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Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues

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February 9, 2018

Congressional Research Service
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www.crs.gov
R43609

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

In an increasingly interconnected world, public health concerns and crises have domestic and international implications. In the United States, the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act or the Act) promotes public health by preventing fraudulent activity with respect to food, drugs, and an array of other public health products that enter interstate commerce. Indeed, the Act's primary purpose is to "safeguard" and "protect" consumers from exposure to dangerous products affecting public health and safety. The FD&C Act does this by regulating covered articles from their introduction into interstate commerce to their delivery to the ultimate consumer. This report provides an overview of the FD&C Act, answers frequently asked questions about the Act's enforcement, and discusses the Act's various civil and criminal enforcement provisions.

The FD&C Act is the main federal law regulating the safety of most foods, food additives, color additives, dietary supplements, prescription and non-prescription drugs, medical devices, cosmetics, and tobacco products. While the Act regulates a host of disparate products, it generally prohibits two basic acts: "adulteration" and "misbranding." Specifically, FD&C Act Section 301 makes it illegal to distribute directly or indirectly a covered product in interstate commerce that is adulterated or misbranded. The Act defines the terms "adulteration" and "misbranding" with respect to specific products.

The FD&C Act is chiefly enforced by the U.S. Food and Drug Administration (FDA), an agency whose general mission is to promote and protect the public health by ensuring the safety, efficacy, and truthful labeling of the products it regulates. FDA enforces the Act through administrative mechanisms, such as pre-market reviews of certain products, examinations and investigations, and dissemination of information to the public. While primarily focused on interstate commerce, FDA's authority extends to intrastate activities that have a nexus with interstate commerce and concern a product that the Act covers. Supreme Court precedent recognizes that FDA enjoys significant discretion over enforcement of most FD&C Act provisions. Because FDA, like most executive agencies, does not have independent litigating authority, it must coordinate with the Department of Justice (DOJ) to pursue criminal or civil remedies. In addition to DOJ, other federal agencies play a role in enforcing discrete parts of the Act; private parties, however, do not have rights to enforce the FD&C Act through lawsuits.

For serious FD&C Act violations, the FDA, in coordination with DOJ, has a wide range of civil and criminal remedies. For example, the FD&C Act authorizes the government to sue violators of the Act in court in order to punish or prevent future violations. Such civil actions include imposing money penalties, injunctions, and seizures. Other enforcement actions include warning letters, import alerts, recalls, and debarments. For extremely serious violations, FDA and DOJ may collaborate to bring criminal charges. A criminal violation of the FD&C Act does not require that the perpetrator have a "guilty mind." Intentional or repeated violations of the Act may result in multiple years of imprisonment and significant criminal fines.

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Introduction

In an increasingly interconnected world, public health concerns and crises have domestic and international implications. In 2015, a salmonella outbreak associated with cucumbers imported from Mexico affected 907 people in 40 states, causing 6 deaths;[1] while an October 2012 outbreak of fungal meningitis caused by steroid injections prepared at a Massachusetts compounding pharmacy resulted in over 60 deaths.[2] In another incident, counterfeit Heparin imported from China in 2008 resulted in at least 80 deaths in the United States, and contaminated products in at least 10 other countries' drug supplies.[3] Beyond preventing public health crises, Congress has a strong interest in ensuring that products consumed by Americans work as intended and are truthfully labeled.[4]

The Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act or the Act) promotes national public health by preventing fraudulent activity with respect to food, drugs, and an array of other public health products.[5] The FD&C Act and its implementing regulations contain standards to protect and promote public health, including requirements for prescription drug approval[6] and food safety.[7] Providing an overview of the Act's enforcement, this report discusses the Act's civil and criminal provisions and enforcement mechanisms.

Overview of the Food, Drug, and Cosmetic Act

The FD&C Act regulates most foods,[8] food additives,[9] color additives,[10] dietary supplements,[11] prescription and non-prescription drugs,[12] medical devices,[13] cosmetics,[14] and tobacco products[15]

[1] CDC, MULTISTATE OUTBREAK OF SALMONELLA POONA INFECTIONS LINKED TO IMPORTED CUCUMBERS, https://www.cdc.gov/salmonella/poona-09-15/index.html (last visited Nov. 16, 2017).

[2] CDC, Multistate Fungal Meningitis Outbreak Investigation—Current Case Count (2015) https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html.

[3] *See* THE PARTNERSHIP FOR SAFE ONLINE PHARMACIES, COUNTERFEIT HEPARIN BLAMED FOR WORLDWIDE DEATHS (Aug. 30, 2009), http://www.safemedicines.org/2009/08/counterfeit-he.html; *see also* Ed Edelson, *Report Confirms Source of Contaminated Heparin*, WASH. POST (Dec. 3, 2008), http://www.washingtonpost.com/wp-dyn/content/article/2008/12/03/AR2008120302758.html.

[4] United States v. Lee, 131 F.2d 464, 466 (7th Cir. 1941) (noting Congress's interest in promoting public health and preventing fraud).

[5] 21 U.S.C. §§ 301, *et seq*.

[6] CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by (name redacted)

[7] CRS Report RS22600, *The Federal Food Safety System: A Primer*, by (name redacted)

[8] The FD&C Act generally defines the term "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f).

[9] The FD&C Act generally defines the phrase "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food ... if such substance is not generally recognized ... to be safe under the conditions of its intended use." *Id*. § 321(s).

[10] The FD&C Act generally defines the phrase "color additive" as "a material which–(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.... " *Id.* § 321(t).

[11] The FD&C Act generally defines the phrase "dietary supplement" to mean "a product ... intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
(continued...)

for safety.[16] Congress enacted the FD&C Act in 1938,[17] acting pursuant to its constitutional authority to regulate interstate commerce.[18] The Act's primary purpose is to "safeguard" and "protect" consumers from "dangerous products" affecting public health and safety by regulating covered articles from the "moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer."[19] The FD&C Act is enforced through a variety of measures such as formal and informal administrative actions, criminal and civil penalties, injunctions, recalls, and/or seizures of FD&C Act-covered goods.[20]

Though the FD&C Act has been "substantially amended since 1938," the Act "still retains its basic structure."[21] The "heart of the enforcement provisions of the" FD&C Act is Section 301, which enumerates specific prohibited acts.[22] The FD&C Act prohibitions have been described as "a catalogue of definitions elaborating two basic concepts: 'adulteration' and 'misbranding.'"[23] Section 301 generally makes it illegal to distribute directly or indirectly a covered product in

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(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical;
(D) an amino acid;
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." *Id*. § 321(ff).

[12] The FD&C Act generally defines the term "drug" as " (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)." *Id*. § 321(g).

[13] The FD&C Act generally defines the term "device" as "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is - (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." *Id*. § 321(h).

[14] The FD&C Act generally defines the term "cosmetic" as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." *Id*. § 321(i).

[15] The FD&C Act generally defines the term "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id*. § 321(rr).

[16] For a general description of the scope of products regulated under the FD&C Act, see PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, FOOD AND DRUG LAW 12-16 (Foundation Press, 3d ed. 2007).

[17] Pub. L. No. 75-717, 52 Stat. 1057 (1938).

[18] Hipolite Egg Co. v. United States, 220 U.S. 45, 57 (1911) (noting that the Pure Food and Drug Act of 1906, the precursor to the FD&C Act, rested "upon the power of Congress to regulate interstate commerce").

[19] United States v. Sullivan, 332 U.S. 689, 696 (1948).

[20] *See infra* "Civil Enforcement of the FD&C Act."

[21] *See* Diana R. H. Winters, *Not Sick Yet: Food-Safety-Impact Litigation and Barriers to Justiciability*, 77 BROOKLYN L. REV. 905, 911 (2013).

[22] *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1196. Section 301 is codified at 21 U.S.C. § 331.

[23] *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 13.

interstate commerce that is "adulterated" or "misbranded."[24] The FD&C Act "ascrib[es] the labels 'adulterated' or 'misbranded' to products whose composition, production or labeling fails" to meet the Act's substantive requirements.[25] For example, the FD&C Act deems a "food" adulterated if it has been held under "insanitary conditions,"[26] and a "drug" misbranded if its label does not contain the "name and place of business of the manufacturer, packer, or distributor."[27] The language of the FD&C Act is "purposefully broad,"[28] providing the executive branch significant discretion over implementing rules and guidelines.[29] **Table 1** notes FD&C Act sections that identify when a particular product can be deemed "adulterated" or "misbranded."

Table 1. Adulteration and Misbranding Provisions of the FD&C Act

Article Regulated	FD&C Act Section	Adulteration	Misbranding
Food & Food Additives	402	X	
Food & Food Additives	403		X
Infant Formula	412	X	
Dietary Supplements	413	X	
Dietary Supplements	403(s)		X
Drugs & Devices	501	X	
Drugs & Devices	502		X
Cosmetics	601	X	
Cosmetics	602		X
Tobacco Products	902	X	
Tobacco Products	903		X

Source: 21 U.S.C. §§ 301 *et. seq.*

General Questions About the Enforcement of the FD&C Act

This section answers several basic and overarching questions about the Act's enforcement.

Who Enforces the FD&C Act?

Established under FD&C Act Section 1003, the U.S. Food and Drug Administration (FDA) is the primary agency that administers and enforces the Act.[30] Generally, FDA's mission is to promote and protect public health by ensuring the safety, efficacy, and truthful labeling of products subject

[24] *See* 21 U.S.C. § 331(a)-(c).

[25] *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 13.

[26] 21 U.S.C. § 342(a)(4).

[27] *Id.* § 352(b)(1).

[28] *See* JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 6.1 (2d ed. 2005).

[29] 21 U.S.C. § 371 (providing the Secretary of Health and Human Services with "the authority to promulgate regulations for the efficient enforcement of" the FD&C Act).

[30] 21 U.S.C. § 393(a).

to the Act.[31] Consistent with this mission, FDA is statutorily empowered to provide administrative guidance on the FD&C Act's broad mandates[32] and to enforce the Act through administrative actions. For example, before certain articles may lawfully be sold in interstate commerce, FDA must rigorously review them to ensure that they meet certain standards, such as being safe and effective for their intended use.[33] In addition to such pre-market authority, FDA also possesses significant post-market authority to monitor regulated products that have entered interstate commerce to ensure the product continues to adhere to the Act.[34] For example, the Act empowers FDA to request information from pharmaceutical manufacturers,[35] to inspect food producer facilities,[36] or to order recalls of medical devices that may cause "serious, adverse health consequences."[37] The FD&C Act also authorizes FDA to "conduct examinations and investigations" to administer the Act,[38] to disseminate information about regulated products involving "imminent danger to health" or "gross deception to the consumer,"[39] and to publicize information on all formal enforcement actions resolved in court.[40] FDA also uses "other enforcement tools not detailed in the FD&C Act," such as issuing warning and information letters to regulated entities that are violating the Act.[41] These practices are discussed later in this report.[42]

FDA, however, is not the only federal agency that enforces the FD&C Act. Indeed, while FDA has significant authority to promote compliance with and to investigate violations of the Act, FDA, like most executive agencies, does not have independent litigating authority.[43] Thus, to address noncompliance, FDA must coordinate with the Department of Justice (DOJ) to enforce the Act through product seizures, injunctions, civil penalty proceedings, or criminal prosecutions.[44] To this end, when FDA discovers that the Act has been or is being violated, the relevant FDA district office, in consultation with FDA's Office of the Chief Counsel, generally evaluates the violation and determines whether to refer it to DOJ's Office of Consumer Litigation (OCL).[45] The OCL and DOJ's field representative, the U.S. Attorney for the judicial district in

[31] *See* U.S. FOOD & DRUG ADMIN., WHAT WE DO, https://www.fda.gov/AboutFDA/WhatWeDo/ (last visited Nov. 16, 2017); *see also* 21 U.S.C. § 393(b).

[32] *See* 21 U.S.C. § 371.

[33] *See, e.g.*, *id*. § 348 (imposing a premarket approval requirement for food additives); *id*. § 379e (requiring premarket approval for color additives); *id*. § 355 (prohibiting the introduction or delivery into interstate commerce of any new drug, unless FDA has approved a new drug application); *id*. § 360b (extending the new drug premarket approval process to new animal drugs); *id*. § 360c(a)(1)(C) (subjecting certain medical devices to a premarket approval process); *id*. § 387j(a)(2) (requiring "new tobacco products" to undergo premarket review).

[34] *See generally* O'REILLY, *supra* note 28, at § 6.1 (noting that FDA has an "effective arsenal of weapons to deal with large, medium and small violations" of the FD&C Act).

[35] *See* 21 U.S.C. § 355(k)(2).

[36] *See id*. § 374.

[37] *See* 21 U.S.C. § 360h(e).

[38] *Id*. § 372(a).

[39] *Id*. § 375(b)

[40] *Id*. § 375(a).

[41] *See* ROSEANN B. TERMINI, FOOD AND DRUG LAW 40 (6th ed. 2013); *see also* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1339 (describing "warning letters" as letters that "warn[] a violator that a formal enforcement [is] likely in the absence of voluntary compliance" and "information letters" as letters that "request[] voluntary correction but ma[ke] no representation that formal enforcement action [is] imminent.").

[42] *See infra* "Civil Enforcement of the FD&C Act."

[43] *See* Linda Horton, *International Harmonization and Mutual Recognition Agreements*, 29 SETON HALL L. REV 692, 698 (1998).

[44] *See Id.*

[45] Vandya Swaminathan and Matthew Avery, *FDA Enforcement of Criminal Liability for Clinical Investigator Fraud*, (continued...)

which FDA anticipates seeking judicial relief, in consultation with FDA, ultimately decide whether to seek judicial relief on behalf of FDA.[46]

In addition to DOJ, several other agencies have FD&C Act enforcement roles. To administer federal laws relating to imports, exports, and duties, the U.S. Customs and Border Protection (CBP) "must work in close cooperation" with FDA to prevent articles that violate the FD&C Act from entering the United States.[47] As a result, CBP alerts FDA when an FD&C Act-regulated product arrives at a port of entry. If FDA finds the product's importation would violate the Act, FDA asks CBP to issue a "Notice of Refusal of Admission" to the importer and to destroy any shipment that is not exported within 90 days.[48]

More broadly, because the Act covers a range of products and subject matters, other federal and state agencies have roles in regulating FD&C Act-covered products. For example, under the Act, FDA is to ensure that drug and device manufacturers properly label their products so as not to mislead consumers,[49] a power that courts have broadly interpreted to allow FDA to regulate advertising relating to drugs or medical devices.[50] However, the Federal Trade Commission (FTC), an independent agency tasked with promoting economic competition and consumer protection by eliminating "unfair or deceptive" acts or practices,[51] likewise has authority over advertising of goods, including drugs and medical devices, in interstate commerce.[52] Because their jurisdictions overlap, FDA and FTC have entered into a memorandum of understanding (MOU) regarding their respective authorities over the marketing of FD&C Act-regulated products.[53] As a consequence, FTC is the primary agency overseeing over-the-counter drugs and medical device advertising.[54]

FDA has also entered into MOUs with other government agencies, including the U.S. Department of Agriculture (USDA),[55] the Department of the Treasury,[56] the Department of Defense (DoD),[57]

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4 HASTINGS SCI. & TECH. L.J. 325, 350 (Summer 2012); *see also* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1217.

[46] *See* O'REILLY, *supra* note 28, at § 6.1; *see generally* U.S. DEP'T JUSTICE, MONOGRAPH, OFFICE OF CONSUMER LITIGATION 2-3 (2011) https://www.justice.gov/sites/default/files/civil/legacy/2011/09/06/CPB_Monograph.pdf

[47] U.S. FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL (hereinafter "REGULATORY PROCEDURES MANUAL"), Ch. 9-1-2 (2017) https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm.

[48] *Id.* at 9-36.

[49] 21 U.S.C. § 352.

[50] *See* Kordel v. United States, 335 U.S. 345, 349-51 (1948).

[51] 15 U.S.C. § 45.

[52] *See* FTC v. Colgate-Palmolive Co., 380 U.S. 374, 392 (1965).

[53] FTC-FDA Memorandum of Understanding, 36 Fed. Reg. 18,539 (1971).

[54] *See* 15 U.S.C. §§ 41, 52-53; *see also* 36 Fed. Reg. at 18,539 (explaining that FTC, not FDA, has the primary responsibility for overseeing the advertising of over over-the-counter drugs and medical devices).

[55] *See, e.g.*, Memorandum of Understanding Between the Food and Drug Administration, U.S. Department of Health and Human Services, and the Food Safety and Inspection Service, U.S. Department of Agriculture, Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products, 65 Fed. Reg. 33,330 (May 23, 2000) (establishing the working relationship between FDA and USDA's Food Safety and Inspection Service with respect to the sanctioning of food ingredients and sources of radiation subject to FDA regulation and intended for use in the production of meat and meat products); *see generally* U.S. FOOD & DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL, 3.2.1.4 (2017), https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123506.pdf (discussing the various MOUs entered between different sub-agencies within USDA and FDA).

[56] *See, e.g.*, Memorandum of Understanding Between the Food and Drug Administration and the [Department of the (continued...)

and the Centers for Disease Control and Prevention (CDC).[58] Other "principal cooperating agencies" that FDA works with include the Environmental Protection Agency, the Consumer Product Safety Commission, the Drug Enforcement Administration, the National Institutes of Health, the Nuclear Regulatory Commission, the Office of Management and Budget, and the Securities and Exchange Commission.[59] In addition, the FD&C Act authorizes state governments, working in conjunction with FDA, to enforce certain aspects of the Act.[60] In short, while FDA is the primary agency enforcing the FD&C Act, other entities have roles.

Significantly, the FD&C Act does not contain a private right of action under which members of the public can sue to enforce the Act.[61] Instead, under the FD&C Act, generally all proceedings "for the enforcement, or to restrain violations, of" the Act must be in the name of the United States.[62] As the Supreme Court has noted, "the [FD&C Act] and its regulations provide the United States with nearly exclusive enforcement authority," and "[p]rivate parties may not bring enforcement suits."[63] While the Supreme Court has recognized that private lawsuits can be used to enforce laws with mandates similar to those of the FD&C Act,[64] the onus for enforcing the Act lies almost exclusively with the federal government.

What is FDA's Enforcement Jurisdiction?

FDA's regulatory authority comes from Congress's constitutional power to regulate interstate commerce.[65] Article I, Section 8, Clause 3 of the U.S. Constitution grants Congress power "[t]o regulate commerce with foreign nations, and among the several States, and with the Indian Tribes."[66] While early 20th century case law interpreted the Commerce Clause narrowly to preclude federal regulation of local economic activity that had only "indirect" impacts on interstate commerce,[67] in 1937, the Supreme Court began reading the Commerce Clause more

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Treasury's] Bureau of Alcohol, Tobacco, and Firearms , 52 Fed. Reg. 45,502 (Nov. 30, 1987) (delineating the responsibilities of each agency with respect alcoholic beverages considered adulterated under the FD&C Act and for other related purposes).

[57] *See, e.g.*, Memorandum of Understanding Between the Department of Defense and the Food and Drug Administration, 52 Fed. Reg. 33,472 (1987) (establishing the procedures to be followed by DoD regarding the investigational use of drugs, including antibiotics and biologics, and medical devices).

[58] See, e.g. Memorandum of Understanding Between the Food and Drug Administration and the Centers for Disease Control and Prevention, 71 Fed. Reg. 43,491 (Aug. 1, 2006) (providing the principles and procedures by which information exchanges between the two agencies shall take place).

[59] *See* O'REILLY, *supra* note 28, at § 24.1.

[60] *See* 21 U.S.C. § 337(b) (authorizing the states to enforce some of the FD&C Act's food labeling requirements if certain criteria are met); *see also* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1369-70.

[61] *See* 21 U.S.C. § 337(a).

[62] *Id.*

[63] *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2235 (2014).

[64] *Id.* at 22239 (noting that the "centralization of FD&C Act enforcement authority in the Federal government does not indicate that Congress intended to foreclose private enforcement of other federal statutes," such as the Lanham Act); *see also* Wyeth v. Levine, 555 U.S. 555, 574 (2009) (concluding that Congress intended private state law tort claims regarding drug labeling to proceed despite the existence of the FD&C Act).

[65] *See* Hipolite Egg Co. v. United States, 220 U.S. 45, 57 (1911) (noting that the Pure Food and Drug Act of 1906, the precursor to the FD&C Act, rested "upon the power of Congress to regulate interstate commerce").

[66] U.S. CONST., Art. I, § 8, cl. 3.

[67] *See, e.g.*, Hammer v. Dagenhart, 247 U.S. 251, 273 (1918); Carter v. Carter Coal Co., 298 U.S. 238, 308 (1936).

expansively,[68] finding Congress to have power to regulate intrastate economic activity that has "a substantial effect on interstate commerce."[69] The Court's expansive interpretations of the Commerce Clause have led one commentator to state that "Congress ... appears to retain virtually unlimited power to regulate even the wholly intrastate production and sale of food, drugs, devices, and cosmetics."[70]

A product's nexus with interstate commerce may arise from many activities. For example, an individual can "introduce" an adulterated good into interstate commerce by directly selling and shipping the good into another state, contracting to do so, or even by selling or shipping a good with the knowledge that it will enter another state.[71] Moreover, an individual can violate the Act by selling or "holding for sale" a misbranded article *after* its shipment in interstate commerce "without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment."[72] Under the most expansive interpretations of the FD&C Act, courts have held that FDA has jurisdiction over products that contain only a single ingredient that was shipped in interstate commerce.[73] Thus, although Congress has not provided FDA with all Congress's commerce clause, the FD&C Act's reach, which extends to any intrastate economic activities having a substantial effect on interstate commerce,[74] is significant. As a consequence, recent federal court decisions have found that the FD&C Act requirement that articles be in interstate commerce poses "no obstacle" to FDA enforcing the Act with respect to seemingly wholly intrastate activities.[75]

FDA authority to apply the FD&C Act to seemingly wholly intrastate activities is limited: the FD&C Act applies only to certain articles. For example, prior to enactment of the Family Smoking Prevention and Tobacco Control Act of 2009,[76] the FD&C Act did not appear to authorize FDA to regulate tobacco products expressly. In 1996, FDA issued regulations governing

[68] *See* NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 41(1937) (holding that, "[w]e have often said interstate commerce itself is a practical conception. It is equally true that interferences with that commerce must be appraised by a judgement that does not ignore actual experience.").

[69] Gonzales v. Raich, 545 U.S. 1, 17 (2005) ("Our case law firmly establishes Congress' power to regulate purely local activities that are part of an economic 'class of activities' that have a substantial effect on interstate commerce."). *See* Wickard v. Filburn, 317 U.S. 111, 128-29 (1942) (holding that, "the power to regulate commerce includes the power to regulate the prices at which commodities in that commerce are dealt in and practices affecting such prices…[thus,] Congress may have properly considered that wheat consumed on the farm where grown if wholly outside the scheme of regulation would have a substantial effect in defeating and obstructing its purpose to stimulate trade therein at increased prices.").

[70] *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1220 (citing *Raich*, 545 U.S. 1).

[71] *See* United States v. 7 Barrels, etc. of Spray Dried Whole Egg, 141 F.2d 767, 770 (7th Cir. 1944); *see also* United States v. Sanders, 196 F.2d 895, 898 (10th Cir. 1952) ("To be guilty of violating the Act, it was not necessary that appellee be engaged in interstate commerce with respect to a misbranded drug. It was sufficient if he was engaged in delivering such a drug for introduction into interstate commerce.").

[72] United States v. Sullivan, 332 U.S. 689, 696 (1948).

[73] *See* Baker v. United States, 932 F.2d 813 (9th Cir. 1991); United States v. An Article of Food, 752 F.2d 11, 14 (1st Cir. 1985) ("Because it is undisputed that the potassium nitrate added to the seized beverages was shipped in interstate commerce, those beverages [, although mixed and sold only intrastate,] clearly fall within the scope of statutory forfeiture jurisdiction.").

[74] *See* Gonzales v. Raich, 545 U.S. 1, 17 (2005).

[75] United States v. Regenerative Scis., LLC, 741 F.3d 1314, 1320 (D.C. Cir. 2014). It should be noted that just because FDA likely possesses the legal power to enforce the FD&C Act's provisions against many purely local activities, such as with respect to a local grocery, restaurant or vending machine, FDA, as a matter of its discretion, has largely "ceded the regulation of such establishments to state and local governments." *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1234.

[76] *See* P.L. 111-31, 123 Stat 1776 (2009).

"access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents" on the grounds that nicotine is a "drug."[77] In *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court rejected FDA's argument, holding that Congress had "clearly precluded the FDA from asserting jurisdiction over tobacco products."[78] While Congress has since provided FDA with explicit statutory authority to regulate tobacco products,[79] *Brown & Williamson* illustrates that FDA's authority under the Act has limits.[80]

Does FDA Address Every Violation of the FD&C Act?

Given the breadth of articles that the FD&C Act regulates and the reach of FDA's enforcement authority, questions often arise as to whether FDA has discretion over initiating enforcement proceedings under the Act. The Supreme Court discussed FDA's enforcement discretion in *Heckler v. Cheney*.[81] In *Heckler,* a death row inmate sentenced to die by lethal injection petitioned FDA to take enforcement actions against state officials who were administering the drug cocktail to be used in the execution.[82] The petitioner argued that the injection would constitute use of a misbranded drug, as using the drug cocktail for a human execution was an "unapproved use of an approved drug" in violation of Sections 301(a) and 502(f) of the FD&C Act.[83] The Supreme Court did not address the merits of the petitioner's misbranding argument, unanimously holding that FDA generally has "absolute discretion" over whether to prosecute or enforce FD&C Act violations through civil or criminal processes.[84] For the Court, the FD&C Act's general enforcement provision, Section 702, was permissive in nature, merely "authorizing" the Secretary of Health and Human Services (and through a delegation of that authority, the Commissioner of FDA) "to conduct examinations and investigations for the purposes of" the Act, and indicated Congress's intent to give FDA discretion over initiating enforcement proceedings.[85] Described as the "high-water mark of FDA discretionary selection of remedies," *Heckler* established that FDA has discretion over FD&C Act enforcement.[86]

Notwithstanding *Heckler's* holding, the Supreme Court recognized that an executive agency's nonenforcement decisions are only "presumptively" unreviewable.[87] Put another way, the presumption that an executive agency has enforcement discretion "may be rebutted where the

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[77] *See* 61 Fed. Reg. 44396, 44632-44633 (1996).

[78] 529 U.S. 120, 126 (2000).

[79] *See* Family Smoking Prevention and Tobacco Control Act, P.L. 111-31, 123 Stat 1776 (2009).

[80] *See, e.g.*, United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1243-44 (M.D. Fla. 2011) (holding that FDA's authorities over "new drugs" did not provide the agency with the authority to regulate the traditional pharmacy compounding of animal drugs); *see also* Independent Turtle Farmers of La., Inc. v. United States, 703 F. Supp. 2d 604, 618 (W.D. La. 2010) (questioning whether the FD&C Act provided FDA with the authority to regulate the sale of animals); United States v. 29 Cartons of ... an Article of Food, 987 F.2d 33, 38 (1st Cir. 1993) (holding that FDA did not have the authority to regulate dietary supplements under its "food additive" authorities).

[81] The text of the FD&C Act does explicitly state that the Act should not be construed to require FDA to refer "minor violations of the Act" for prosecution or the institution of injunctive relief to the DOJ. *See* 21 U.S.C. § 336. The Supreme Court has construed this provision to only apply to FDA's discretion "where a violation has already been established to the satisfaction of the agency." Heckler v. Chaney, 470 U.S. 821, 837 (1985).

[82] *Id.* at 823-24.

[83] *Id.*

[84] *Id.* at 831.

[85] *Id.* at 835.

[86] *See* O'REILLY, *supra* note 28, at § 6.1

[87] 470 U.S. at 832.

substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers."[88] Courts have found that the presumption against reviewing FDA's Section 702 enforcement decisions does not apply to other FD&C Act provisions. For example, in *Cook v. FDA*, a case similar to *Heckler*, a group of death row inmates sued FDA for allowing several state correctional facilities to import sodium thiopental, arguing that the drug, as used in lethal injections, was "a misbranded and unapproved new drug" and its import into the country violated Section 801 of the FD&C Act.[89] In ruling against FDA, the D.C. Circuit Court of Appeals distinguished *Heckler*, noting that Section 801 mandates that, when FDA, through CBP, identifies certain imported drugs that are adulterated, misbranded, or unapproved, the drugs "shall be refused admission," and that this language "unambiguously imposes mandatory duties upon FDA" to refuse admission to the drugs.[90] In other words, while *Heckler* recognized that FDA had significant discretion over enforcing Section 702, in *Cook*, the D.C. Circuit held that Congress had limited FDA's discretion over enforcing Section 801.[91]

FDA's enforcement discretion is central to many of the most contentious political disputes surrounding the agency. FDA is often faced with the difficult decision of whether to "ignore a safety issue and [potentially] precipitate deaths through nonfeasance" or "shut down an entire industry within a week through maximum sanctions."[92] FDA has set enforcement priorities through policy statements, such as choosing to take actions against drugs with safety risks before taking actions against drugs that lack proof of effectiveness.[93] The agency's enforcement discretion is of "perennial" interest to Congress.[94]

Civil Enforcement of the FD&C Act

Enforcement actions for FD&C Act violations can be civil or criminal in nature. Absent DOJ involvement, FDA has several administrative tools for enforcing the Act, including warning and untitled letters, import alerts, recalls, debarments, and civil money penalties. FDA's other civil enforcement actions, including injunctions and seizures, require DOJ assistance.

Warning and Untitled Letters

Although not required by law, depending on the type of FD&C Act violation and the public health threat, FDA usually provides individuals or firms with an opportunity to comply voluntarily before initiating other enforcement actions.[95] FDA does this by issuing "advisory action letters," also referred to as "regulatory letters," which include both "warning" and "untitled" letters.[96]

FDA issues warning letters to alert individuals or firms that the agency has identified "violations of regulatory significance" and to request corrective action, with the expectation that most

[88] *Id.* at 833.

[89] Cook v. FDA, 733 F.3d 1, 3 (D.C. Cir. 2013).

[90] *Id.* at 10.

[91] *Id.* at 12.

[92] *See* O'REILLY, *supra* note 28, at § 6.1.

[93] *See generally* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1197-1200.

[94] *See* O'REILLY, *supra* note 28, at § 6.1.

[95] *See* REGULATORY PROCEDURES MANUAL, 4-1-1 (2017).

[96] *Id.* at 4-1, 4-2.

recipients will voluntarily come into compliance with the law.[97] While warning letters may include notice of FDA's intention to take further enforcement actions if the recipient does not comply, FDA considers these letters to be informal and advisory in nature.[98] Consequently, FDA has maintained that warning letters do not constitute "final agency action,"[99] a prerequisite for filing a lawsuit against a federal agency under the Administrative Procedure Act (APA).[100] Courts have largely agreed with FDA's position, holding that an APA suit may not be based on a warning letter.[101]

Similarly, FDA considers untitled letters to be advisory and uses them to address violations that do not merit a warning letter.[102] For example, FDA may issue an untitled letter to a firm when its promotional materials omit certain risk information and are misleading.[103] Alternatively, FDA may issue a warning letter if FDA had previously communicated the same concerns to the firm, if the promotional materials failed to include any risk information at all, or if the risks omitted are particularly serious.[104] Untitled letters do not include a warning that failure to comply may result in subsequent enforcement action.[105] Because untitled letters are less serious than warning letters, it is unlikely that recipients could challenge untitled letters under the APA as final agency action.[106]

Import Alerts

FDA bases its authority to issue import alerts, or automatic detention lists, on Section 801(a) of the FD&C Act, which provides that articles "*appear[ing],* from samples or *otherwise*," to violate the Act "shall be refused admission" into the United States.[107] Thus, if persuasive evidence exists,

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[97] *Id.* at 4-1-1.

[98] *Id.*

[99] The Supreme Court in *Bennett v. Spear* set out a two-part test for what constitutes final agency action. *See* 520 U.S. 154, 177-78 (1997) ("As a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which "rights or obligations have been determined,' or from which 'legal consequences will flow.'").

[100] 5 U.S.C. § 704.

[101] *See* Holistic Candlers and Consumers Ass'n v. U.S. Food and Drug Admin., 664 F.3d 940, 944-45 (D.C. Cir. 2012) (holding that, "like other agency advice letters that we have reviewed over the years, FDA warning letters do not represent final agency action subject to judicial review."); *see also* Cody Laboratories, Inc. v. Sebelius, 446 Fed. Appx. 964, 969 (10th Cir. 2011) (noting that, "[i]t appears that every court to consider the question has held that an FDA warning letter does not constitute 'final agency action.'").

[102] *See* U.S. FOOD AND DRUG ADMIN., ADVISORY ACTION LETTERS, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/ucm042132.htm (last visited Nov. 16, 2017), *see also* Arthur Levine, FDA ENFORCEMENT MANUAL, Volume I, § 1071, available at http://prod-admin1.tmg.atex.cniweb.net:8080/preview/www/2.3427/2.5267 (Nov. 16, 2017).

[103] *See generally* U.S. FOOD AND DRUG ADMIN., WARNING LETTERS AND NOTICE OF VIOLATION LETTERS TO PHARMACEUTICAL COMPANIES, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm (last visited Nov. 16, 2017).

[104] *Id*.

[105] *Id*.

[106] *Cf.* Holistic Candlers and Consumers Ass'n v. U.S. Food and Drug Admin., 664 F.3d 940, 944-45 (D.C. Cir. 2012) (holding that, "like other agency advice letters that we have reviewed over the years, FDA warning letters do not represent final agency action subject to judicial review.").

[107] *See* 21 U.S.C. § 381(a). *See also* REGULATORY PROCEDURES MANUAL, Ch. 9-8, 9-15 (2017).

such as a history of violations or a failed facility inspection,[108] that an article may violate the FD&C Act, FDA may place that entity or product on an import alert list to communicate to border officials that such articles should be automatically detained without physical examination until further notice.[109] Once articles are detained, the owner or consignee has the opportunity to testify on the articles' admissibility.[110] Depending on this information, FDA may either permit or refuse the articles' entry into the United States.[111]

FDA's use of import alerts to detain articles automatically prior to inspection has been challenged in court, primarily on procedural grounds. Plaintiffs have generally prevailed in cases where FDA effectively used an import alert to change the rules of admissibility for a range of products without prior notice. For example, in *Bellarno International Ltd.v. FDA*, a federal district court in New York held that FDA violated the APA by failing to conduct notice-and-comment rulemaking procedures prior to instituting a rule, by way of an import alert, that required articles to have a complete chain of custody prior to entry.[112] Finding that the rule provided no enforcement discretion and was, therefore, a "substantive rule of general applicability ... rather than a discretionary statement of policy,"[113] the court held that the rule was subject to APA-required notice-and-comment rulemaking.[114] Likewise, in *Benten v. Kessler*, a district court determined that an import alert, banning abortifacient drugs previously admissible under the agency's personal importation policy, constituted a substantive rule subject to notice-and-comment rulemaking because it was essentially binding in its effect, leaving no room for enforcement discretion.[115]

Alternatively, FDA has prevailed when it used import alerts to identify and detain articles suspected of violating *existing* rules. For instance, in *Seabrook International Foods Inc. v. Harris*, a federal district court in the District of Columbia held that "[section 801 (a) of the FD&C Act] authorizes the [refusal of] admission of an article, without the introduction of testimony or evidence, as long as that article 'appears' to be adulterated."[116] Accordingly, the court held that, because FDA officials had already identified a number of Indian shrimp facilities as having sanitation issues, the agency was "justified in concluding that the shrimp 'appeared' adulterated

[108] *See* U.S. FOOD AND DRUG ADMIN. IMPORT ALERT 66-40, https://www.accessdata.fda.gov/cms_ia/importalert_189.html (last visited Nov. 16, 2017).

[109] *See* REGULATORY PROCEDURES MANUAL, Ch. 9-8, 9-15 (2017). As discussed above, the 2013 ruling in *Cook v. FDA* stands for the proposition that upon knowing that an article is in violation of the FD&C Act, FDA must refuse that product admission. *See* 733 F.3d 1, 10 (D.C. Cir. 2013). It is unclear whether there is a similar obligation on the agency requiring that it place a product on import alert upon notice of an appearance of a violation.

[110] *See* REGULATORY PROCEDURES MANUAL, Ch. 9-8-2 (2017).

[111] *Id*.

[112] *See* 678 F. Supp. 410, 416 (E.D.N.Y. 1988).

[113] *Id*. at 415. In reaching its conclusion, the court articulated four interrelated factors for determining whether an import alert constitutes a substantive or legislative rule subject to notice and comment rulemaking, as opposed to an interpretative rule or general statement of policy that is not subject to those procedures: (1) the binding effect of the pronouncement; (2) the degree of discretion accorded the agency in applying the pronouncement; (3) the language of the pronouncement itself; and (4) the deference to the agency's characterization of the pronouncement. *Id*. at 412-16.

[114] Id. at 415. For further discussion of the APA's notice and comment requirements for agency rulemaking, see CRS Report R44356, *The Good Cause Exception to Notice and Comment Rulemaking: Judicial Review of Agency Action*, by (name redacted)

[115] *See* 799 F. Supp. 281, 288 (E.D.N.Y. 1992).

[116] 501 F. Supp. 1086, 1090-91 (D.D.C. 1980).

and should be barred [absent any] satisfactory showing by the importer that it was not harvested from or packed in the insanity sites earlier observed by FDA inspectors in India."[117]

Recalls

FD&C Act regulated articles that are already in distribution may be "recalled" or removed from market if FDA identifies FD&C Act violations that present consumer safety issues.[118] Recalls may be more efficient than other formal or administrative processes for removing potentially hazardous products from market and alerting the public, thereby creating additional incentive for companies to comply with the Act.[119]

Recalls may be voluntary or mandatory.[120] Most recalls are *voluntary*[121]—that is, either requested by FDA or initiated by the firm or manufacturer itself.[122] Firms or manufacturers must report any voluntary recalls they initiate to FDA and are subject to agency oversight.[123] FDA can *request* a recall when it determines that a regulated product in distribution presents a "risk of illness, injury, or gross consumer deception" that necessitates agency action to protect public health.[124] FDA typically requests recalls in urgent situations where FDA has evidence to support formal legal action, such as seizure.[125] While a firm may disregard an FDA-requested recall, it does so at the risk of a subsequent FDA enforcement action. Alternatively, FDA has limited authority to *mandate* or order a firm to recall its products. More specifically, when certain criteria are met, FDA has mandatory recall authority over medical devices,[126] biological products,[127] human tissue intended for transplantation,[128] infant formula,[129] tobacco products,[130] and foods,[131] but it does not have mandatory recall authority over drug products.[132] The procedures for mandatory recalls depend upon the product at issue, but generally, FDA institutes a mandatory recall by issuing an administrative order, which provides the recipient an opportunity to present its views on the order at an informal hearing before a presiding officer.[133]

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[117] *Id*. at 1093.

[118] *See* REGULATORY PROCEDURES MANUAL, Ch. 7-2 (2017).

[119] *See* REGULATORY PROCEDURES MANUAL, Ch. 7-2, 7-7 (2017).

[120] *See* REGULATORY PROCEDURES MANUAL, Ch. 7-3 (2017).

[121] U.S. FOOD AND DRUG ADMIN., FDA 101: PRODUCT RECALLS, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm (last visited Nov. 17, 2017) ("Recalls are almost always voluntary.").

[122] Products voluntarily removed from market will only be considered "recalled" if FDA regards the product as involving a violation of the FD&C Act subject to legal action. In such cases, the firm must provide certain information regarding the recall to FDA. *See* 21 C.F. R. § 7.46.

[123] *See id*. *See also*, REGULATORY PROCEDURES MANUAL, Ch. 7-5-1 (2017).

[124] *See* 21. C.F.R. § 7.45.

[125] *See* REGULATORY PROCEDURES MANUAL, Ch. 7-5-2 (2017).

[126] *See* 21 U.S.C. § 360h(e)(1), *see also* 21 C.F.R. part 810.

[127] *See* 42 U.S.C. § 262(d).

[128] *See id*. at § 262(d)(1), *see also* 21 C.F.R. § 1271.440.

[129] *See* 21 U.S.C. § 350a(e), *see also* 21 C.F.R. part 107, subpart E.

[130] *See* 21 U.S.C. § 387h(c)(1).

[131] *See id.* § 350l(a).

[132] For a description of the various sections of law that authorize FDA to order a recall, see REGULATORY PROCEDURES MANUAL, Ch. 7-5-3 (2017).

[133] *See supra* notes 126-131 and accompanying text.

Debarment

Under section 306 of the FD&C Act, FDA is authorized to "debar" or prohibit corporations or individuals from participating in certain FDA-regulated activities based on their related conduct.[134] For example, FDA may debar a clinical investigator, who was convicted of falsifying records in a clinical study, from "providing any services in any capacity to a person that has an approved or pending drug product application."[135] Because debarment poses significant consequences for those participating in FDA-regulated industries, possibly necessitating career changes, debarment appears to create strong incentives to comply with the FD&C Act.[136]

The FD&C Act sets forth two types of debarment—mandatory and permissive.[137] The statute also describes the criteria applying to individuals and corporations involved in the drug industry, as well as food importers.[138] For mandatory debarment, debarment is permanent. For permissive debarment, debarment is for a period of "not more than five years," the length of which is based on six factors.[139] FDA provides a notice of proposal for debarment to persons it seeks to debar, who may then request a hearing to show why debarment is not appropriate.[140] Persons subject to permissive debarment may apply for a termination of debarment.[141] Persons subject to debarment may also petition the United States Court of Appeals for the District of Columbia or the circuit in which they reside to review whether the debarment should be modified or set aside.[142]

Civil Money Penalties

Under the FD&C Act, FDA may impose monetary civil penalties[143] for specified violations of the Act. These include violations relating to prescription drug marketing practices,[144] medical devices,[145] electronic products,[146] tobacco products,[147] pesticide residues in food,[148] generic drug

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[134] *See* 21 U.S.C. § 335a. For a more thorough description of the FD&C Act's debarment provisions, see John R. Fleder, *The History, Provisions, and Implementation of the Generic Drug Enforcement Act of 1992*, 49 FOOD & DRUG L.J., 89, 92-100 (1994).

[135] *See* 21 U.S.C. § 355a(a)(2); *see, e.g.*, 76 Fed. Reg. 19100-01 (Apr. 6, 2011) (permanently disbarring clinical investigator for failing to maintain accurate records with an intent to defraud or mislead).

[136] *See* Fleder, *supra* note 144, at 95. ("There can be no serious dispute that a debarment would have a major impact on a person regulated by the FDA. The heart and soul of the [statute authorizing debarment] is to alter a person's ability to maintain his or her prior regulatory relationship with the FDA in situations where the person, in the Congress' view, has violated the public trust.").

[137] *See* 21 U.S.C. § 335a(a)-(b).

[138] *Id.*

[139] The six factors the agency considers when assessing the appropriate period for permissive debarment include (1) the nature and the seriousness of the offense; (2) the nature and extent of management participation involved; (3) the nature and extent of voluntary steps to mitigate the impact on the public; (4) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not recur; (5) whether there is evidence to show that the current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements; and (6) whether there are prior convictions under the FD&C Act or other acts administered by FDA. *See id*. § 335a(c).

[140] *See* 21 U.S.C. § 335a(i), 21 C.F.R. part 12.

[141] *See* 21 U.S.C. § 335a(d).

[142] *See id*. § 335a(j).

[143] For a complete list of civil money penalties that may be imposed administratively by FDA, *see* 21 C.F.R § 17.1.

[144] 21 U.S.C. § 333(b).

[145] *Id*. § 333(f)(1).

applications,[149] and improper dissemination of direct-to-consumer advertisements for approved drugs or biological products.[150] The maximum penalty that FDA may assess ranges from approximately $1,000 to over $1 million per violation depending on the prohibited act.[151] To determine the penalty for many violations, the agency must consider the nature and circumstances surrounding the violation, the person's ability to pay, the effect on the person's ability to continue to do business, and any history of similar acts.[152] FDA may assess penalties against both individuals and corporations.

If FDA finds that a monetary civil penalty is warranted, it may assess the penalty absent DOJ's or the courts' involvement.[153] Under FDA's regulations, FDA initiates a penalty proceeding by serving a complaint that alleges that the recipient is violating the Act and seeks a civil money penalty.[154] The recipient must answer the complaint and may request a hearing on it.[155] Following the hearing, an administrative law judge renders a decision, which may be appealed to the Department of Health and Human Service's Departmental Appeals Board (DAB).[156] A decision by the DAB is considered final agency action ripe for judicial review.[157]

Seizures

To prevent harmful goods from reaching consumers, the FD&C Act provides for the seizure of foods, drugs, devices, cosmetics, and tobacco products that are adulterated or misbranded.[158] According to a House report accompanying the FD&C Act, a seizure is considered the harshest civil remedy under the Act, and "should be discouraged or confined to those cases where the public protection requires such action."[159] Seizures may be small, involving only a specific lot or batch of defective products, or large,[160] involving multiple seizure actions filed simultaneously in various locations and potentially halting the national distribution of a product.[161]

(...continued)

[146] *Id*. § 360pp(b).

[147] *Id*. § 333(f)(9).

[148] *Id*. §333(f)(2)(A).

[149] *Id*. § 335b.

[150] *Id*. § 333(g).

[151] Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, FDA is required to adjust these amounts at least once every four years. *See* 28 U.S.C. § 2461 note. For a table entitled "Civil Monetary Penalties Authorities Administered by HHS Agencies and Penalty Amount," see 45 C.F.R. § 102.3.

[152] *See* 21 U.S.C. § 335b(b)(2); *id*. § 333(f)(5)(B).

[153] 21 C.F.R. §§ 17.1-17.54. However, under the FD&C Act, some provisions expressly provide that the relevant civil money penalty action must be imposed by a federal court. *See, e.g.*, 21 U.S.C. § 360pp (providing that civil money penalties related to the distribution of electronic products must be enforced in the district courts of the United States).

[154] 21 C.F.R. § 17.5.

[155] *Id*. §§ 17.9- 17.13. Note that if the respondent does not answer the complaint, the opportunity for a hearing is forfeited.

[156] *Id*. §§ 17.45-17.47.

[157] *Id*. § 17.51.

[158] 21 U.S.C. § 334. *See generally* O'REILLY, *supra* note 28, at § 7:3.

[159] *See* H.R. REP. No. 75-2139, at 4 (1938).

[160] *See* O' REILLY, *supra* note 28, at § 7:10.

[161] *See id*.

While FDA lacks authority to seize products, the U.S. Attorney may take such actions based on FDA's recommendation. In general, the U.S. Attorney commences a seizure action by filing a complaint in federal court on behalf of FDA and obtaining a warrant that directs the U.S. Marshal to take custody of the goods.[162] FDA is not obligated to notify a manufacturer that its products violate the FD&C Act before undertaking a seizure action, and the Supreme Court has found that seizing products without a prior judicial hearing does not raise due process concerns.[163]

Under the FD&C Act, when a product may be seized depends on the product type and the alleged violation.[164] In general, seizure proceedings involving food, drugs, and cosmetics may be initiated "when introduced into or while in interstate commerce or while held for sale ... after shipment in interstate commerce."[165] However, for counterfeit drugs and the materials used to make them, as well as adulterated or misbranded medical devices and tobacco products, seizure may occur at any time (and before a complaint is filed).[166] With some exceptions, FDA may not initiate seizure actions against a food that is misbranded due to its advertising, or that is being sold to consumers in an establishment not owned or operated by the food's manufacturer, packer, or distributor.[167]

If goods are seized, a company with an ownership interest in the goods has the option of claiming the article and contesting the seizure by filing an answer to the complaint.[168] Often, the company will have the option of filing a claim to the article while admitting the violation and entering into a Consent Decree with the government.[169] It has been noted that more than 90% of FDA seizure actions are not contested.[170]

Injunctions

The FD&C Act authorizes federal district courts to issue injunctions to prevent violations of the Act.[171] Under the Act, injunctions are used to stem the flow of adulterated, misbranded, or otherwise violative goods in interstate commerce and to correct conditions causing violations.[172] Injunctions can take the form of a prohibition, such as an order not to distribute a product, or a command to take certain actions, such as an order to clean a facility.[173] Injunctions may be temporary or permanent in nature.

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[162] *See generally* REGULATORY PROCEDURES MANUAL, Ch. 6-1 (2015).

[163] *See* Ewing v. Casselberry, 339 U.S. 594, 601 (1950) (holding that, "[t]he decision of Congress was that the administrative determination to make multiple seizures should be made without a hearing. We cannot say that due process requires one at that stage."); *see also* United States v. One Unlabeled Unit, More or Less, of an Article of Device and Promotional Brochures, 885 F. Supp. 1025, 1028 (ND Ohio 1995) (holding that, "[t]he Supreme Court long ago concluded that the government's interest in protecting the public from potentially dangerous products permitted Congress to establish a procedure for post-seizure hearings in the [FD&C] Act.").

[164] *See* Patrick O'Leary, *Credible Deterrence: FDA and the* Park *Doctrine in the 21st Century*, 68 FOOD DRUG L.J. 137, 156 n.135 (2013).

[165] 21 U.S.C. § 334(a)(1).

[166] *See id*. §§ 334(a)(2) and 372(e)(5).

[167] *Id*. § 334(a)(3).

[168] *Id*. § 334(d); REGULATORY PROCEDURES MANUAL, Ch. 6-1-9 (2015).

[169] REGULATORY PROCEDURES MANUAL, Ch. 6-1-9 (2015).

[170] Levine, *supra* note 102, at § 1160. The lack of challenges generally stems from the likelihood that FDA prevails in these actions, as well as the expense of litigation. *Id*.

[171] 21 U.S.C. § 332.

[172] REGULATORY PROCEDURES MANUAL, Ch. 6-2 (2015).

[173] It has been noted that the three most common violations that result in FDA injunction cases are (1) deviations from the good manufacturing practice regulations for the various FDA-regulated products; (2) marketing a product without (continued...)

According to FDA guidance, an injunction "may be considered for any significant out-of-compliance circumstance, but particularly when a health hazard has been identified."[174] FDA has indicated that an injunction is the agency's remedy of choice when there are

- current and definite health hazards or a gross consumer deception requiring immediate action to stop the violative practice and a seizure is impractical;
- significant amounts of violative products owned by the same person, a voluntary recall by the firm was refused or is significantly inadequate to protect the public, and a seizure is impractical or uneconomical; or
- long-standing (chronic) violative practices that have not produced a health hazard or consumer fraud, but which have not been corrected through use of voluntary or other regulatory approaches.[175]

Similar to seizures, injunctions involve FDA and DOJ cooperation. Based on FDA's recommendation, the U.S. Attorney files, in federal court, to enjoin an individual or company from violating the Act.[176] In general, courts have granted injunctions when DOJ has demonstrated that the defendants violated and are likely to continue to violate the FD&C Act.[177] If the court enters an injunction, the individual or company must comply immediately, unless it obtains a stay of the court order, pending an appeal. Most injunction cases under the FD&C Act are resolved through the entry of a negotiated consent decree.[178]

Criminal Enforcement of the FD&C Act

In addition to civil enforcement mechanisms, the FD&C Act also subjects individuals to criminal penalties, including fines and imprisonment, for violating certain provisions of the Act.[179] Criminal prosecutions under the FD&C Act are rare, with one commentator finding that "only a miniscule fraction of 1 per cent of the [FDA's] inspections will result in criminal prosecution,"[180] and "extremely technical infractions" of the Act are very unlikely to result in criminal punishment.[181] According to FDA's enforcement manual, the agency usually affords individuals and firms an opportunity to comply voluntarily prior to initiating a criminal prosecution, as long as "a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations."[182] Although criminal prosecutions are rare under the Act, the threat

(...continued)

the required FDA approval; and (3) deviations from FDA requirements concerning labeling and promotion. Levine, *supra* note 102, at § 1202.

[174] REGULATORY PROCEDURES MANUAL, Ch.6-2-4 (2015).

[175] *Id*. FDA has also stated that in some instances, a history of prior violations, and that previous attempts to correct these acts, may be considered. *Id*.

[176] Levine, *supra* note 102, at § 1200.

[177] *See, e.g.*, United States v. N.Y. Fish, Inc., 10 F. Supp. 3d 355, 379 (E.D.N.Y. 2014); United States v. Organic Pastures Dairy Co., 708 F. Supp. 2d 1005, 1011 (E.D. Cal. 2010); United States v. Endotec, Inc., No. 6:06-cv-1281, 2009 U.S. Dist. LEXIS 93985, at *21-22 (M.D. Fla. Sept. 28, 2009).

[178] Levine, *supra* note 102, at § 1250.

[179] *See* 21 U.S.C. § 333.

[180] *See* O'REILLY, *supra* note 28, at § 8.2.

[181] *Id.* at § 8.1.

[182] *See* REGULATORY PROCEDURES MANUAL, Ch. 6-5-13 (2015).

of criminal penalties may create incentives to comply.[183] Whereas economic penalties resulting from the civil enforcement tools "might ... be seen as merely an extra cost of business" for an entity regulated under the FD&C Act, criminal penalties potentially threaten the liberty of individuals such as the "factory manager, the corporate chief executive, or the researcher."

FDA's Office of Criminal Investigations (OCI) is the primary entity that investigates suspected criminal violations of the FD&C Act and related laws.[184] If OCI finds prosecution to be appropriate, FDA may give the alleged violator notice and an opportunity to present his "views ... with regard to such contemplated proceeding" pursuant to Section 305.[185] Although the Supreme Court has held that hearings are not required,[186] FDA generally provides hearings absent a regulatory bar.[187] If prosecution is appropriate, OCI makes a recommendation to DOJ, which has authority to prosecute FD&C Act violations.[188] DOJ, including the local U.S. Attorney's office, then reviews FDA's recommendation and, if warranted, institutes criminal proceedings against the alleged violator.[189] While DOJ has discretion to reject FDA's recommendation, DOJ will typically "adhere to the recommendations of the FDA" and "act, as closely as possible, in partnership with attorneys from the FDA."[190]

Criminal Violations of the FD&C Act

Under the FD&C Act, criminal convictions generally require proof of three elements. First, the government must prove that the article, which the statutory violation concerns, is either a "food," "drug," "device," "tobacco," or "cosmetic."[191] Second, the article at issue generally[192] must be "adulterated" or "misbranded."[193] Third, the article at issue must have been introduced into interstate commerce.[194] Importantly, contrary to the typical requirement of American criminal law, FD&C Act criminal provisions do not include a *mens rea* or "guilty mind" requirement.[195] Instead, the standard for criminal liability under the FD&C Act is strict liability, such that a

[183] *See* O'REILLY, *supra* note 28, at § 8.1.

[184] *See* Food & Drug Admin., Inspections, Compliance, Enforcement, and Criminal Investigations: about oci, (Nov. 17, 2017), https://www.fda.gov/ICECI/CriminalInvestigations/ucm550316.htm

[185] 21 U.S.C. § 335.

[186] United States v. Dotterweich, 320 U.S. 277, 279 (1943) ("We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution.").

[187] *See* 21 C.F.R. § 7.84(a) (providing that a Section 305 administrative hearing is not needed if (1) if the Commissioner has reason to believe that notice and an opportunity may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution; or (2) if the Commissioner is considering recommending further investigation by the DOJ).

[188] *See* O'REILLY, *supra* note 28, at § 8.3.

[189] *See* John W. Lundquist and Sandra L. Conroy, *Defending Against Food & Drug Prosecutions*, 21 CHAMPION 20, 21 (1997).

[190] *Id.* (internal citations omitted).

[191] *See, e.g.*, 21 U.S.C. § 331(a)-(c).

[192] Section 301 of the FD&C Act, which contains the Act's prohibited acts, generally centers its prohibitions on the concepts of adulteration and misbranding. *See infra* "Overview of the Food, Drug, and Cosmetics Act." Nonetheless, the Act contains other prohibited acts that do not rely upon adulteration or misbranding charges. Most notably, under Section 301(d), the introduction of a drug into interstate commerce in violation of the Act's "new drug" provisions, which require FDA to approve a new drug application before a drug can enter interstate commerce, violates the FD&C Act. *See* 21 U.S.C. § 331(d).

[193] *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1310.

[194] *Id.*

[195] *Id.*

defendant can be held criminally liable without proof of knowledge of the event or intention to perform the act that results in a violation.[196]

Two Supreme Court cases established this principle. In *United States v. Dotterweich,* Justice Frankfurter, writing for a five-member majority, explained that the FD&C Act "dispenses with the conventional requirement for criminal conduct awareness of some wrongdoing"[197] and that criminal accountability extends to all who have "a responsible share in the furtherance of the transaction which the statute outlaws."[198] The Court reasoned that the strict liability standard was necessary because "[i]n the interest of the larger good [the Act placed] the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[199] Over thirty years later, in *United States v. Park,* the Supreme Court reaffirmed *Dotterweich*. In articulating what is known as the "responsible corporate officer" or "*Park*" doctrine, the Court held that a showing of criminal liability under the FD&C Act did not require an "awareness of some wrongdoing" by the defendant, but instead merely required the defendant to be in a "position in [a] corporation" in which he had "responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[200] In so holding, the Court noted that while the strict liability standard imposed by the FD&C Act is "beyond question demanding" the standard is "no more stringent" than what should be expected of "those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."[201]

While the lack of a *mens rea* element in FD&C Act criminal cases could theoretically allow FDA and DOJ to "bring a criminal action ... in virtually every serious case" of an FD&C Act violation,[202] two defenses may diminish the potential reach of the Act's criminal sanctions. First, an individual accused of an FD&C Act crime could raise the affirmative defense of "impossibility." The "impossibility defense" is available to a corporate officer who can introduce evidence that "he exercised extraordinary care, but was nevertheless unable to prevent violations of [the FD&C Act]."[203] Upon such a showing, the burden of proof then shifts to the government to prove beyond a reasonable doubt that the officer was not actually powerless to prevent or correct the violation.[204] Second, under the "guaranty clause" contained in Section 303(c) of the FD&C Act, a person who in "good faith" merely receives and later delivers an illegal article cannot be subjected to criminal penalties under the Act.[205] Likewise, a person who introduced a misbranded or adulterated product into commerce is also exempt under Section 303(c) if that

[196] *Id.*

[197] 320 U.S. 277, 281 (1943).

[198] *Id.* at 284.

[199] *Id.* at 281.

[200] 421 U.S. 658, 672-74 (1975). In 2016 the Supreme Court denied a petition to review whether the *Park* doctrine should be overruled after the U.S. Court of Appeals for the Eighth Circuit upheld a three-month prison term for two "responsible corporate officers" that plead guilty to misdemeanor violations of the FD&C Act. *See* United States v. DeCoster, 828 F.3d 626, 629 (8th Cir. 2016), *cert. denied*, 137 S. Ct. 2160, 198 L. Ed. 2d 232 (2017).

[201] *Id.* at 672.

[202] *See* O'REILLY, *supra* note 28, at § 8.2.

[203] United States v. Gel Spice Co., 773 F.2d 427, 434-35 (2d Cir. 1985) (quoting United States v. New England Grocers Co., 488 F. Supp. 230, 234 (D. Mass. 1980)).

[204] *Id.* Some commentators have raised concerns about how successful the impossibility defense is in FD&C Act criminal cases. *See, e.g.*, Andrew C. Baird, *The New Park Doctrine: Missing the Mark*, 91 N.C.L. REV. 949, 978 n.179 (2013) ("A search of every case that cites *Park* wherein the objective impossibility defense was raised and addressed reveals that no court, state or federal, has ever sided with a defendant raising this argument.").

[205] *See* 21 U.S.C. § 333(c)(1).

person received the article in "good faith" and has obtained a written guaranty that the product does not violate the Act.[206] Under the guaranty clause, pharmacists who, in good faith, distributed misbranded or adulterated drugs from a drug manufacturer or distributor have escaped criminal liability.[207]

Criminal Penalties Resulting from an FD&C Act Violation

Under Section 303(a)(1) of the FD&C Act, criminal violations of the Act are generally treated as misdemeanors,[208] meaning they are punishable by a fine or imprisonment of a year or less.[209] Nonetheless, FD&C Act violations may constitute a felony if the violation is a second offense or is done with the "intent to defraud or mislead."[210] For a defendant to act with an "intent to defraud or mislead" under the Act, the defendant must "design[] his conduct to avoid the regulatory scrutiny of the FDA,"[211] meaning that, for a defendant to incur a felony conviction under the Act, he must have intended to defraud or mislead not only the product's ultimate consumers but also state and federal government enforcement agencies.[212]

Section 303(a) establishes default criminal penalties for individuals who commit misdemeanors or felonies under the FD&C Act.[213] The Act provides for a $1,000 fine, imprisonment of up to one year, or both for simple violations of the Act.[214] The Act further provides for fines of up to $10,000, imprisonment for up to three years, or both for subsequent convictions or convictions demonstrating intent to defraud or mislead.[215] However, under the Sentencing Reform Act of 1984, as amended by the Criminal Fines Improvement Act of 1987, all criminal fines in the United States Code, including FD&C Act fines, are subject to modification to achieve certain uniform levels.[216] Consequently, for FD&C Act misdemeanors not resulting in death, the current maximum fine for an individual is $100,000,[217] while for FD&C Act misdemeanors resulting in death or for FD&C Act felonies, the current maximum fine for an individual is $250,000.[218] Likewise, for FD&C Act misdemeanors, the current maximum fine for an organization is

[206] *Id.* § 333(c)(2). Giving a false guaranty that a product is not adulterated or misbranded is prohibited under Section 301(h) of the FD&C Act. *See* 21 U.S.C. § 331(h).

[207] *See* Richard R. Abood, *Physician Dispensing: Issues of Law, Legislation and Social Policy*, 14 AM. J. L. & MED. 307, 341 n.186 (1989).

[208] *See* 21 U.S.C. § 333(a)(1).

[209] *See generally* United States v. Graham, 169 F.3d 787, 792 (3d Cir. 1999).

[210] 21 U.S.C. § 333(a)(2).

[211] *See* United States v. Ellis, 326 F.3d 550, 554 (4th Cir. 2003).

[212] *See* United States v. Bradshaw, 840 F.2d 871, 874-75 (11th Cir. 1988); *see also* United States v. Cambra, 933 F.2d 752, 755 (9th Cir. 1991); United States v. Arlen, 947 F.2d 139, 143 (5th Cir. 1991).

[213] *See* 21 U.S.C. § 333(a). The FD&C Act does contain some exceptions to the default criminal penalties provided for in Section 303(a). For example, a person who "knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition" may be punished by a maximum term of imprisonment of five years. *See id*. § 333(e)(1).

[214] *Id*. § 333(a)(1).

[215] *Id.* § 333(a)(2).

[216] *See* Sentencing Reform Act of 1984, P.L. 98-473, 98 Stat. 1837; Criminal Fine Improvements Act of 1987, P.L. 100-185, 101 Stat. 1279.

[217] 18 U.S.C. § 3571(b)(5).

[218] *Id.* § 3571(b)(3)-(4).

$200,000[219] while, for FD&C Act misdemeanors resulting in death or for FD&C Act felonies, the current maximum fine for an organization is $500,000.[220]

Pursuant to the U.S. Sentencing Guidelines, defendants convicted of violating the Act receive a base offense level of six,[221] resulting in a guideline recommendation of a final sentence of zero to eighteen months in prison, depending on the defendant's criminal history.[222] If the defendant had previously violated the Act or if the offense involved fraud, the sentence could increase considerably.[223] The Sentencing Guidelines also provide that an "upward departure" "may be warranted" if the offense "created a substantial risk of bodily injury or death; or bodily injury, death, extreme psychological injury, property damage, or monetary loss resulted from the offense."[224]

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[219] *Id.* § 3571(c)(5).

[220] *Id.* § 3571(c)(3)-(4). Other criminal laws may be invoked in the enforcement of the FD&C Act, including federal criminal conspiracy laws, federal mail and wire fraud laws, or federal laws punishing false statements or perjury. *See* HUTT, MERRILL, AND GROSSMAN, *supra* note 16, at 1328-29 (collecting various cases).

[221] *See* U.S.S.G. MANUAL § 2N2.1.

[222] *See id.* Chapter 5, Part A.

[223] *See id.* § 2N2.1.

[224] *See id.* § 2N2.1, cmt. 3.