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'The Basics of FDA Enforcement Actions,' by James Fraser and Krupa Patel

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Introduction

Under the Food, Drug, and Cosmetic Act (FDCA), the federal government may bring several different types of enforcement actions against drug and medical device companies (and other FDA-regulated companies) for alleged violations of the FDCA. This article provides an overview of such actions.

Section 301 of the FDCA

Any FDA enforcement action must be based on an allegation that a party committed one or more of the "prohibited acts" listed in Section 301 of the FDCA [21 U.S.C. § 331]. Section 301 prohibited acts are too numerous to list here. But frequently alleged prohibited acts include the interstate distribution of "adulterated" or "misbranded" foods, drugs (including biologics), medical devices, cosmetics, and tobacco products. *See* 21 U.S.C. § 331(a).

Other product-specific sections of the FDCA define "adulterated" and "misbranded."*See, e.g.*, 21 U.S.C. §§ 351 (adulterated drugs and devices), 352 (misbranded drugs and devices).[i] Those product-specific sections are themselves quite lengthy and list several different bases upon which a product can be deemed adulterated or misbranded. For example, a drug is deemed to be adulterated if it is not manufactured in accordance with FDA's current good manufacturing practice (cGMP) regulations for drugs.[ii]

Opportunity for Corrective Action

Before it pursues an enforcement action, the FDA typically gives the allegedly offending party an opportunity to voluntarily bring its conduct into compliance with the law. *See* FDA Regulatory Procedures Manual, Chapter 4, at 3 (Jun. 2022) (noting that in most situations "it is [FDA's] practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action").

The issuance of a "Warning Letter is the agency's principal means of achieving prompt voluntary compliance."*Id.* But FDA cautions that it "is under no obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action." *Id.*[iii]

Civil Money Penalties

The FDCA provides for civil money penalties (CMPs) for certain prohibited acts. For example, any prohibited act with respect to a medical device can result in a CMP of up to $31,076 per act, not to exceed $2,071,819 for all such acts adjudicated in a single proceeding.[iv] Some, but not all, prohibited acts relating to drugs can result in a CMP. See, e.g., 21 U.S.C. § 333(g)(1) (CMP for false or misleading DTC advertising of approved drugs and biologics).

FDA's regulations for CMP hearings provide a list of the FDCA's CMP provisions. See 21 C.F.R. § 17.1. Although most FDA CMP actions in recent years have related to tobacco products, FDA has pursued CMP actions related to medical products.[v]

Unlike all other FDCA enforcement actions (discussed below), CMP actions are neither initiated by the Department of Justice (DOJ) nor

brought in a district court. Instead, the FDA Office of the Chief Counsel files a complaint on behalf of the relevant FDA product center (e.g., the Center for Devices and Radiological Health) with the Civil Remedies Division of the HHS Departmental Appeals Board (DAB). 21 C.F.R. § 17.5. If the respondent demands a hearing, the case is litigated before a DAB administrative law judge. 21 C.F.R. § 17.9. A final decision by the DAB may be appealed to the D.C. Circuit or the respondent's home circuit. *See, e.g.*, *Orton Motor, Inc. v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).[vi]

Injunctions

Section 302(a) of the FDCA [21 U.S.C. § 332(a)] provides that district courts may enter injunctions "to restrain violations of section 301." Injunction actions are FDA's preferred judicial enforcement tool.

A typical FDCA injunction puts conditions on the defendant's ability to continue its operations. Such conditions normally include, among others, that (1) defendant cease operations until an independent expert (paid for by defendant) certifies to FDA that defendant has taken steps sufficient to bring its operations into compliance with the law; (2) after defendant resumes operations, an independent auditor (paid for by defendant) conducts periodic audits of defendant and certifies to FDA that defendant is still in compliance with the law; and (3) any time after defendant resumes operations, FDA may order defendant to cease operations if the agency finds defendant has again violated the FDCA.[vii] A defendant who violates an FDCA injunction may be prosecuted for contempt of court, with a maximum penalty of six months imprisonment and a maximum fine of $1,000.00. *See* 18 U.S.C. § 402.

Although section 302 does not mention disgorgement of profits or restitution to consumers, some circuits have held that courts issuing FDCA injunctions have the authority to order disgorgement and restitution. *See, e.g., United States v. RxDepot, Inc*., 438 F.3d 1052, 1058 (10th Cir. 2006) (disgorgement); *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 229 (3d Cir. 2005) (restitution). That said, FDA does not routinely seek disgorgement or restitution. Moreover, in 2021 the Supreme Court held that courts issuing injunctions under the Federal Trade Commission Act do not have the authority to order disgorgement or restitution. *See AMG Capital Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1344 (2021). So, defendants in any future cases where FDA seeks disgorgement or restitution awards will likely argue that AMG Capital precludes such awards.[viii]

Because only DOJ can represent FDA in court, see 28 U.S.C. § 516, FDA must rely on DOJ to initiate injunction actions (and the other enforcement actions discussed below). When the FDA wants to pursue an injunction action, the FDA Office of the Chief Counsel sends a referral package to DOJ's Consumer Protection Branch (CPB). The referral package includes a detailed memorandum outlining the evidence and proposed "charges" (*i.e.*, the defendant's prohibited acts), a draft complaint, and a draft "consent decree" (more on consent decrees below).

DOJ is under no obligation to grant FDA's request to initiate an enforcement action*See Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 599 (1950) ("Whether [an FDA enforcement action] will be instituted depends on the Attorney General, not on [FDA]. He may or may not accept the agency's recommendation *** [and these] suits are dependent on the discretion of the Attorney General.").[ix]

When DOJ agrees to pursue an FDA injunction action, lawyers in FDA's Office of the Chief Counsel work closely with DOJ in pursuing that action. DOJ's typical first step is to send defendant a "sign-or-sue" letter that asks defendant to agree to enter into a "consent decree" of permanent injunction. A consent decree is settlement agreement between the parties that is incorporated into a district court order; the court retains jurisdiction over the case after it enters the order.[x] Unlike typical settlement agreements between two private parties, the terms of a consent decree are public.

The government's proposed consent decrees normally include all (if not more) of the injunction terms the government would seek if it tried the case to verdict. FDA will usually negotiate with defendant over some of the terms of the consent decree. But the FDA will rarely (if ever) agree to terms that permit defendant to resume operations before FDA determines the defendant has brought its products into compliance with the law.

Most defendants in FDA injunction actions eventually agree to a consent decree. When a defendant does not agree to a consent decree, the government bears the burden to establish (either via a summary judgment motion or at a bench trial), that "there exists some cognizable danger of a recurrent violation." *United States v. Laerdal Mfg. Corp*., 73 F.3d 852, 854 (9th Cir. 1995) (quoting United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953)). A court may consider multiple factors in deciding whether such a danger exists.[xi]

Seizures

Section 304 of the FDCA [21 U.S.C. § 334] provides that district courts may order the seizure and condemnation (i.e., destruction) of violative products. At one time, FDA frequently used this enforcement tool. However, FDA has brought very few seizure actions in the past few years.[xii]

FDA refers seizure actions to the United States Attorney's office for the district in which the products at issue are located. Seizures are carried out by the U.S. Marshals Service.

In any seizure action, the owner of the seized products has the right to litigate the issue of whether the products violate the FDCA. Seizure actions can be decided on a motion for judgment on the pleadings or a motion for summary judgement. *See, e.g., United States v. 286,161 Bottles,* No. 19 C 3876, 2021 U.S. Dist. LEXIS 84754, *8-10 (N.D. Ill. May 4, 2021) (granting judgment on the pleadings for the government because the owner's answer to the complaint conceded that the products at issue—dietary supplements—were adulterated). If the case is not resolved via motion, the product owner is entitled to a jury trial on factual issues. See 21 U.S.C. § 334(b).[xiii]

Criminal Prosecutions

Section 303 of the FDCA [21 U.S.C. § 333] authorizes a misdemeanor conviction for any section 301 prohibited act. See 21 U.S.C. § 333(a)(1) ("Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both."). Section 303 also authorizes felony convictions for various prohibited acts. See, e.g., 21 U.S.C. §§ 333(a)(2) (three years in prison and/or $10,000 fine for committing prohibited act "with intent to defraud"), 333(b)(1)(B) (ten years in prison and/or $250,000 fine for knowingly selling a drug sample).

Under the *Park* doctrine, high-level corporate officials may be subject to a misdemeanor conviction for prohibited acts occurring within the company even if such officials were unaware of the prohibited acts. *See United States v. Park*, 421 U.S. 658 (1975).

FDA's Office of Criminal Investigations (OCI) investigates potential FDCA criminal cases, often in coordination with other federal law enforcement agencies. FDA refers criminal cases to the relevant United States Attorney's Office for potential prosecution.

Where to Find More Information

FDA has several publications (all available on FDA's website) that provide information relevant to enforcement matters. Those publications include the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, and FDA guidance documents.

Endnotes

[i] *See also* 21 U.S.C. §§ 342 (adulterated food), 343 (misbranded food), 361 (adulterated cosmetics), 362 (misbranded cosmetics), 387b (adulterated tobacco products), 387c (misbranded tobacco products).

[ii] 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Parts 210 and 211.

[iii] The FDCA authorizes FDA to issue Warning Letters. *See* 21 U.S.C. § 336.

[iv] *See* 21 U.S.C. § 333(f)(1)(A); 45 C.F.R. § 102.3 (adjusting CMP amounts for inflation).

[v] *See Center for Devices and Radiological Health v. Alzate*, No. C-14-867, 2014 HHSDAB LEXIS 537 (Sept. 30, 2014).

[vi] The Supreme Court recently granted cert. on the issue of whether the SEC's administrative CMP process violates the Seventh Amendment right to a jury trial. *See Securities and Exchange Commission v. Jarkesy*, S. Ct. Case No. 22-859, order granting cert. (Jun. 30, 2023). Depending on the outcome of that case, FDA may face constitutional challenges to its CMP regulations.

[vii] *See, e.g., United States v. Innovative BioDefense, Inc*, 2020 U.S. Dist. LEXIS 155959 (C.D. Cal. May 4, 2020) (Order of Permanent Injunction).

[viii] See C. Roberts, *Statutory Interpretation and Agency Disgorgement Power*, 96 ST. JOHN'S L. REV. 243, 269 (2022) ("If the FDA pursues an aggressive disgorgement posture, then the FDA's use of disgorgement would be ripe for Supreme Court review.").

[ix] FDA's Freedom of Information Act (FOIA) regulations provide that if DOJ denies an FDA request to initiate an enforcement action, FDA's written correspondence with DOJ regarding the request (including the draft complaint) may be obtained via a FOIA request. See 21 C.F.R. § 20.102(b).

[x] *See generally Johnson v. Lodge # 93 of FOP*, 393 F.3d 1096, 1101 (10th Cir. 2004); *Beckett v. Air Line Pilots Ass'n*, 995 F.2d 280, 286 (D.C. Cir. 1993).

[xi] Those factors include, among others, "the degree of scienter involved" in defendant's violations, "the isolated or recurrent nature" of defendant's violations, and "the defendant's recognition of the wrongful nature of his conduct." *Laerdal Mfg. Corp.*, 73 F.3d at 854-55.

[xii] FDA has a website (separate from fda.gov) on which it posts data regarding its inspection and enforcement activities. According to that website, the government conducted one FDCA seizure in 2018, two in 2019, none in 2020, two in 2021, none in 2022, and none to date in

2023. *See*https://datadashboard.fda.gov/ora/cd/complianceactions.htm (last accessed Sept. 1, 2023).
