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EXPERT ANALYSIS

Ninth Circuit Confounds Practice of Medicine And Off-Label Use Issues

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A problematic decision from the Ninth Circuit appears to impermissibly grant the FDA authority to regulate the practice of medicine, and to further muddy the regulatory morass governing off-label use of products. We hope other courts recognize this decision for what it is: a bad set of facts that led to bad law.

Last month, the U.S. Court of Appeals for the Ninth Circuit affirmed the felony conviction and 48-month imprisonment of Dr. Michael Stanley Kaplan, a Nevada urologist, for conspiracy to commit adulteration under the Federal Food, Drug, and Cosmetic Act ("FDC Act"). *United States v. Kaplan*, No. 15-10241, 2016 WL 4709870 (9th Cir. Sept. 9, 2016).

Based on a complaint by Dr. Kaplan's own medical assistants to the Nevada State Medical Board, the FDA's Office of Criminal Investigations ("OCI") opened an investigation and confirmed that Dr. Kaplan used plastic single-use needle guides in multiple invasive prostate procedures.

These procedures involve a physician injecting a needle via a needle guide to pierce the rectal wall and to remove tissue from the prostate for analysis. During the procedure, the needle guide comes into contact with "tissue, blood, and fecal matter, along with any bacteria and viruses." Decision at 5.

Although the plastic needle guides were indicated for single use only, and contained clear warnings against reuse, Dr. Kaplan attempted to sterilize the needle guides so that he could reuse them in subsequent procedures. The medical assistants complained that they could not remove "brown scratches" on the guides during the disinfecting process and that the used guides became "discolored." *Id.* at 8.

Section 301(k) of the FDC Act prohibits "the doing of any ... act with respect to ... [a] drug [or] device ... if such act is done while such article is held for sale ... after shipment in interstate commerce and results in such article being adulterated." 21 U.S.C. § 331(k).

A product is adulterated if, inter alia, it "has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

At trial, Kaplan argued that the needle guides were not "held for sale" because he never transferred their ownership to the patients, but merely used them in the treatment of a patient. The district court rejected this argument.

On appeal, Dr. Kaplan renewed his objection to the "held for sale" provision, and also contended that his reuse of single-use needle guides constituted the allowable off-label use of a device under the FDC Act.

While noting that the "held for sale" argument Kaplan posed was "an issue of first impression," rather than taking the opportunity to draft a well-reasoned opinion in an area where case law is scarce, the

The Kaplan decision clouds, rather than clarifies, important issues. There can be no dispute that Congress did not intend FDA to regulate the practice of medicine via the FDC Act.

Ninth Circuit simply affirmed the lower court's decision citing the handful of cases broadly touching the issue. Decision at 13 (citing *United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981); *United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975); *United States v. Rhody Dairy, LLC*, 812 F. Supp. 2d 1239, 1244 (W.D. Wash. 2011); *United States v. Device Labeled "Cameron Spitler Amblyo-Syntonizer,"* 261 F. Supp. 243, 246 (D. Neb. 1966)).

The court attempted to distinguish the single case from the Ninth Circuit that held the opposite, *United States v. Geborde*, 278 F.3d 926 (9th Cir. 2002), by explaining that Dr. Geborde engaged in noncommercial transactions when he distributed his homemade recreational drugs free of charge to patients.

> The district court in [Kaplan's] case, therefore, properly focused on the commercial nature of Kaplan's business, a medical practice operated for profit, reasoning that patients who paid Kaplan for the medical services he performed were also paying for the cost of products used in the course of treatment, including biopsies, and that the patients were therefore the ultimate consumers of the guides. Kaplan is a physician engaged in the business of providing medical services in exchange for payment: a commercial actor in a commercial setting, using a commercial product. We hold that his use of the plastic guides is covered by the "held for sale" provision of § 331(k).

Id. at 16.

Although the outcome for Dr. Kaplan may have been based on the nature of his conduct, the decision unfortunately clouds, rather than clarifies, important issues. There can be no dispute that Congress did not intend FDA to regulate the practice of medicine via the FDC Act: "Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396.

One of the reasons for this carve out was to recognize there are robust traditional means to redress harms caused by physicians, either through state medical boards or medical malpractice suits. Here, the matter was appropriately referred to the Nevada State Board of Medical Examiners, which took action to suspend Dr. Kaplan's license to practice medicine (the license was later reinstated by stipulation, but a new amended complaint is pending).

The Ninth Circuit holding, however, criminalizes Dr. Kaplan's practice of medicine via a logically tortuous path by characterizing his use of a device in treating patients as a commercial act (*i.e.*, holding for sale).

The court left open questions such as whether a physician's use of a device in the provision of free medical services or the use of general office equipment to treat a patient would be covered under § 331(k).

The court also dismissed Dr. Kaplan's contention that his actions constituted permissible off-label use under the FDC Act:

> [O]ff-label use does not immunize a physician who uses adulterated products. Though off-label use "allow[s] physicians to prescribe ... lawful drugs for unapproved uses," [citing *Evers*], off-label use of adulterated products is beyond the scope of the privilege. While a physician may exercise professional judgment in the off-label use of unadulterated products, nothing in the FDCA or case law suggests that the use of adulterated products is ever permissible.

Id. at 18-19.

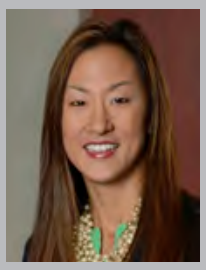
This less-than-clear explanation carries a strong risk of being taken out of context. The court's "bright-line" rule prohibiting the use of adulterated products fails to consider the nuances of the FDC Act, which considers a device adulterated if it has a new intended use for which it is required to, but lacks, pre-market approval. *See* 21 U.S.C. § 351(f).

What the *Kaplan* court should have clarified is that its holding is limited to products that are adulterated under section 351(a)(2)(B) because they were held under insanitary conditions, which is what was charged here, and not because they were adulterated under section 352(f) for being used off-label use (*i.e.*, single use versus reuse). This distinction was discussed at oral argument, but did not work its way into the published opinion.

Presumably if Dr. Kaplan had shown that his protocol worked to sanitize the needle guides, it may not have met the standard for adulteration. Unfortunately, the court's holding may be used by less-discerning audiences to hold a doctor guilty of violating the FDC Act if she uses a device for an off-label purpose.

One final point: FDA's Office of Criminal Investigations recently has come under renewed scrutiny by the media and Congress over its questionable use of resources and investigative practices. Query whether OCI's involvement in this matter, which may have been more appropriately adjudicated by the state medical board and medical malpractice suits, is another example of OCI's misplaced attention. WJ

The Ninth Circuit holding criminalizes Dr. Kaplan's practice of medicine via characterizing his use of a device in treating patients as a commercial act.



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