Cases to Watch

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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.