Cooley

Proceed With Caution: Federal Courts of Appeal Uphold Criminal Convictions for Misbranding Violations Under FDCA

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Voluntary compliance may be the backbone of the Federal Food, Drug, and Cosmetic Act (FDCA), but when the US government believes that a company is unwilling or unable to achieve compliance, it will seek to enforce the FDCA both civilly and criminally. Two recent cases reaffirm that the federal government will not hesitate to **criminally** prosecute misbranding violations under the FDCA – and that such convictions are difficult to challenge on appeal.

In September 2023, **the US Court of Appeals for the Ninth Circuit upheld a felony conviction for selling misbranded drugs**, holding that the version of the offense that applies to repeat offenders does not require proof that the defendant **knew** the drugs were misbranded. And in December 2023, **the US Court of Appeals for the First Circuit upheld multiple misdemeanor convictions** related to an adulterated and misbranded medical device. Perhaps most importantly, the First Circuit held that the convictions did not violate the First Amendment, even though the defendants asserted that the government relied on promotional speech to prove its case.

The upshot of these cases is that companies and executives should be vigilant about compliance with the FDCA – and mindful that criminal enforcement may follow any failure to voluntarily comply.

Federal Food, Drug and Cosmetic Act

The FDCA was enacted in 1938, and amended numerous times since then, to protect the public health. Key provisions of the FDCA include:

- **Section 331(a)**, which prohibits the introduction of any adulterated or misbranded device or drug (among others) into interstate commerce.
- **Section 333(a)(1)**, which provides that any person who violates Section 331 may be imprisoned for up to one year and/or fined.
- **Section 333(a)(2)**, which provides that any person who violates Section 331 **with** the intent to defraud or mislead or who repeatedly violates Section 331 (both of which are felonies) may be imprisoned up to three years and/or fined.

Executives also should take note that under the Responsible Corporate Officer Doctrine (also known as the "RCO Doctrine" or "*Park* Doctrine"), individual corporate officers may be held liable for violations of federal laws, even without the officer's intent, knowledge or direct participation in the wrongdoing, as long as the officer had the power and authority to prevent or correct the violation. This "strict liability" theory applies to cases against executives operating in US Food and Drug Administration-regulated industries – including against executives at food, pharmaceutical and medical device companies – for FDCA violations that occur on their watch. The potential consequences include, but are not limited to, monetary penalties, probation, and imprisonment.

Ninth Circuit holds scienter not required for felony misbranding convictions

In ***US v. Marschall***, the defendant – a naturopathic doctor previously convicted in 2017 for selling misbranded drugs – claimed that two products (the "Dynamic Duo") could treat a myriad of bacterial, viral, fungal and parasitic infections, including COVID-19. Neither one of the "Dynamic Duo" was listed with the FDA or had been approved by the FDA, nor were the drugs exempted from receiving approval as new drugs. The indictment alleged that the labels were false or misleading because the defendant misrepresented himself as a naturopathic doctor on the labels, but in fact his ND license had been suspended after his 2017 conviction. The indictment further alleged that the drugs were misbranded because they were "not included in any list of drugs manufactured, prepared, propagated, compounded, and processed in a registered establishment" per the drug producer registration requirements of the FDCA. The defendant was indicted on the charge of introducing misbranded drugs into interstate commerce after a prior conviction under Section 333(a)(2). After a jury trial, he was found guilty and sentenced to eight months in prison and one year of supervised release.

On appeal, the defendant argued that the indictment was defective because it failed to allege that he **intentionally and**

knowingly introduced misbranded drugs into interstate commerce (i.e., that he acted with scienter). The Ninth Circuit rejected this argument, holding that the aggravated version of the offense that applies to recidivists under Section 333(a)(2) does **not** require proof of scienter, even though it is a felony.

No language imposing scienter requirement in underlying prohibition or penalties provision

The court first closely examined the language of various related provisions, including Section 331, and found that none contained a scienter requirement. The court noted that the relevant definition of "drug" "arguably **could** be understood" to refer to the defendant's state of mind, because it referenced the "intended" use of the article. However, the court determined that this was in fact an **objective** inquiry into the article's likely use, given its features and labeling, rather than a subjective scienter requirement. Similarly, the court found that the relevant penalties provision – Section 333(a)(2) – contained no reference to scienter.

No scienter required for public welfare offense

In perhaps the most notable aspect of the Ninth Circuit's ruling, the court applied the framework established in ***US v. Dotterweich***, the seminal case in which the US Supreme Court held that the defendant's conviction involving misbranded and adulterated drugs did not require evidence of wrongdoing or even knowledge of such wrongdoing for executives operating in FDA-regulated industries, given the potential harm to the public health. In essence, the Supreme Court acknowledged a limited category of strict liability "public welfare offenses" involving items that could harm or injure the public (who otherwise would be helpless to defend against such danger). While *Dotterweich* had been confined to a limited scope – with the presumption of scienter being used only for public welfare cases with "minor penalties" – *Marschall* is significant in applying the presumption to a **felony** charge. The Ninth Circuit extended *Dotterweich* in this way partially because the recidivist provision applies only to those who have a previous conviction under Section 333 and thus are "personally aware" of the FDCA's requirements. As the court explained, "a prior criminal conviction under § 333 effectively serves as a functional substitute for a scienter requirement."

First Circuit rejects First Amendment, due process challenges to misbranding convictions

Misbranding also was at issue in ***US v. Facteau***. In that case, two former executives of medical device manufacturer Acclarent were found guilty of multiple misdemeanor violations for commercially distributing an adulterated and misbranded medical device. Under the FDCA, a device is adulterated or misbranded if it is marketed for an "intended use" (determined "objectively by the seller's statements and conduct") that is different from the use authorized by the FDA. Here, the FDA initially cleared Acclarent's device, referred to as "Stratus," for the purpose of dispensing saline solution to the ethmoid sinuses and preserving an opening created by sinus surgery. In contrast, the government presented evidence at trial that Acclarent designed – and later marketed – Stratus for use with the steroid drug Kenalog to treat ethmoid sinusitis by reducing sinus inflammation, an "off-label" (or unapproved) use. The FDA previously had denied Acclarent's request to expand the device's existing cleared intended use to accommodate this new intended use, directing the company to obtain a new, separate clearance before marketing the device for this different intended use.

According to the First Circuit, the record reflected "a scheme that from the beginning was aimed at marketing Stratus to deliver Kenalog rather than saline." With respect to design, the evidence reflected that the size of Stratus's pores had been calibrated to accommodate Kenalog's specific viscosity – meaning that Stratus did not even work to deliver saline, which is much less viscous and would rapidly seep out. With respect to sales, the government introduced evidence that Stratus "was promoted with a sales strategy devised to get physicians to associate Stratus with Kenalog and consider using it for drug delivery." For example, sales trainees were not taught or given marketing materials for Stratus describing benefits of use with saline, and instead focused on the off-label uses related to Kenalog.

After a jury trial, Acclarent's former CEO and former vice president of sales were convicted of 10 misdemeanor counts for distributing an adulterated and misbranded device by failing to submit a required premarket notification under 21 U.S.C. §§ 331(a), 333(a)(1), 351(f) and 352(o). The defendants challenged their convictions on appeal, arguing (among other things) that the convictions violated the First and Fifth Amendments.

First Amendment does not preclude use of speech as evidence of intended use

The defendants challenged the government's use of their promotional speech as evidence to support a misbranding violation, arguing that such use effectively criminalizes the speech itself in violation of the First Amendment.

In 1993, the Supreme Court ruled in ***Wisconsin v. Mitchell*** that the First Amendment does not generally apply to the "evidentiary use of speech to establish the elements of a crime or to prove motive or intent." However, the *Facteau*

defendants relied on a 2012 Second Circuit ruling (***US v. Caronia***), where the court held that a misbranding conviction violated the First Amendment. In that case, "the prosecution repeatedly argued that engaged in criminal conduct by promoting and marketing the off-label use of an FDA-approved drug." In other words, the defendant's "speech was **itself** the proscribed conduct" (emphasis added).

In the wake of *Caronia*, many questioned whether and how the government could use a defendant's statements about the intended use of a drug or device as evidence of misbranding. But in *Facteau*, the First Circuit distinguished *Caronia* and relied on the Supreme Court's seminal holding that the evidentiary use of speech does not violate the First Amendment. The First Circuit held that the facts of *Caronia* were "meaningfully different" from *Facteau*, including that, unlike in *Caronia*, the government relied on "a wide array of evidence," not just the promotional speech. As the court explained, the government's evidence included "not only promotional speech about off-label uses but also internal communications regarding regulatory and marketing strategy and the product's physical design."

Additionally, in *Facteau*, the government's argument and court's instructions made clear that the defendants' speech **itself** was not the target, but was only being used to "shed light" on how the defendants intended Stratus to be used. In contrast, in *Caronia*, "the government set out to punish appellants for what they said about the product." The court also observed that the theory of misbranding adopted by the jury – that Stratus lacked the appropriate regulatory clearance – was not "intertwined" with the defendants' speech. Finally, the court noted that unlike Caronia (who was a sales representative), the two defendants in *Facteau* were "high-level executives" who were "responsible not just for what was said about Stratus publicly but also for internal decisions on product design and regulatory strategy (in the case of Facteau), as well as sales strategy (in the case of both executives)," implicitly raising the RCO Doctrine.

Having identified the ways in which the facts of *Facteau* differed "meaningfully" from *Caronia*, the court held that there was "no basis to depart from the rule in *Mitchell* that the evidentiary use of speech does to violate the First Amendment." The court further noted that its holding aligned with rulings from other federal courts of appeal (including the Second, Seventh, and DC Circuits), which similarly held that "using speech merely as evidence of a misbranding offense under the FDCA does not raise First Amendment concerns."

'Intended use' not unconstitutionally vague

The defendants also argued that their convictions violated the Fifth Amendment's due process clause, claiming that the phrase "intended use" is unconstitutionally vague because it may take into account "all circumstances from any relevant source relating to the device." This, too, was rejected by the First Circuit, which held that the provision gives fair notice of what is forbidden. As the court explained, the provision is not unconstitutionally vague simply because it casts a "wide net" as to the "broad range of conduct that may reasonably reflect a device's intended use."

The court also rejected a related due process challenge, which the court characterized as a "fair warning" claim. In short, one defendant argued that after *Caronia* was decided, the government expanded its definition of intended use to go beyond promotional statements, given that *Caronia* may have made it more difficult to "carry a conviction based on promotional statements alone." However, the defendant argued that he lacked notice of this "novel and more expansive interpretation" at the time of his conduct, which took place before *Caronia*. In response, the First Circuit explained that before *Caronia*, neither the government nor the courts were limited to proving or determining intended use **only** through promotional speech, and thus there was no broadening **after** *Caronia* – in other words, before and after *Caronia*, the authorities reflect that "relevant evidence of intended use can come from many sources," not just promotional statements. Additionally, the court observed that the defendants received actual notice of their legal obligations when the FDA responded to Acclarent's supplemental submission to the company's 510(k) file notifying the company that it needed to receive additional clearance to market Stratus for the new and different use. As the First Circuit explained, "aving been notified of the government's view, complaint of unfair surprise at being prosecuted for marketing Stratus to deliver Kenalog despite Acclarent's failure to obtain such approval rings hollow."

Takeaways

Taken together, these cases reaffirm that companies and executives should be vigilant about voluntary compliance with the FDCA. If compliance is not achieved, the government may very well pursue criminal prosecution – which, under the RCO Doctrine, may include liability for individual corporate officers, even when those officers were not directly involved in the wrongdoing.

Going forward, individuals and companies should be aware of the risk of felony charges without criminal intent. Under *Marschall*, the aggravated version of a misbranding offense that applies to recidivists under Section 333(a)(2) does **not** require proof of scienter, even though it is a felony with severe penalties. As the Supreme Court explained in *Dotterweich*

– and as the Ninth Circuit wholeheartedly agreed – though "ardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting," the onus to comply with the FDCA falls on those companies and individuals who have the opportunity to protect consumers, "rather than to throw the hazard on the innocent public who are wholly helpless."

Likewise, *Facteau* clarifies that the government can use truthful, non-misleading speech as evidence of an unapproved intended use without violating the First Amendment, and intended use can be determined from "any relevant source" of evidence. With this ruling in the First Circuit, life sciences companies located in Maine, Massachusetts, New Hampshire, Puerto Rico and Rhode Island, where this ruling is controlling, should pay particular attention to their compliance practices, including training for their sales forces, given that sales force activity may be introduced as evidence of intended use for a company's FDA-regulated medical products.

United States v. Marschall, No. 22-30048 (9th Cir. Sept. 20, 2023).

United States v. Facteau, No. 21-1080 (1st Cir. Dec. 14, 2023).

21 U.S.C. § 333(a)(1). Fines under Section 333 follow the Alternative Fines Act. See18 U.S.C. § 3571(d).

United States v. Park, 421 U.S. 658 (1975).

See Plea Agmts., *United States v. The Purdue Frederick Co. et al*., No. 07-00029 (W.D. Va. May 10, 2007).

This doctrine has been applied in cases such as ***US v. Quality Egg***, where two food executives were **sentenced to three months in prison and fined $100,000 each**.

21 U.S.C. § 352(a)(1).

21 U.S.C. § 352(o).

The court expressly invoked the RCO Doctrine when analyzing a separate sufficiency of the evidence claim brought by *Facteau* defendant Patrick Fabian. The court held that the record was "replete" with the relevant evidence, then further explained that "even in the absence of evidence specifically tying Fabian to the strategy of marketing Stratus to deliver Kenalog," the jury verdict would stand under *Park* because as vice president of sales, Fabian was "well-situated to prevent or correct the marketing of adulterated and misbranded Stratus."

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