme Court in *Zauderer*. Just as litigation is expected over FDA’s decision to compel declaration of “added sugars,” it is likely to expect that similar litigation would follow finalization of USDA’s Proposed Rule.

FSMA IMPLEMENTING RULES

Throughout 2016, FDA finalized multiple rules related to the FDA Food Safety Modernization Act (FSMA),²¹ described by the agency as the most sweeping reform of our nation’s food safety laws in more than 70 years.

Sanitary Transportation of Human and Animal Food

In April 2016, FDA finalize its rule on Sanitary Transportation of Human and Animal Food. The goal of this rule is to prevent practices during transportation that create food safety risks (e.g., failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food). The rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food related to sanitary practices to ensure the safety of such food. These requirements relate to vehicles and transportation

²¹ FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified at 21 U.S.C. § 301 et seq.).

equipment, transportation operations, records, training, and waivers. The rule's requirements do not, however, apply to transportation by ship or air.

*Mitigation Strategies to Protect Food Against
Intentional Adulteration*

In May 2016, the Agency finalized its rule on Mitigation Strategies to Protect Food Against Intentional Adulteration.²² The purpose of the rule is to protect food from intentional acts of adulteration where there is an intent to cause wide-scale harm to public health. This final rule established various food defense measures that an owner, operator, or agent in charge of a covered facility is required to implement to protect against such adulteration. The rule does not cover other types of intentional adulteration, such as acts by disgruntled employees, consumers, and competitors, and economically motivated adulteration, because such acts, in FDA's view, are unlikely to cause wide-scale public health harm.

Amendments to Registration of Food Facilities

In July 2016, FDA finalized its rule on Amendments to Registration of Food Facilities.²³ In this rule, FDA amended its regulations for registration of food facilities that require domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the agency. This rule added new provisions to the current regulations to codify certain provisions of FSMA that were self-implementing and effective upon enactment of FSMA, including the requirement of an email address for registration, required renewal of registration every two years, and that all food facility registrations must contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FDCA.

The rule also requires that all food facility registrations must be submitted to FDA electronically; this requirement does not take effect until January 4, 2020. Finally, and per the rule, registrations are now required (effective on July 14, 2016) to contain the type of activity conducted at the facility for each food product category. The final rule also amended the definition of a retail food establishment, a change which expands the number of establishments that are considered retail food establishments and thus not required to register with FDA as food facilities. Regardless of whether or not a food establishment has to register with the agency, however, it has a responsibility to ensure its food is safe.

²² Mitigation Strategies To Protect Food Against Intentional Adulteration; Final Rule, 81 Fed. Reg. 34,166 (May 27, 2016) (to be codified at 21 C.F.R. Parts 11 and 121).

²³ Amendments to Registration of Food Facilities; Final Rule, 81 Fed. Reg. 45,912 (July 14, 2016).

Extension and Clarification of Compliance Dates

In August 2016, FDA finalized a rule to extend and clarify compliance dates for certain provisions of four of the seven rules implementing FSMA:²⁴

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food;²⁵
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals;²⁶
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals;²⁷ and
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.²⁸

The text of the final rule contains charts outlining the previously announced compliance dates and the compliance dates with the extensions granted.²⁹

FTC ENFORCEMENT STATEMENT ON HOMEOPATHIC PRODUCTS

In November 2016, FTC announced a new enforcement policy statement regarding marketing claims for over-the-counter (OTC) homeopathic drug products (the Statement).³⁰ The Statement was informed by a workshop held by the Commission in September 2015 to examine how such products are marketed to consumers. Although the Statement itself is not binding on the Commission or the public, it does seem to set out clearly how FTC will, through enforcement of the FTC Act, now hold OTC homeopathic drug products' claims to the same standard as other OTC drug claims. In addition to potentially imposing a significant burden on the homeopathic industry, FTC's Statement is notable because the Commission does not have the authority to regulate the safety and effectiveness of OTC homeopathic drug products. Yet, the Statement could be seen by some to impose de facto safety and effectiveness requirements on products that millions of Americans currently use.

²⁴ The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules; Final Rule, 81 Fed. Reg. 57,784 (Aug. 24, 2016) (to be codified at 21 C.F.R. Parts 1, 11, 16, 106, 110, 111, 112, 114, 117, 120, 123, 129, 179, 211, and 507).

²⁵ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule, 80 Fed. Reg. 55,908 (Sept. 17, 2015) (to be codified at 21 C.F.R. Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211).

²⁶ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule, 80 Fed. Reg. 56,170 (80 Fed. Reg. 56,170) (to be codified at 21 C.F.R. Parts 11, 16, 117, 500, 507, and 579).

²⁷ Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Final Rule, 80 Fed. Reg. 74,226 (Nov. 27, 2015) (to be codified at 21 C.F.R. Parts 1, 11, and 111).

²⁸ Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule, 80 Fed. Reg. 74,354 (Nov. 27, 2015) (to be codified at 21 C.F.R. Parts 11, 16, and 112).

²⁹ 81 Fed. Reg. at 57,786-57,793.

³⁰ FTC, "Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs", Nov. 2016, http://www.ftc.gov/system/files/documents/public_statements/996984/p114505_otc_homeopathic_drug_enforcement_policy_statement.pdf.

Homeopathic products³¹ are regulated as drugs under the FDCA, but per agency policy, FDA does not evaluate such products for safety or effectiveness. Per FDA's Compliance Policy Guide (CPG) 400.400, "Conditions Under Which Homeopathic Drugs May be Marketed,"³² homeopathic products offered for use in self-limiting conditions recognizable by consumers may be marketed OTC, if certain conditions are met. In addition, per FDA's CPG, homeopathic drugs generally must, among other things, meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopeia and be labeled in accordance with Sections 502 and 503 of the Act and 21 C.F.R. Part 201.

According to FTC's Statement, in order for marketers of homeopathic products to make safety and efficacy claims, the companies would first need to possess competent and reliable scientific evidence (CRSE) for health-related claims, including claims that a product can treat specific conditions. FTC's defines CRSE as:

Tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has 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.³³

This standard is typically interpreted as requiring at least two adequate and well-controlled clinical trials. The effect of the Statement cannot be understated. Per the Commission, for the vast majority of OTC homeopathic drugs, there are "no valid studies using current scientific methods showing the product's efficacy" and thus the marketing claims for such products are "likely misleading, in violation of the FTC Act."

Although the Commission indicated that it "has long recognized that marketing claims may include additional explanatory information to prevent the claims from being misleading," the explanatory information it suggests appear on certain homeopathic products is likely not acceptable to marketers of such products. If an OTC homeopathic drug claim is not supported by CRSE, the Commission has indicated that such a claim *might* not be deceptive if the advertisement or label where the claim appears effectively communicates that: "(1) there is no scientific evidence that the product works; and (2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts."

In order to be included in the Homeopathic Pharmacopeia of the United States (HPUS), which is recognized as an official compendium under Section 201(j) of the Act, a drug product must undergo a "proving," synonymous with the homeopathic procedure (identified in HPUS as a "Research Procedure") which is employed in healthy individuals to determine the dose of a drug sufficient to produce symptoms. The HPUS is a compilation of standards for source, composition, and preparation of

³¹ Homeopathy, the first basic principles of which were formulated by Samuel Hahnemann in the late 1700s, is based on the belief that disease symptoms can be cured by small doses of substances which produce similar symptoms in healthy people. *See* FDA, CPG 400.400- "Conditions Under Which Homeopathic Drugs May be Marketed", issued May 31, 1988 (rev. March 1995), <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm>.

³² *Id.*

³³ *See* Consent Decree, *United States v. Bayer Corp.*, Civ. Action No. 07-01 (HAA), at 2 (D.N.J. Jan. 3, 2007); *see also* *In the Matter of Schering Corp.*, 118 F.T.C. 1030, 1127 (1994).

homeopathic drugs. HPUS contains monographs of drug ingredients used in homeopathic treatment. FTC’s indication that an OTC homeopathic product claim *might* not be deceptive if the advertisement or label indicates that there is no evidence that the product works and that homeopathy is outdated and not accepted science—beyond being incredibly unpalatable to the homeopathic industry—ignores FDA’s enforcement policy regarding such products and that the agency, not FTC, has the authority to regulate the safety and effectiveness of such products.

POSTSCRIPT

On March 10, 2017, President Trump nominated Scott Gottlieb to serve as FDA Commissioner. Gottlieb is a physician, a conservative health policy expert (currently a resident fellow at the American Enterprise Institute), and a partner at venture capital fund New Enterprise Associates. Gottlieb, who served as deputy FDA Commissioner under President George W. Bush, has longstanding ties to the pharmaceutical and biotech industries. Notably, he “favors deregulation and loosening the agency’s requirements for the approval of medical products.”³⁴ Gottlieb has even indicated that “FDA needs to tolerate a little more uncertainty when it assesses the effectiveness of a new drug.”³⁵

Industry response to Gottlieb’s nomination has been widely positive. E-cigarette and cigar companies seem optimistic about President Trump’s decision, and hopeful that under Gottlieb’s leadership, FDA will roll back the agency’s Deeming Rule,³⁶ which subjects these and other tobacco products to burdensome marketing requirements. While some of these hopes might be misplaced, it is reasonable to expect that Gottlieb could have a significant deregulatory impact at the agency. Whether or not this approach would extend to all products under FDA’s authority remains to be seen.

One has to imagine that between Executive Order No. 13,771 and, if confirmed, Scott Gottlieb’s leadership of FDA, the 2017 regulatory report could look quite different than the 2016 report.

³⁴ Bronwyn Mixter, BNA’s Health Care Daily Report™, “Potential Picks to Lead FDA Would Shake Up Agency,” Dec. 19, 2016, <http://www.bna.com/potential-picks-lead-n73014448800/>.

³⁵ Robert Lowes, Medscape Medical News, “Trump Nominates Scott Gottlieb, MD, to Head FDA,” Mar. 10, 2007, <http://www.medscape.com/viewarticle/877115> (Gottlieb once said at a symposium on cancer cures that FDA “is paralyzed ‘by the risk that they will approve a drug on the basis of an observation of a benefit that isn’t 100% . . . certain.’ . . . Likewise, he wrote in *Forbes* last year that the agency’s premarket review of novel products such as gene and cell therapies can’t ferret out all risks by itself, and that ‘the FDA needs to take a more active approach to risk mitigation once products gain market entry.’”).

³⁶ 81 Fed. Reg. 28,974.

Cases to Watch

ANAND AGNESHWAR* AND JOCELYN A. WIESNER**

Some of the cases written about in the rest of this book are potential game changers. As we look ahead, we don't see quite those pivotal decisions but an interesting year nonetheless. On our radar is an upcoming Ninth Circuit decision that will interpret the Supreme Court's decision in *Escobar*. Food and drug attorneys should also pay attention to a recent challenge to FDA's interpretation of the Orphan Drug Act and a petition to the Supreme Court to re-think the *Park* Doctrine.

THE NINTH CIRCUIT TO TACKLE KEY *ESCOBAR* QUESTIONS

While not a case involving drugs, the Ninth Circuit's forthcoming ruling in *United States ex rel Rose v. Stephens Institute a/b/a Academy of Art University*, Case No. 16-80167 (9th Cir.), which will interpret *Universal Health Services v. United States ex rel Escobar*, will certainly impact false claims act cases involving pharmaceuticals and healthcare.

In this case, the Academy of Art University (AAU) participates in federal student financial aid programs under the Higher Education Act of 1964, and receives access to federal funding as a result. As a condition of participation, AAU agreed to comply with various statutory, regulatory, and contractual requirements. Relators—four former admission representatives—filed a qui tam lawsuit against AAU alleging that it violated the False Claims Act by impliedly certifying compliance with the Incentive Compensation Ban (ICB) when it submitted requests for Title IV funds on behalf of its eligible student borrowers. The ICB prohibits colleges and universities from giving recruiters compensation based on enrollment success.

The district court initially permitted Relator's implied certification theory to proceed but after *Escobar*, AAU sought reconsideration. According to AAU, *Escobar* created a "rigid" two-part test for falsity: (1) the claim must make a specific representation about the goods or services provided and (2) the defendant's failure to disclose noncompliance with material requirements makes those representations misleading half-truths. The district court disagreed, holding that the "language in *Escobar* that AAU relies upon does not purport to set out, as an absolute requirement, that implied false certification liability can *only* attach when these two conditions are met." *Rose v. Stephens Institute*, Case No. 4:09-cv-05966 (N.D. Ca. Sept 20, 2016) Doc. No. 208 at 8.

The court did, however, recognize a split in post-*Escobar* authority and therefore certified its order for interlocutory appeal, paving the way for the Ninth Circuit to address whether *Escobar* created a "rigid" two-part test or not.

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FDA FACES CHALLENGES TO ORPHAN DRUG REGULATIONS

Eagle Pharmaceuticals, Inc. is challenging FDA's interpretation of the Orphan Drug Act in its lawsuit against FDA, filed in the U.S. District Court for the District of Columbia. *Eagle Pharm. Inc. v. Burwell et al*, Case No. 1:16-cv-00790 (D.D.C.).

Under the Orphan Drug Act, Pub. L. No. 97-414(b)(4), companies can, among other things, obtain a seven-year market exclusivity grant. According to its Second Amended Complaint, Eagle Pharmaceuticals applied for orphan drug status for its product Bendeka, which treats two rare lymphocytic cancers. FDA designated Bendeka as an orphan drug in 2014, and later approved Bendeka for use in 2015. Second Am. Compl. at 2. Despite its initial grant of orphan drug status, however, FDA denied Eagle Pharmaceuticals market exclusivity as an orphan drug. FDA stated that it had failed to provide "sufficient evidence that Bendeka is *in fact* clinically superior" to an existing approved drug. *Id.* at 4 (emphasis added). This ruling, according to Eagle Pharmaceuticals, is contrary to the text of the Orphan Drug Act.

FDA has lost this battle before. In *Depomed, Inc. v. U.S. Dept of Health & Human Servs.*, 66 F. Supp. 3d 217 (D.D.C. 2014), the district court held that the plain language of the Orphan Drug Act *requires* FDA to grant market exclusivity when it has given a drug orphan status and approval, without any additional requirements. *Id.* at 233.

Instead of appealing that decision, FDA announced that it was treating *Depomed* as limited to the facts of the case. Policy on Orphan-Drug Exclusivity; Clarification, 79 Fed Reg. 76,888-01 (Dec. 23, 2014).

Eagle Pharmaceutical's suit for injunctive and declaratory relief will give the D.C. district court a second chance to review FDA's regulations and the case will perhaps this time lead to a circuit level decision.

THE *PARK* DOCTRINE COMES UNDER ATTACK

Former executives of Quality Egg are asking the Supreme Court to overturn the decades-long precedent that executives can be held criminally liable for company violations of the FDCA. The so-called *Park* Doctrine, established in *United States v. Park* 421 U.S. 658 (1975), holds that an officer or employee may be criminally liable for a corporate violation of the FDCA, whether or not the individual had "knowledge of, or personal participation in, the act made criminal by the statute." *Park*, 421 U.S. at 670. Under the *Park* Doctrine, liability exists so long as the individual had, by reason of his or her position, responsibility and authority to prevent or correct the violations. *Id.* at 673-74.

Here, the government brought criminal charges against Quality Egg for allegedly introducing adulterated eggs into interstate commerce after a 2010 salmonella outbreak was traced back to it. *See* Petition at 9. The government also brought a single criminal count against the owner and Chief Compliance Officer, based on their status as responsible corporate officers. *Id.* The executives pled guilty (without conceding any actual knowledge of the violations), but sharply contested the punishment. More specifically, they claim that the trial court violated their due process rights when it sentenced them to three months imprisonment. *Id.* at 10.

The executives appealed the sentence to the Eight Circuit. There they argued that their conviction amounted to vicarious liability, which, they argued, cannot be punished through imprisonment. Although the Eighth Circuit agreed that vicarious liability cannot be punished through imprisonment, it reasoned that the *Park* Doctrine does not amount to vicarious liability and, as a result, imprisonment does not violate due process. *United States v. DeCoster*, 828 F.3d 626 (8th Cir. 2016).

The executives are now asking the Supreme Court to review the decision. According to petitioners, the decision directly contradicts existing precedent that, where criminal liability is premised on the defendant's "responsible relation" to the unlawful activity and not on participation in the activity, imprisonment would violate due process. *See* Petition at 13 (citing *Lady J. Lingerie, Inc. v. City of Jacksonville*, 176 F.3d 1358 (11th Cir. 1999)). Petitioners are asking the Court not only to overturn their sentence, but also to "revisit and correct" the *Park* Doctrine.

Given FDA's 2010 decision to resurrect the *Park* Doctrine, this decision could have important ramifications on prosecutions going forward. *See* March 4, 2010 Letter from FDA Commissioner Margaret Hamburg to Sen. Charles Grassley.

For more discussion of the *DeCoster* case and its relevance to the future of the Responsible Corporate Officer doctrine, see Ralph F. Hall's chapter in this volume.

For more discussion of the *Escobar* case and current related litigation, see the chapter by Mark E. Haddad and Naomi A. Igra.