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5 Important Drug And Medical Device Developments In 2014

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Now that 2014 is over, we took the opportunity to reflect on some of the year's legal developments with the most impact for our drug and medical device clients. Thanks to several court decisions — and lack of decisions — litigation over drugs and devices remains a hotbed of contested interpretations over free speech, differential diagnosis requirements, adverse event reporting, preemption and innovator liability. Below is a brief assessment of the implications for five of the most significant developments in 2014.

1. First Amendment Protections for Off-Label Promotional "Speech"

In 2011, the U.S. Supreme Court held that "[s]peech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment." Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2659 (2011).

In United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), the Second Circuit followed the Sorrell analysis and vacated the criminal conviction of a sales representative who had been prosecuted for "misbranding" by off-label promotion.[1] The court determined that the government, despite its protestations to the contrary, did indeed prosecute sales representative Alfred Caronia for his speech promoting Xyrem for off-label uses. The court concluded that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the [federal Food, Drug, and Cosmetic Act] for speech promoting the lawful, off-label use of an [U.S. Food and Drug Administration]-approved drug." The decision opened the door to arguments over whether the government can use the False Claims Act to attack off-label promotions as vehicles to inciting doctors to submit claims for unreimburseable uses, or whether companies can use the First Amendment to promote drugs for certain uses without having to first seek FDA approval.

Fast forward two years and 34 Caronia-citing decisions later. A sales-representative-turned whistleblower in California alleged that Schering-Plough Corp. (now part ofMerck & Co. Inc.) and Millenium Pharmaceuticals Inc. promoted off-label uses of blood thinner Integrilin. U.S. ex rel. Solis v. Millennium Pharmaceuticals Inc. et al., no. 2:09-cv-03010 (E.D. Cal.). The sales rep claimed that the companies provided one-sided scientific studies to encourage off-label promotion.

Neither the U.S. Department of Justice nor the Pharmaceutical Research and Manufacturers of America is party to the Solis lawsuit, but they have engaged in an amicus briefing battle over whether "truthful speech" to doctors promoting off-label use is protected under the First Amendment or if it is evidence of intent to incite doctors to submit "false claims" for insurance reimbursement. Plaintiff attorneys claim that hiding behind the "truthfulness" of the speech provides loopholes for companies to get around the need for FDA approval of additional indications. Defense attorneys maintain that the First Amendment shields truthful comments, including off-label promotional statements, and that the "inciting false claims" argument requires some activity beyond protected speech — which is the extent of the off-label promotion at issue. The case is presently pending.

A defense verdict here, after the industry win in Caronia, would suggest that the government is losing ways to battle off-label promotion. But regardless of the eventual court decision on the First Amendment protection — that is, if the court even decides the case on the merits — we expect to see several more qui tam lawsuits litigated over the larger constitutional question.

2. Experts Do Not Have to Consider "All" Potential Causes in Eighth Circuit

In June, the Eighth Circuit — surprisingly and contrary to other courts around the country — concluded that experts do not necessarily have to rule out all possible alternative explanations for their opinions to be sufficiently reliable and therefore admissible. Johnson v. Mead Johnson & Co. LLC, 754 F.3d 557 (8th Cir. 2014), cert. denied, 135 S. Ct. 489 (Nov. 10, 2014).

The plaintiff sued Mead Johnson over injuries plaintiff claimed were caused by allegedly contaminated powered infant formula. The district court agreed with Mead Johnson that the plaintiff's three causation experts did not consider or test evidence of other potential causes of the injuries and the court granted summary judgment.

On review, the Eighth Circuit reversed. The court concluded that the district court violated the liberal admission standard created by Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), and Federal Rule of Evidence 702, which should resolve doubts in favor of admitting the evidence. Weighing the conflicting expert opinions is the role of the jury, not the court.

Although the Eighth Circuit's liberal view of the admissibility of a differential diagnosis is contrary to rulings across the country, the Supreme Court refused to hear the case, denying Mead Johnson's petition in November. Attorneys in the Eighth Circuit should be prepared for greater challenges in excluding expert opinions. For additional analysis, see Amy Fiterman and Lariss Jude's July 2, 2014, analysis, "Expert Witnesses Not Required to Rule Out All Possible Causes in Product Liability Actions."

3. The Stengel Implications for Preemption and Adverse Event Reporting Processes

On June 23, 2014, the Supreme Court denied Medtronic's request for review of the Ninth Circuit's en banc decision in Stengel v. Medtronic 704 F.3d 1224 (9th Cir. 2013). The denial of certiorari deepens the circuit split over whether certain state law claims against device manufacturers are preempted or simply are "parallel" and allowed.

The plaintiff had sued Medtronic in the District of Arizona, claiming that the company's implantable pain pump, a premarket approval medical device, caused his injury. The district court granted Medtronic's motion to dismiss the plaintiff's tort claims as preempted. A three-judge panel for the Ninth Circuit initially affirmed, but the circuit sitting en banc subsequently reversed and remanded. The court stated

that the "[Medical Device Amendments do] not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty." In Stengel, the en banc panel concluded that the state law "duty to use reasonable care" to report adverse events to the FDA as required under the MDA paralleled but did not add to federal requirements for manufacturers and thus avoided preemption.

Not only does the Stengel decision and denial of cert tip the circuit split toward plaintiffs, but the Ninth Circuit's acceptance of a failure-to-report claim effectively carved out a new state law cause of action from Arizona's general negligence law. Under Stengel, a plaintiff can viably claim that a device manufacturer breached its general duty to warn by failing to inform the FDA (or other similar third parties) of newly discovered safety risks, such as those identified in adverse event reports. However, plaintiffs still have an uphill battle to prove causation between a reporting breach and their injuries — that the FDA would have provided that information to prospective patients and their prescribing or implanting physician.

The Stengel decision and the court's denial of certiorari reaffirm the importance of a rigorous adverse event reporting process. Manufacturers should review their reporting procedures to ensure their written rules and actual practices comply with FDA requirements. Andrew Campbell and Peter Meyer delve deeper into the decision in their June 25, 2014, article, "Supreme Court Reinforces Need for Robust Adverse Event Reporting Process."

4. The Status of Innovator Liability

In January 2013, in an 8-1 decision, the Alabama Supreme Court held in Weeks v. Wyeth Inc., No. 1101397 (Ala. Jan. 11, 2013), that brand-name drug manufacturers can be liable for injuries caused by generic drugs. The court agreed to reconsider its decision and again came to the same conclusion on Aug. 15, 2014, this time in a 6-3 decision. See Weeks v. Wyeth Inc., No. 1101397 (Ala. Aug. 15, 2014).

The issue was before the court from the U.S. District Court for the Middle District of Alabama, which had certified the following question:

Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?

The court answered the question in the affirmative both times, although the second time around two additional justices dissented. The majority focused on the alleged misrepresentations in the brand labeling, which generic manufacturers must use under FDA regulations, instead of a "defect" in the generic drug itself. The "alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the [FDA], by the generic manufacturer," according to the court.

The court denied that it was creating a new "innovator liability" cause of action and instead was following the foreseeability analysis of PLIVA v. Mensing, 131 S. Ct. 2567 (2011). A brand-drug manufacturer reasonably could foresee that generic manufacturers would copy the brand labeling and the innovator therefore owed a duty of care to a generic drug user.

However, the vast majority of courts that have considered whether a brand-name drug manufacturer can be liable for a product it did not manufacture have come to the opposite conclusion, even after

Mensing. Most courts refuse to hold a manufacturer liable for a product it did not actually manufacture. Only a handful of courts have been willing to rely on foreseeability to overcome the "bedrock legal principles of duty and privity," as Justice Tom Parker deemed them in his dissent. See Conte v. Wyeth Inc., 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008); Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010); Dolin v. SmithKline Beecham Corp., No. 12 C 6403 (N.D. Ill. Feb. 28, 2014).

While innovator companies can expect an increase in filings in Alabama, choice-of-law rules hopefully will limit the Weeks law to Alabama resident-plaintiffs. And although Weeks adds one more jurisdiction for plaintiffs to bring claims in and to add to string cites, plaintiffs still will have to overcome the traditional defenses to failure-to-warn claims to succeed against innovator companies, as explained by Bridget Ahmann in her Aug. 19, 2014, discussion, "Alabama Supreme Court Reaffirms That Plaintiffs Who Use Generic Drugs Can Recover From Brand-Name Manufacturers."

5. Pom Wonderful Decision and Its Applicability to Drugs and Devices

On June 12, 2014, the Supreme Court released its long-awaited decision in Pom Wonderful LLC v. Coca-Cola Co., 134 S.Ct. 2228 (2014). The Supreme Court unanimously held that Pom Wonderful may assert a false advertising claim under the Lanham Act against Coca-Cola, its competitor, rejecting Coca-Cola's claims that the FDA's comprehensive regulation of the juice labeling precluded such private claims.

The Supreme Court reversed the Ninth Circuit, which held in 2012 that 21 U.S.C. § 337(a) allowed for no private right of action and that the FDA's primary jurisdiction precluded direct and indirect challenges to the agency's labeling judgments, including those asserted under the Lanham Act's prohibition on false advertising. The Ninth Circuit had reasoned that "courts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments."

But rather than finding a conflict between the Lanham Act and FDCA, the Supreme Court concluded that the statutory schemes were complementary and may serve to foster the same goal — "provide incentives for manufacturers to behave well." In addition, neither the Lanham Act nor the FDCA contain an express prohibition against Lanham Act claims for products regulated by the FDA, and the Supreme Court inferred that the two may coexist.

Although Pom Wonderful involved allegations of false and misleading juice labeling, the Supreme Court's decision has implications beyond food litigation. For starters, the decision brought an abrupt end to a hitherto plausible defense against drug and device plaintiffs' labeling arguments, such as their frequent complaints that companies should have used larger or more emphatic fonts in their FDA-approved labeling.

The Pom Wonderful decision also has already surfaced in litigation over an injectable epinephrine product, where one drug manufacturer sued others under the Lanham Act, claiming that the other epinephrine manufacturers made false claims of FDA approval and safety. See JHP Pharms. LLC v. Hospira Inc. (C.D. Cal., Oct. 7, 2014). The district court largely rejected the defendants' arguments that the Pom Wonderful holding was limited to the less-regulated food and beverage industry.

While it is true that the Supreme Court makes frequent mention of "food and drink" or "food and beverage" in the course of its opinion, the arguments, logic and holding in Pom Wonderful are couched in much broader language and strongly suggest a more wide-ranging application.

The logical building blocks of the Supreme Court's specific holding with regard to food and beverage

labeling would seem to be equally applicable to food and beverage advertising, drug marketing, medical device labeling, cosmetics branding or any other kind of marking or representation which would fall under both the Lanham Act and FDCA, unless preclusion is required for some specific reason. The general presumption following Pom Wonderful, then, is that Lanham Act claims with regard to FDCA-regulated products are permissible and, indeed, desirable.

The district court separated the permissive Lanham Act claims where "the subject of the claim touches the area of authority of the FDCA" from those precluded claims where the court would be "called upon to make determinations within the exclusive purview of FDA authority."

Depending on one's point of view on truth-in-labeling disputes, the Pom Wonderful decision may or may not be wonderful. It opens the door for companies to bring false advertising claims against competitors — which can cut both ways. It will be interesting to see how courts determine what claims require the "exclusive purview" of the FDA and how far courts are willing to take the Pom Wonderful "arguments, logic and holding."

For other important positive 2014 developments, we refer to the annual list in the Drug and Device Law blog, "Thumbs Up — The Ten Best Prescription Drug/Medical Device Decisions of 2014," for a well-analyzed and entertaining discussion of this year's key wins.

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[1] The Federal Food, Drug and Cosmetic Act prohibits pharmaceutical companies from "misbranding" pharmaceuticals or "introduc[ing] or deliver[ing] for introduction into interstate commerce of any ... drug ... that is ... misbranded." 21 U.S.C. § 331(a).
