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# 5 Of The Top Drug And Device Developments In 2015

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As 2015 winds down, we reflected on some of the year's most significant legal developments for drug and device manufacturers. In our opinion, the bench got it right (for the most part) this year. Here is a brief recap and assessment of the implications for five of the most significant developments in 2015:

**1. The Amarin Implications for Off-Label Promotional "Speech"**

As we noted last year, courts have been slowly chipping away at the U.S. Food and Drug Administration's tight reins on a drug or device manufacturer's right to make "truthful" but off-label statements about its products. The well-publicized Amarin decision continued the trend, rejecting the FDA's assertions that it can distinguish "truthful speech" from intent to engage in off-label promotion. Amarin Pharma Inc. v. FDA, No. 1:15-cv-3588, 2015 U.S. Dist. LEXIS 103944 (S.D.N.Y. filed May 7, 2015).

Let's set the scene. In 2011, the United States 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). The Second Circuit followed suit in 2012, vacating the criminal conviction of a sales representative who had been prosecuted for "misbranding" through the "lawful, off-label use of an FDA-approved drug." United States v. Caronia, 703 F.3d 149 (2d Cir. 2012). Questions remained over whether off-label promotions incite doctors to submit claims for nonreimbursable uses (and therefore violate the False Claims Act) and whether companies can use the First Amendment to promote drugs for certain uses without having to first seek FDA approval.

The United States District Court for the Southern District of New York attempted to answer these questions in Amarin. Amarin had sued the FDA, seeking an injunction to allow the company to promote its Vascepa drug for an expanded indication, including discussions of its positive clinical data. Vascepa is approved to treat patients with very high levels of triglycerides and Amarin wanted to promote its clinical data demonstrating Vascepa's benefits for somewhat lower triglyceride levels.

The court granted a preliminary injunction for Amarin in August 2015, noting that nonmisleading, off-label speech is beyond the FDA's reach. The judge disagreed with the FDA's attempt to distinguish Caronia as limited to the actual act of speaking as opposed to using speech as evidence of intent to make off-label promotions.

The court granted Amarin and the FDA's request to stay the litigation until Feb. 17, 2016, while they pursue settlement.

***Takeaway:*** The Amarin decision has already been used as a springboard for attempts by other manufacturers to affirm their off-label (but truthful) speech. For example, Pacira Pharmaceuticals sued the FDA in September 2015, after the FDA issued a warning letter over promotional materials related to use of Pacira's Exparel drug for nonapproved uses. Pacira Pharmaceuticals Inc. v. FDA, 1:15-cv-07055 (S.D.N.Y., filed Sept. 8, 2015). The parties reportedly have settled the dispute. We forecast that off-label litigation will narrow from whether drug and device manufacturers can engage in truthful, nonmisleading off-label speech to whether specific speech is both truthful and nonmisleading.

**2. 3-D Printing Gets Off the Ground**

This year marked the first case (to our knowledge) applying product liability principles to a 3-D printed product. Buckley v. Align Technology Inc., No. 5:13-cv-02812-EJD, 2015 U.S. Dist. LEXIS 133388 (N.D. Cal. Sept. 29, 2015). In Buckley, the plaintiff had sued Align, the manufacturer of the Invisalign dental aligners, alleging that the aligners failed to correct her severe malocclusion over two years. The aligners are custom-made by 3-D printing the individual's dental impressions. The plaintiff used the custom nature of the aligners to claim that Align "medically evaluated" the impressions before printing them. She claimed that Align therefore had a duty to warn her directly that the aligners would not correct her type of malocclusion.

The United States District Court for the Northern District of California rejected the plaintiff's suggestion that a 3-D manufacturer was a "medical evaluator." The court applied the learned intermediary doctrine traditionally applied in prescription drug and device cases:

The Invisalign aligners are prescribed exclusively by the dentist and are custom-manufactured by Align ... It appears, thus that Align stands in the position of a manufacturer not a medical evaluator. As such, Align has a duty to warn the dentist about any dangerous side effects pertaining to the Invisalign treatment, but has no duty to directly warn the plaintiff.

The court dismissed the plaintiff's claims because she failed to allege that Align did not adequately warn her dentist and failed to allege any false or misleading statements.

***Takeaway:*** New technology is likely to trigger more attempts to shoehorn claims into existing theories of liability. For now, even though a 3-D printer may involve more customization for a patient, the learned intermediary doctrine still applies for a prescribed drug or device, at least in the Northern District of California.

**3. The Post-Tincher World**

In Tincher v. Omega Flex Inc., 104 A.3d 328 (Pa. 2014), the Pennsylvania Supreme Court, at long last, corrected conflicting interpretations of strict liability. Before Tincher, Pennsylvania's state courts had often applied a harsh reading of Restatement (Second) of Torts § 402A, and Pennsylvania's federal courts had often applied Restatement (Third) of Torts. Although the Pennsylvania Supreme Court declined to adopt the Restatement (Third) in Tincher, it did clarify that strict liability requires more than just demonstrating that a product defect existed. Rather, the court held that a strict liability claim also "requires proof, in the alternative, either of the ordinary consumer's expectations or of the risk-utility of the product."

While Tincher was a good decision for product manufacturers, it had limited impact on prescription drug and device manufacturers, who were protected from strict liability theories under comment k, as established in Hahn v. Richter, 673 A.2d 888 (Pa. 1996). However, following Tincher, plaintiffs claimed prescription products were now subject to the new enunciation of strict liability.

Fortunately, in June 2015, two federal courts rejected this argument, one implicitly, one expressly. First, in Runner v. C.R. Bard, ___ F. Supp.3d ___, 2015 U.S. Dist. 72174 (E.D. Pa. June 3, 2015), the United States District Court for the Eastern District of Pennsylvania applied comment k without addressing potential Tincher implications. Second, in Batty v. Zimmer Inc. (In re Zimmer Nexgen Knee Implant Products Liability Litigation), 2015 U.S. Dist. 77475 (N.D. Ill. June 12, 2015), the United States District Court for the Northern District of Illinois, applying Pennsylvania law in multidistrict litigation, dismissed the plaintiff's strict liability claim on summary judgment, concluding that Tincher actually acknowledged the exception for prescription products. The court also rejected the plaintiff's argument that Tincher had silently distinguished drugs from devices in its application.

***Takeaway:*** Both prescription drug and device manufacturers remain subject to only negligence theories in Pennsylvania. We expect continued litigation on the tentacles of Tincher in 2016.

**4. FDA Alert Regarding Medical Device "Cybersecurity Vulnerabilities"**

Medical device cybersecurity received heightened attention this year. In July 2015, the FDA and the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team issued a safety alert, reporting on the "cybersecurity vulnerabilities" of the Hospira Symbiq Infusion System, a computerized pain pump. The system can communicate with a hospital-based information system to control the pump. According to the FDA, "Hospira and an independent researcher confirmed that Hospira's Symbiq Infusion System could be accessed remotely through a hospital's network. This could allow an unauthorized user to control the device and change the dosage the pump delivers, which could lead to over- or under-infusion of critical patient therapies."

According to the government, "no known public exploits specifically target this vulnerability," but even "an attacker with medium skill" could exploit it. At the time of the alert, Hospira was no longer selling the pump system for other reasons, but the FDA was concerned about existing users and third-party sales of the system. The FDA suggested that users transition to a different system. It provided recommendations to follow during the transition to mitigate the risk of unauthorized access.

***Takeaway:*** While a novel development in the drug and device field, the FDA is treating cybersecurity vulnerabilities just like more traditional product risks. Currently, both the device manufacturer and the hospital provider share the responsibility for limiting potential exposure to hacking attacks. See Cybersecurity for Medical Devices and Hospital Networks: FDA Safety Communication, issued June 13, 2013. We expect that drug and device manufacturers will continue to explore computerized methods to enhance their products. That means that this development is likely here to stay.

**5. Implied Preemption — Applying Bartlett to Brand Drugs**

This year, the Sixth Circuit gave us the first federal appellate decision applying implied preemption to design defect claims for brand name pharmaceuticals. Yates v. Ortho-McNeil-Janssen Pharmaceuticals Inc., No. 15-3104 (6th Cir. Dec. 11, 2015). In Yates, the plaintiff made two design defect claims: (1) the company should have changed the formulation of the Ortho Evra patch before the FDA approved it and

(2) the company should have reduced the dosage after the FDA approved it.

The Sixth Circuit noted that impossibility preemption "is a demanding defense," but concluded that both pre- and post-approval types of design defect claims are preempted under Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013). As the court noted, the plaintiff "essentially argue[d] that defendants should have never sold the FDA-approved formulation ... in the first place." But, if the manufacturer's drug complies with federal law, a plaintiff is impliedly preempted from claiming the manufacturer should not sell the drug in order to comply with state law. As for the post-approval design claim, the court concluded that because a manufacturer could not change the approved drug's dosage without FDA approval, under 21 C.F.R. § 314.70(b)(2)(i), the manufacturer could not have altered the drug to meet state law requirements without violating federal law. The design claims were therefore preempted.

The court succinctly summarized the impact for brand name pharmaceuticals:

[C]ontrary to Yates's contention that the impossibility preemption in Mensing and Bartlett is limited to generic drugs, we view Levine, Mensing and Bartlett as together stating the same test for impossibility preemption. Because the federal statutes and regulations for brand-name and generic drugs are sometimes different, however, brand-name and generic drugs may face different impossibility preemption results in some circumstances.

***Takeaway:*** The Yates decision is a key development against plaintiffs' "don't sell" design defect theory and clarifies that brand drugs may demonstrate impossibility preemption. Although defendants have argued the implied preemption defense for years, this is the first federal appellate court decision squarely addressing the issue and finding preemption.

As we ring in 2016, we look forward to a new year of defense wins.

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