September 17, 2020

District Court Upholds Acclarent Executives' Strict Liability Conviction for Off-Label Promotion

On September 14, 2020, in a long-awaited ruling, Judge Allison Burroughs of the District of Massachusetts denied the post-trial motion for acquittal or new trial made by William Facteau and Patrick Fabian, two former Acclarent executives convicted in July 2016 of ten counts of misdemeanor adulteration and misbranding. The post-trial motion had been pending for nearly four years, during which time sentencing was suspended.

Background

Facteau and Fabian were charged with various offenses related to off-label promotion of Acclarent's Stratus Microflow Spacer ("Stratus") device. The Stratus was FDA-cleared in 2006 for use as a perforated sinus spacer device able to release saline to moisten the sinuses over a 14-day period. However, Acclarent's internal design documents showed that the Stratus was specifically designed to deliver steroids—not saline—into the sinuses, and had a larger pore size that made the device incapable of retaining saline for more than a few minutes. Evidence showed that Facteau himself had signed off on a specification sheet indicating that a "key requirement" was that the Stratus be capable of delivering steroids.

Evidence introduced at trial also established that Acclarent essentially marketed the Stratus *only* for use with a steroid, specifically a substance known as Kenalog-40 that was more viscous than saline and other liquid drugs. This position was supported by internal documents, such as trainings and discussion guides that encouraged the sales team to pitch the Stratus as a drug delivery device and testimony from sales representatives both that they were trained to ask physicians probing questions that would lead to a discussion about off-label use of the Stratus with Kenalog-40, and that they would tell physicians that the device was approved for use with Kenalog-40 outside of the United States. It was also bolstered by testimony by sales representatives that they had never marketed the device for use with saline, and had only trained physicians to use the Stratus with Kenalog-40. Evidence also showed that FDA denied Acclarent's request for additional clearance to market the Stratus for drug delivery, because the agency found that "combining drug delivery with a device would render the Stratus a combination product that would require a more extensive approval process."

The government alleged that the defendants violated the Federal Food, Drug, and Cosmetic Act ("FDCA") by introducing the Stratus into interstate commerce without obtaining required 510(k) clearance or premarket approval for the "intended use" for which the product was marketed and distributed—as a delivery mechanism for steroids. Following a twenty-seven-day trial, Facteau and Fabian were acquitted of all felony charges, but convicted of misdemeanor counts of adulteration and misbranding. The defendants filed a post-trial motion, arguing that (1) the Government's reliance on truthful, non-misleading speech to support their convictions violated the First Amendment, and (2) their Due Process rights were violated by being held liable on a strict liability basis, based on a vague and impermissible interpretation of "intended use."

In discussing the challenges that led to the delay in resolving the motion, the court highlighted its struggle with the complicated charging theories used by DOJ to prosecute the defendants, suggesting that Congress may not have intended to criminalize the conduct at issue. Specifically, the opinion expressed the belief that "the statutory and regulatory scheme needs to be rethought," noting that while public policy considerations warrant close regulation of the healthcare industry, the gravity of a conviction under the relevant statutes warrants a regime that clearly spells out "what is and is not prohibited conduct." However, the opinion—which will likely be appealed to the First Circuit —ultimately concluded that DOJ had articulated and proven a permissible theory of liability based on prohibited acts that were not themselves speech, though speech was relied on as evidence to prove them.

First Amendment Analysis Related to Truthful Speech

Defendants asserted that their convictions violated the First Amendment because the evidence of their "intended use" of the Stratus as a drug delivery device consisted of only truthful, non-misleading speech. However, the court distinguished prior cases that held that the FDCA could not be construed to prohibit truthful and non-misleading speech alone to find that the convictions in this case did not run afoul of the First Amendment. Based on the holdings of *United States v. Caronia* in the Second Circuit, and *Amarin Pharma, Inc. v. FDA* in the SDNY, the court identified "a distinction between truthful, non-misleading off-label speech alone, and speech in connection with the act of mislabeling for an intended use." The court cited *Caronia* and *Amarin* approvingly to note that speech alone cannot be the *subject* of the prosecution, and that there has to be an underlying non-speech criminal act, or *actus reus*. However, the court found that those cases left the door open for the government to use off-label speech as *evidence* of intended use.

In an analysis that relied heavily on the specific evidence presented at trial, the court found that the prosecution of Facteau and Fabian had correctly threaded this needle. The court noted that unlike in *Caronia*—where the government never argued that evidence of off-label promotion was merely evidence of intent—the government introduced evidence that Facteau and Fabian actively marketed and promoted the Stratus off-label in the context of establishing their *intent* regarding the "intended use" of the Stratus. For example, the court cited excerpts from the government's closing argument where it asked the jury to consider *all circumstances* surrounding distribution of the device to figure out its intended use, and noted that the failure to submit a premarket notification was the underlying *actus reus* for the misbranding count. Similarly, the adulteration count was grounded in the failure to obtain premarket approval for the drug delivery indication, which was required in the absence of 510(k) clearance for the indication. The court also noted that unlike in *Caronia*, the jury instructions clearly warned that "truthful, non-misleading speech cannot be a criminal act in and of itself."

Ropes & Gray submitted an amicus brief in support of defendants' First Amendment arguments on behalf of its client, the Medical Information Working Group ("MIWG"), arguing that truthful, non-misleading statements about lawful, off-label uses for drugs or devices should not be sharply restricted, given that this speech provides valuable information to providers and drives innovation. The opinion appeared to acknowledge the merits of this policy argument, although it noted the court's view that statutory or regulatory changes would be needed to effectuate the MIWG's arguments. The court also noted that it did not believe its ruling would chill speech related to off-label uses in light of various FDA safe harbors, such as responding to a provider's unsolicited request for off-label information.

Vagueness Analysis Related to Regulations Concerning "Intended Use"

The defendants also argued that the prosecution had violated their Due Process rights, asserting, among other things, that (i) the meaning of "intended use" under FDA's regulations is impermissibly vague; and (ii) the government's use of *internal* Acclarent communications improperly expanded the scope of evidence used to determine intended use. The court rejected both arguments.

First, the court rejected the idea that FDA's definition of "intended use" in 21 C.F.R. § 801.4 is impermissibly vague, reasoning that "the fact that a statute or regulation requires interpretation does not render it unconstitutionally vague." In rejecting the defendants' argument that intended use can only be discerned through external communications, the court cited the 1957 *V.E. Irons* case for the proposition that one can look to "all relevant sources" to determine the intended use of a product. The court noted that "although [*V.E. Irons*] did not explicitly delineate what materials it intended to bring within the scope of 'all relevant sources,' it did not articulate any limitations on the concept." Significant to the court's analysis, *V.E. Irons* did not say that internal communications could *not* be reviewed in determining intended use. Additionally, although the defendants cited several cases in support of their arguments that evidence of intended use is limited to externally directed statements, the court found these to be unavailing because none of the cases expressly state that promotional representations are the *only* relevant source that can be used. Furthermore, the court held that the plain

language of § 801.4 "provides examples of what may be used to determine 'objective' intent, some of which are directed externally ('labeling claims, advertising matter'), and some of which ('oral and written statements' and 'circumstances') are not limited to external communications." Notably, the government's evidence at trial included a significant number of both internal *and external* communications that supported the theory that Acclarent intended to market the Stratus as a drug delivery device, including testimony by numerous sales representatives that they solely pitched the device for use with steroids.

Strict Liability under *United States v. Park*

The defendants also raised a Due Process claim relating to the fact that the misdemeanor charges under which they were convicted held the defendants strictly liable without requiring the prosecution to prove that the defendants acted with criminal intent. Most criminal statutes require that a person act with intent – known as *mens rea* – to be convicted of a criminal offense, often requiring that the illegal act be committed "knowingly" or "willfully." The court relied on the Supreme Court's 1975 decision in *United States v. Park* to find that holding a corporate officer strictly liable for adulteration does not violate Due Process, given the need to enforce executive accountability in the food and drug industries where public health is paramount. The *Facteau* opinion noted that while there was "something troubling" about a criminal conviction where the accused had no knowledge of the conduct at issue, it did not need to grapple with the limits of strict liability, given that the evidence against Facteau and Fabian established that the defendants personally participated in the charged conduct.

Implications

The court's order denying defendants' motion for acquittal or new trial was heavily grounded in the facts, and the court was unable to find on the record presented at trial that allowing the verdict to stand would be a "miscarriage of justice" or that the evidence presented "preponderates heavily against the verdict." In reaching its conclusion, the court also affirmed the legal validity of the charging theories presented and in so doing, may have breathed new life into the government's ability to prosecute off-label cases. However, given the fact-bound opinion, even assuming it is upheld on appeal, the success of future prosecutions may turn on the government's ability to prove equally compelling facts, based on a similarly large volume and variety of evidence, as supported this ruling. Given the court's discomfort with the regulatory scheme, as well as a trend in increased First Amendment scrutiny, enforcement actions based on less strong facts may be on shakier ground.

Although the court distinguished *Caronia* and *Amarin* on the facts, the opinion reinforced their central principle that truthful, non-misleading speech cannot form the basis for a criminal conviction and that a separate, non-speech *actus reus* is required. The opinion also concluded that off-label promotional speech can serve as "evidence of [defendants'] intent that the device be used for a purpose that the FDA had not approved." The line between the two categories is far from clear, and in future cases that rely heavily on speech-based evidence, courts may have to decide how to distinguish between speech introduced as evidence of a defendant's intent versus speech relied on as the criminal act. Finally, while the court suggested discomfort with the prospect of holding corporate officers strictly liable for misdemeanor offenses including adulteration and misbranding, it found that concern inapplicable here due to what the court regarded as evidence of defendants' personal participation in the conduct at issue, which the court believed obviated the need to address the legality of strict liability criminal offenses and the *Park* Doctrine. The use of the *Park* Doctrine by DOJ is an underlying concern in any FDCA investigation, but DOJ has pursued such charges sparingly. The thorough opinion issued by Judge Burroughs provides additional fodder for future negotiations with DOJ over potential *Park* charges.

The ultimate impact of the decision on the landscape for manufacturer communications remains to be seen. Defendants are likely to appeal, and it is unclear whether the First Circuit, or potentially the Supreme Court, will agree with the district court's analysis.

Furthermore, FDA continues to evaluate the definition of intended use, and any regulatory revisions could affect future enforcement based on the provisions at issue in this case, and the use of other similar charging theories. The agency is expected to issue proposed amendments to the intended use regulations any day now, and the details of that proposal are not yet public. Ropes & Gray will continue to monitor developments in this space. For any questions, please contact your usual Ropes & Gray advisor.