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Fourth Circuit Ruling Guts the Practice of Medicine Defense in FDA Cases

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Last week, the US Court of Appeals for the Fourth Circuit in *United States v. Jackson*[1] upheld a doctor's conviction under Section 301(k) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 USC § 331(k) (Section 301(k)), for a four-year, $4.7 million Medicare fraud scheme involving repeated use of surgical devices approved for one-time use.

Notably, *Jackson* is the second-ever federal appellate ruling – and the very first since the US Supreme Court's landmark opinion in *Loper Bright Enterprises v. Raimondo*[2] last year – to endorse the government's expansive reading of Section 301(k).[3] That provision criminalizes "[t]he alteration, mutilation, destruction, obliteration, or [label] removal of … a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) … and results in such article being adulterated or misbranded."[4] In addition, *Jackson* newly interpreted the term "legally marketed device" to exclude adulterated devices, which may inadvertently and severely undermine the "practice of medicine" defense dictated by Section 1006 of the FDCA, 21 USC § 396 (Section 1006).

Jackson squarely rejected common defenses asserted by the physician, Dr. Anita Jackson, who argued that her decision to reuse the medical devices at issue:

1. Fell outside Section 301(k)'s criminal prohibition for holding adulterated medical devices for "resale," since she had used the devices solely for bona fide surgeries and had never actually sold any devices to patients.[5]
2. Fit squarely within her expert medical judgment, which Congress expressly placed outside the reach of the FDCA, including Section 301(k).[6]

During the first Trump administration, the US Department of Justice (DOJ) brought record-breaking criminal charges and recoveries for healthcare fraud.[7] Now, with newfound vigor in the wake of *Jackson*, we expect DOJ and the US Food and Drug Administration (FDA) under the second Trump administration to continue aggressively prosecuting fraud involving medical devices by supplementing long-standing enforcement mechanisms with additional charges under Section 301(k).

Key factual background

Jackson was an ear, nose and throat (ENT) surgeon specializing in balloon sinuplasty surgery to treat chronic sinus infections. Balloon sinuplasty surgery involves inserting a medical device – in Jackson's case, the Entellus XprESS – into a patient's nose and inflating a small balloon to widen the nasal cavity. Because it touches a patient's hair and bodily fluid during surgery, FDA had approved marketing of the Entellus for one-time use only, with the expectation that each device would be discarded after a single patient's surgery.

Jackson oversaw multiple offices that performed balloon sinuplasty with reused Entellus devices, and her staff aggressively solicited patients to receive the procedure.[8] She would then bill Medicare and falsely claim reimbursement for the surgery and the full cost of a new Entellus. Through this fraud scheme, Jackson charged Medicare more than $46 million for balloon sinuplasty

surgery; at one point, she was the nation's leading Medicare biller for the procedure.[9]

Crucially, during these surgeries, Jackson and her staff would frequently reuse a single Entellus on multiple patients, cleaning the device each time between surgeries. However, the Entellus was approved by FDA only for one-time use, and so the medical industry had no established practices to adequately sanitize the device for reuse. Indeed, Jackson's staff testified that reused Entellus devices could not be fully sterilized, and that the devices became rusty and difficult to operate over time.[10]

Following a federal grand jury indictment and trial, a jury in the US District Court for the Eastern District of North Carolina convicted Jackson on all 20 counts, including for holding adulterated Entellus devices for sale in violation of Section 301(k), and for making materially false statements in response to Medicare audits.[11] After the court sentenced her to 25 years in prison and more than $5.7 million in restitution, Jackson appealed the verdict.

The Fourth Circuit's opinion in *Jackson*

Jackson focused her appeal on challenging her Section 301(k) conviction as beyond the scope of the FDCA, and further asserted that her conviction on that count prejudicially tainted the jury's verdict on the remaining 19 counts. She raised two primary arguments against the government's broad interpretation of its Section 301(k) prosecutorial authority.

First, Jackson argued that, during her many balloon sinuplasty surgeries, no Entellus device was ever "held for sale (whether or not the first sale)," nor did she ever pass ownership or title of any devices to her patients. Under Jackson's theory, the statute's plain text requires an attempt to sell adulterated devices to sustain a Section 301(k) conviction.

Despite Jackson's failure to preserve this argument below, the Fourth Circuit largely reached the merits by holding that the trial court did not plainly err in determining that Jackson's conduct – soliciting patients for, and profiting from, the procedure using the Entellus – equated to holding them for sale, such that her conduct fell within Section 301(k)'s prohibition.

For support, the Fourth Circuit favorably cited the US Court of Appeals for the Ninth Circuit in *United States v. Kaplan*.[12] *Kaplan*, the first-ever circuit case interpreting Section 301(k)'s held-for-sale requirement, held that Section 301(k)'s held-for-sale requirement is met when the medical device is used in any "commercial relationship between the doctor and the patient."[13] Even as *Jackson* did not need to tackle *Kaplan*'s interpretation of Section 301(k) head on, the Fourth Circuit acknowledged *Kaplan*'s "common-sense persuasiveness," representing the very first time that another circuit has endorsed the Ninth Circuit's broad reading and suggesting it may adopt *Kaplan*'s reading as its own in a future case.[14]

Second, Jackson argued that another section of the FDCA, Section 1006, precludes the government from prosecuting her for reusing Entellus devices for surgeries. Section 1006 exempts from liability actions falling within "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." In Jackson's estimation, reusing a medical device labeled for one-time use in legitimate surgeries merely reflected off-label usage within her discretion as a learned medical practitioner.

The Fourth Circuit disagreed. In its view, Jackson was conflating using a device off label, which may fall within the legitimate practice of medicine, with holding "adulterated" Entellus devices for sale, which is illegal for physicians and non-physicians alike.[15] The jury found that she had failed to adequately sanitize the same Entellus device between different patient surgeries so as to render those devices "adulterated." Moreover, her reuse of "adulterated" Entellus devices could not qualify for Section 1006's exemption because that provision protects physicians only to the extent they prescribe or administer a "legally marketed device" – and FDA had never authorized the marketing or sale of the Entellus for multiple uses. If adopted, the court observed that her reading of the FDCA would "thwart congressional intent and create a huge loophole" that reflexively exempts physicians from otherwise unlawful conduct.

In so doing, *Jackson* appears to have severely undermined, if not eliminated, the "practice of medicine" provision under Section 1006. Specifically, the court's use of the term "adulterated" could be read to mean the Entellus lacked adequate sanitation due to multiple uses on different patients.[16] But "adulterated" also is a term of art under Section 501(f)(1)(B), which provides that a device is "adulterated" if it lacks FDA's marketing authorization for a particular intended use (i.e., an "off-label use"), such as the multiple-use indication at issue in *Jackson*. If the second meaning were adopted, it would essentially gut Section 1006, and healthcare practitioners may not rely on that provision at all, as any "off-label use" would practically render the device "adulterated" and, therefore, prohibited under Section 301(k).

Healthcare fraud enforcement post-*Jackson*

The *Jackson* court's determination that the Entellus was not a "legally marketed device" may embolden the government to reject the "practice of medicine" defense any time a healthcare practitioner uses an approved or cleared device for "off-label uses," under the reasoning that any device that violates the FDCA is not "legally marketed."

So while the Fourth Circuit did not officially adopt the Ninth Circuit's holding in *Kaplan* – namely, that medical providers may be prosecuted pursuant to Section 301(k)'s bar on holding an adulterated medical device for sale whenever it is used to treat patients – it clearly resonated with that expansive reading in rejecting Jackson's arguments to the contrary, including its interpretation of the Section 1006 "practice of medicine" defense.

With DOJ and FDA now armed with two circuit opinions (*Kaplan* and *Jackson*) that have taken an expansive approach to Section 301(k), we anticipate that the government will, alongside its existing arsenal of healthcare fraud enforcement tools, wield criminal penalties under the FDCA against hospitals, private practices and medical providers. As such, industry participants can expect close scrutiny by federal and state enforcers over the use of allegedly adulterated medical devices to perpetuate healthcare fraud.

The prospect of robust healthcare fraud enforcement is particularly salient given the new administration's desire to draw attention to – and curb – alleged waste and abuse by recipients of federal funds. During President Donald Trump's first term, DOJ eagerly pursued healthcare fraud prosecutions, including a nationwide takedown of 345 medical professionals for $6 billion in alleged fraud involving opioids,[17] and the largest individual healthcare fraud scheme in DOJ history.[18]

Jackson presages renewed statutory authority for DOJ and FDA to situate Section 301(k) into future healthcare fraud enforcement efforts, and to test the outer boundaries of the FDCA's criminal prohibitions, including Section 301(k), in the months and years ahead.

Notes

1. No. 23–4467, No. 23-4587, 2025 WL 249109, at *7–8 (4th Cir., January 21, 2025).
2. 603 US 369 (2024); see **US Supreme Court's October 2023 Term Administrative Law Trilogy – Holdings, Analyses and Implications of *Jarkesy*, *Loper Bright* and *Corner Post***, Cooley client alert, July 26, 2024.
3. FDCA § 301(k), 21 USC § 331(k). The first and only other circuit opinion interpreting Section 301(k) is *United States v. Kaplan*, 836 F.3d 1199, 1208 (9th Cir., 2016), as discussed below.
4. 21 USC § 331(k).
5. Id. at *7.
6. Id. at *7–8.
7. See, e.g., DOJ press release, **National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over $2 Billion in Fraud Losses**, June 28, 2018.

8. The Fourth Circuit explained that Jackson implemented quotas, incentives and other unorthodox methods to prescribe and administer the surgery. Her former employees testified that she instructed them to recruit patients in Walmart parking lots, churches, barbershops and doctors' offices (*Jackson*, 2025 WL 249109, at *2). To increase the number of sinuplasty surgeries performed, she often skipped routine diagnostics to determine whether it was medically appropriate, and she misled patients into believing that the surgery was simply a "sinus spa" or "sinus rinse" (Id.). Then, to cover up her conduct, she submitted false, incomplete and altered records to the government, including some bearing fake notarizations and forged patient signatures (Id. at *3).
9. DOJ press release, **Raleigh ENT Doctor Sentenced to 25 Years in Prison for Adulterating Surgical Devices, for Defrauding Medicare, and for Stealing Patient Identities**, June 16, 2023.
10. Id.
11. See 21 USC § 331(k); 18 USC §§(a)(2); and DOJ press release, **Raleigh ENT Doctor Sentenced to 25 Years in Prison for Adulterating Surgical Devices, for Defrauding Medicare, and for Stealing Patient Identities**, June 16, 2023.
12. 836 F.3d 1199, 1208 (9th Cir., 2016).
13. Id.
14. 2025 WL 249109 at *6–*7.
15. 2025 WL 249109 at *18.
16. 2025 WL 249109 at *13 (discussing the term "adulterated" in the context of "unsanitary conditions").
17. DOJ press release, **National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over $2 Billion in Fraud Losses**, June 28, 2018.
18. DOJ press release, **South Florida Health Care Facility Owner Sentenced to 20 Years in Prison for Role in Largest Health Care Fraud Scheme Ever Charged by The Department of Justice**, September 12, 2019.

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