Client Alert

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Howard v. Zimmer: Negligence Per Se Based on Violations of the FDCA—Blurring the Line Between Parallel Claims and Preemption

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Last week in *Howard v. Zimmer*, — P.3d —, 2013 WL 1130759 (Okla. 2013), the Oklahoma Supreme Court held that a plaintiff can assert a negligence per se claim against a medical device manufacturer based on the manufacturer's violation of federal regulations, even where the federal regulations provide that their enforcement must be prosecuted by the United States. Though *Howard*'s holding is broad and somewhat novel in medical device and pharmaceutical litigation, it comports with a long line of cases recognizing that negligence per se claims may be based on federal safety regulations.[1] More interesting is how the *Howard* decision fits within the preemption framework outlined by the U.S. Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

FACTUAL AND PROCEDURAL BACKGROUND

The plaintiff, Brian C. Howard, M.D., received a knee-replacement implant manufactured by the defendant, Sulzer Orthopedics, Inc. The implant failed and had to be removed, allegedly because it did not bond to Howard's bone due to Sulzer's failure to remove an oily residue that, according to Howard, was left on the implant in violation of the Good Manufacturing Practices ("GMP") regulations incorporated into the federal Food Drug and Cosmetic Act ("FDCA"). *See* 21 C.F.R. § 820.70(h). The GMP regulations require medical device manufacturers to establish procedures for removing or limiting manufacturing materials from medical devices to the extent the manufacturing materials adversely affect the device's quality. *Id.* Howard alleged that Sulzer's violation of the GMP regulations constituted negligence per se.

THE CERTIFIED QUESTION

Through a convoluted procedural history not relevant to our inquiry, the following question of first impression was certified to the Oklahoma Supreme Court by the Court of Appeals for the Tenth Circuit:

> "Whether 21 U.S.C. § 337 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C § 301 *et seq.*, providing that all violations of the Act shall be prosecuted in the name of the United States, prohibits Oklahoma from recognizing a claim for negligence per se based on violation of a federal regulation under the Medical Device Amendments (MDA) to the FDCA?"

2013 WL 1130759 at *1.

[1] *See Brandes v. Burbank*, 613 F.2d 658 (7th Cir.1980) (federal transportation regulations); *Wallace v. Ener*, 521 F.2d 215 (5th Cir.1975) (same); *see also Teal v. E.I. Dupont de Nemours & Co.*, 728 F.2d 799 (6th Cir.1984) (OSHA regulations); *Arthur v. Flota Mercante Gran Centro Americana, S.A.*, 487 F.2d 561 (5th Cir.1973) (federal safety regulation requiring handrail on bulwark steps); *Taylor v. Pennsylvania R.R. Co.*, 246 F.Supp. 604 (D.Del.1965) (federal motor carrier regulations); *DiRosa v. Showa Denko K.K.*, 44 Cal.App.4th 799, 807-808 (Cal. Ct. App. 1996) (Food and Drug Administration regulation); *McGee v. Cessna Aircraft Co.*, 139 Cal.App.3d 179, 186-187 (Cal. Ct. App. 1983) (federal aviation regulations).

THE OKLAHOMA SUPREME COURT'S ANSWER AND ANALYSIS

The Oklahoma Supreme Court "answered in the negative," drawing "the distinction between attempting to *enforce* a federal regulation," which would be prohibited, and "*allowing* a parallel claim for negligence per se bottomed on violation of the regulation." *Id.* at *1,*7 (emphasis added). The *Howard* court based this decision on its understanding of "parallel claims" and the negligence per se doctrine, which it reasoned allows a plaintiff "to substitute statutory standards for parallel common law, reasonable care duties," so long as the general negligence per se standard is met (i.e., the injury was caused by the violation, the injury was the type of injury intended to be prevented by the statute or regulation, and the injured party was a member of the class intended to be protected by the statute or regulation). *Id.* at *3. This much of the *Howard* decision is easily understood. [2]

Howard becomes more complicated, however, during the court's discussion of whether the FDCA provision providing that enforcement proceedings "shall be by and in the name of the United States" prohibits Howard from moving forward with his negligence per se claim. Sulzer argued that allowing the negligence per se claim would be contrary to the expressed legislative intent that enforcement actions be brought only by the United States. *Id.* at *4. Howard, on the other hand, argued that he did not seek to enforce the federal statute, "but to base his theory of recovery on Sulzer's failure to follow the federal regulation." *Id.* The court found the distinction persuasive, ultimately holding that allowing Howard's negligence per se claim did not amount to allowing private "enforcement" of the federal regulation. *Id.* at *7.

In coming to its conclusion, the *Howard* court relied heavily on the U.S. Supreme Court's decision in *Riegel*, stating that *Riegel* "blessed" its holding because there "the Supreme Court [] acknowledged that the Medical Device Amendments to the FDCA . . . would not prevent a state from providing a damages remedy for claims premised on violation of FDCA regulations." *Id.* at *6. In actuality, the Court in *Riegel* declined to address "parallel claims" because it found those issues were not before it. *Riegel*, 552 U.S. at 330 ("Although [plaintiffs] now argue that their lawsuit raises parallel claims. . . . We decline to address that argument in the first instance.").

Finally, and most striking about the *Howard* decision, is the Oklahoma Supreme Court's lack of explanation as to just how its holding actually fits within the U.S. Supreme Court's preemption jurisprudence. Specifically, we find it difficult to distinguish *Howard*'s negligence per se principle from *Buckman*'s holding that claims which exist "solely by virtue" of FDCA violation are preempted. *Buckman*, 531 U.S. at 353. It seems that, in *Howard*, the plaintiff would be unable to establish liability without the existence of the federal enactment—which is exactly the type of claim that we understand *Buckman* to preempt. *Howard* may be just another decision in the recent line of cases confusing (at best) and chipping away at (at worst) *Buckman*-style preemption. *See Stengel v. Medtronic, Inc.*, ---F.3d---, 2013 WL 106144, 13 C.D.O.S. 365 (9th Cir. 2013) (no preemption for parallel claim based on the MDA); *see also Hughes v. Boston Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) cert. denied 132 S. Ct. 498 (2011).

[2] It is worth noting, however, that other courts have come to the opposite conclusion and have held that negligence per se cannot be based on violations of FDCA-related regulations. *See e.g.*, *Pantages v. Cardinal Health 200, Inc.*, No. 5:08-cv-116-Oc-10GRJ, 2009 WL 2244539 (M.D. Fla. July 27, 2009) ("Plaintiff's claim fails to state a cause of action for which relief can be granted because Florida law does not recognize a claim based upon a theory of negligence per se claim for an alleged violation of this particular federal regulation [21 C.F.R. § 820.130]".]); *Bish v. Smith & Nephew Richards, Inc.*, No. W1998-00373-COA-R9-CV, 2000 WL 1294324 (Tenn. Ct. App. Oct. 29, 2001) ("In concluding that the FDCA requirement for prior approval of a medical device does not itself support a claim for negligence per se…").

CONCLUSION

The *Howard* decision complicates an increasingly gray area of products liability law. Manufacturers should be prepared. This decision allows plaintiffs to bring state-law negligence claims based solely on federal standards. Even though *Buckman* rejected the notion that "any violation of the FDCA will support a state-law claim," *Howard* directly suggests otherwise—at least for cases in Oklahoma. The decision will likely aid plaintiffs in overcoming summary dismissal, and may result in new cases brought against manufacturers asserting negligence per se based on violations of the FDCA, despite the FDCA's provision providing that enforcement actions can only be prosecuted by the United States.

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