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

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## Summary

In an increasingly interconnected country, public health concerns and crises originating from any state have the potential to impact the entire nation. A critical law to help promote national public health and prevent fraudulent activity with respect to food, drugs, and an array of other public health products that enter interstate commerce is the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA or the Act). Indeed, the primary purpose of the Act is to “safeguard” and “protect” the consumer from being exposed to dangerous products affecting public health and safety, and the FDCA does this 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. This report provides an overview of the FDCA, answers frequently asked questions about the enforcement of the Act, and concludes with an overview of the various civil and criminal enforcement provisions contained within the FDCA.

The FDCA is the central 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, the FDCA, in Section 301, generally prohibits two basic acts: “adulteration” and “misbranding.” Specifically, Section 301 makes it illegal to directly or indirectly distribute a covered product in interstate commerce that is adulterated or misbranded. Many other provisions of the Act are devoted to defining what the terms “adulteration” and “misbranding” mean with respect to the specific products covered under the Act.

The FDCA is centrally enforced by the Food and Drug Administration (FDA), an agency whose mission is to “assure that the products it regulates are safe and truthfully labeled.” The FDA enforces the Act through a series of administrative mechanisms, such as pre-market reviews of certain products, examinations and investigations, and the dissemination of information to the public. Nonetheless, because the FDA does not have independent litigating authority, the agency must rely on the Department of Justice (DOJ) if a particular matter requires utilization of criminal or civil remedies. While private parties do not have the right to enforce the FDCA’s mandates through a lawsuit, in addition to the DOJ, a host of other federal agencies help enforce discrete parts of the Act. Still, the FDA remains the primary agency charged with enforcing the FDCA, and the FDA’s authority reaches to even purely intrastate activities that have some sort of nexus with interstate commerce, so long as the activity in question respects a product that is covered under the Act. Supreme Court case law confirms that the FDA enjoys significant discretion in choosing when to enforce most provisions of the FDCA, although certain mandates can eliminate the FDA’s discretion and impose a mandate on the agency to enforce the Act in specific circumstances.

If the agency, with the help of the DOJ, considers a particular matter sufficiently serious, the FDCA provides a wide range of civil and criminal remedies to enforce the substantive provisions of the Act. For example, the FDCA provides the government with the ability to sue violators of the Act in Court to punish or prevent future violations of the FDCA. Civil actions include the imposition of civil monetary penalties, injunctions, and seizures. If someone’s conduct is extremely serious, in rare cases, the FDA and DOJ have collaborated to bring criminal charges against those who violate the Act. While a criminal violation of the FDCA does not require that the perpetrator be aware of his conduct, intentional or repeated violations of the Act can result in multiple years of imprisonment and hefty criminal fines.

## **Contents**

Introduction.....	1
Overview of the Food, Drug, and Cosmetic Act.....	1
General Questions About the Enforcement of the FDCA.....	4
Who Enforces the FDCA?.....	4
What Limits Are There to the Enforcement Jurisdiction of the FDCA? .....	7
Is Every Violation of the FDCA Enforced? .....	9
Civil Enforcement of the FDCA.....	11
Civil Monetary Penalties .....	11
Seizures .....	12
Injunctions .....	13
Criminal Enforcement of the FDCA.....	14
Criminal Violations of the FDCA.....	15
Criminal Penalties Resulting from an FDCA Violation.....	17

## **Tables**

Table 1. Adulteration and Misbranding Provisions of the FDCA.....	3
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## **Contacts**

Author Contact Information.....	18
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## Introduction

In an increasingly interconnected country, public health concerns and crises originating from any state have the potential to impact the entire nation. For example, in 2006, an *E coli* outbreak associated with prepackaged spinach cultivated at a ranch in California affected over 200 people in 26 different states.<sup>1</sup> Public health crises, of course, can originate from other sources than food-borne illnesses. An October 2012 outbreak of fungal meningitis resulting from steroid injections prepared at a Massachusetts compounding pharmacy resulted in over 60 deaths.<sup>2</sup> And beyond preventing public health crises akin to the 2006 spinach outbreak or the drug compounding crisis of 2012, there is strong interest in Congress and elsewhere in ensuring that that public health products that are consumed by Americans work as they should and are truthfully labeled.<sup>3</sup>

A critical law to help promote national public health and prevent fraudulent activity with respect to food, drugs, and an array of other public health products that substantially affect interstate commerce is the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA or the Act).<sup>4</sup> As noted in a series of CRS reports, the FDCA and its implementing regulations contain a host of substantive standards that aim to protect and promote public health, such as the FDCA's requirements with respect to the approval of prescription drugs<sup>5</sup> or the FDCA's provisions aiming to promote food safety.<sup>6</sup> This report provides a brief overview of how the Act's various provisions are enforced. The report begins by providing an overview of the FDCA, discussing the various limitations on the ability of the federal government to enforce the FDCA's provisions, and concludes with an overview of the various civil and criminal enforcement provisions contained within the Act.

## Overview of the Food, Drug, and Cosmetic Act

Federal regulation of the safety of most foods,<sup>7</sup> food additives,<sup>8</sup> color additives,<sup>9</sup> dietary supplements,<sup>10</sup> prescription and non-prescription drugs,<sup>11</sup> medical devices,<sup>12</sup> cosmetics,<sup>13</sup> and

<sup>1</sup> Centers for Disease Control and Prevention, *Investigation of an Escherichia coli 0157:H7 Outbreak Associated with Dole Pre-Packaged Spinach*, [http://www.cdc.gov/nceh/ehs/Docs/Investigation\\_of\\_an\\_E\\_Coli\\_Outbreak\\_Associated\\_with\\_Dole\\_Pre-Packaged\\_Spinach.pdf](http://www.cdc.gov/nceh/ehs/Docs/Investigation_of_an_E_Coli_Outbreak_Associated_with_Dole_Pre-Packaged_Spinach.pdf).

<sup>2</sup> Centers for Disease Control and Prevention, *Multistate Fungal Meningitis Outbreak Investigation—Current Case Count*, <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html>.

<sup>3</sup> *United States v. Lee*, 131 F.2d 464, 466 (7<sup>th</sup> Cir. 1941) (noting Congress's interest in promoting public health and preventing fraud).

<sup>4</sup> 21 U.S.C. §§ 301, *et seq.*

<sup>5</sup> CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by (name redacted).

<sup>6</sup> CRS Report RS22600, *The Federal Food Safety System: A Primer*, by (name redacted).

<sup>7</sup> The FDCA 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).

<sup>8</sup> The FDCA 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.” 21 U.S.C. § 321(s).

<sup>9</sup> The FDCA 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 (continued...))

tobacco products<sup>14</sup> have their central basis in the FDCA.<sup>15</sup> Congress enacted the FDCA in its original form in 1938,<sup>16</sup> acting pursuant to its constitutional authority to regulate interstate commerce.<sup>17</sup> The primary purpose of the Act is to “safeguard” and “protect” the consumer from being exposed to “dangerous products” affecting public health and safety, and the FDCA does this 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.”<sup>18</sup> The mandates of the FDCA are enforced through a variety of legal measures such as formal and informal administrative actions, criminal and civil penalties, injunctions, recalls, and/or seizures of FDCA-covered goods.<sup>19</sup>

Though the FDCA has been “substantially amended since 1938,” the Act “still retains its basic structure.”<sup>20</sup> The “heart of the enforcement provisions of the” FDCA, if not the entire Act, is

(...continued)

with other substance) of imparting color thereto....” 21 U.S.C. § 321(t).

<sup>10</sup> The FDCA generally defines the phrase “dietary supplement” as means “a product ... intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(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).” 21 U.S.C. § 321(ff).

<sup>11</sup> The FDCA 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).” 21 U.S.C. § 321(g).

<sup>12</sup> The FDCA 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.” 21 U.S.C. § 321(h).

<sup>13</sup> The FDCA 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.” 21 U.S.C. § 321(i).

<sup>14</sup> The FDCA 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.” 21 U.S.C. § 321(rr).

<sup>15</sup> For a general description of the scope of products regulated under the FDCA, see PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, *FOOD AND DRUG LAW* 12-16 (Foundation Press, 3d ed. 2007).

<sup>16</sup> P.L.75-717, 52 Stat. 1057 (1938).

<sup>17</sup> *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 FDCA, rested “upon the power of Congress to regulate interstate commerce”).

<sup>18</sup> *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

<sup>19</sup> See *infra* “Civil Enforcement of the FDCA.”

<sup>20</sup> See Diana R. H. Winters, *Not Sick Yet: Food-Safety-Impact Litigation and Barriers to Justiciability*, 77 *BROOKLYN L. REV.* 905, 911 (Spring 2013).

Section 301, which enumerates the specific acts that are prohibited by the statute.<sup>21</sup> The acts that are prohibited by the FDCA have been described as “a catalogue of definitions elaborating two basic concepts: ‘adulteration’ and ‘misbranding.’”<sup>22</sup> Section 301 generally makes it illegal to directly or indirectly distribute a covered product in interstate commerce that is “adulterated” or “misbranded.”<sup>23</sup> The term “adulteration” has its common law origins referencing the corrupting or debasing of a good resulting in its diminished quality,<sup>24</sup> and “misbranding” commonly refers to providing a false or misleading label for a given product.<sup>25</sup> Notwithstanding these general understandings of the two words, the FDCA uses the two terms in a “sense more extended and varying somewhat in substance from their popular definition.”<sup>26</sup> Put another way, “much of the [Act] is devoted to ascribing the labels ‘adulterated’ or ‘misbranded’ to products whose composition, production or labeling fails” to meet the substantive requirements of the FDCA.<sup>27</sup> For example, a “food” is deemed adulterated if it has been held under “insanitary conditions,”<sup>28</sup> and a “drug” is misbranded if its label does not contain the “name and place of business of the manufacturer, packer, or distributor.”<sup>29</sup> The language of the FDCA is “purposefully broad,”<sup>30</sup> delegating a significant amount of discretion to the executive branch to issue rules and guidelines that fill in the gaps created by the legislative scheme.<sup>31</sup> **Table 1** notes the various sections of the FDCA that define and specify when a particular product can be deemed “adulterated” or “misbranded.”

**Table 1. Adulteration and Misbranding Provisions of the FDCA**

Article Regulated	FDCA 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

<sup>21</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 1196. Section 301 is codified at 21 U.S.C. § 331.

<sup>22</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 13.

<sup>23</sup> See 21 U.S.C. § 331(a)-(c).

<sup>24</sup> See, e.g., *Pennsylvania v. Curry*, 4 Pa. Super. 356, 360 (Super. Ct. 1897) (“The term adulteration is derived from the Latin *adultero*, which ... signifies to defile, to debase, to corrupt, ... to counterfeit, etc.”); see generally 2 C.J.S. Adulteration § 1 (2003) (“The word ‘adulteration’ ordinarily signifies the act of corrupting or debasing, the act of mixing something impure with something pure and genuine or of mixing an inferior article with a superior one of the same kind.”).

<sup>25</sup> See, e.g., *Hatcher v. Dunn*, 102 Iowa 411, 415 (1897).

<sup>26</sup> See 2 C.J.S. Adulteration § 1 (2003).

<sup>27</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 13.

<sup>28</sup> 21 U.S.C. § 342(a)(4).

<sup>29</sup> 21 U.S.C. § 352(b)(1).

<sup>30</sup> See JAMES T. O'REILLY, *FOOD AND DRUG ADMINISTRATION* § 6.1 (2d ed. 2005).

<sup>31</sup> 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 FDCA).

Article Regulated	FDCA Section	Adulteration	Misbranding
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 FDCA

Before delving into the specific ways that the FDCA is enforced, this section answers several basic and overarching questions about the enforcement of the Act.

### Who Enforces the FDCA?

The Food and Drug Administration (FDA), established under Section 1003 of the FDCA, is the primary agency that administers and enforces the Act.<sup>32</sup> The central mission of the FDA is to “assure that the products it regulates are safe and truthfully labeled.”<sup>33</sup> In line with this mission, the FDA is statutorily empowered to not only provide administrative guidance as to what the FDCA’s broad mandates specifically entail,<sup>34</sup> but to also enforce the FDCA’s mandates through a host of administrative actions. For example, before certain articles can lawfully be sold in interstate commerce, the FDA must evaluate those goods through a rigorous review process and approve them if they meet certain standards, such as being safe and effective for the product’s intended use.<sup>35</sup> In addition to such pre-market authorities, the FDA also possesses significant “post-market” authorities that enable the agency to monitor a regulated product that has already entered interstate commerce to ensure the product continues to adhere to the FDCA’s mandates.<sup>36</sup> The FDCA empowers the FDA to, for example, request information from a pharmaceutical manufacturer,<sup>37</sup> conduct inspections of the facilities of a food producer,<sup>38</sup> or order a recall of a medical device thought to cause “serious, adverse health consequences.”<sup>39</sup> The FDCA also provides the FDA with the general authority to “conduct examinations and investigations” in the

<sup>32</sup> 21 U.S.C. § 393(a).

<sup>33</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 5; see also 21 U.S.C. § 393(b).

<sup>34</sup> See 21 U.S.C. § 371.

<sup>35</sup> See, e.g. 21 U.S.C. § 348(imposing a premarket approval requirement for food additives); 21 U.S.C. § 379e (requiring premarket approval for color additives); 21 U.S.C. § 355 (prohibiting the introduction or delivery into interstate commerce any new drug, unless the FDA has approved a new drug application); 21 U.S.C. § 360b (extending the new drug premarket approval process to new animal drugs); 21 U.S.C. § 360c(a)(1)(C) (subjecting certain medical devices to a premarket approval process); 21 U.S.C. § 387j(a)(2) (requiring “new tobacco products” to undergo premarket review).

<sup>36</sup> See generally O’Reilly, *supra* note 30, at § 6.1 (noting the FDA has an “effective arsenal of weapons to deal with large, medium and small violations” of the FDCA).

<sup>37</sup> See 21 U.S.C. § 355(k)(2).

<sup>38</sup> See 21 U.S.C. § 374.

<sup>39</sup> See 21 U.S.C. § 360h(e).

aid of administering the Act,<sup>40</sup> to disseminate information about regulated products that involve “imminent danger to health” or “gross deception to the consumer,”<sup>41</sup> and to issue information to the public on all formal enforcement actions resolved in court.<sup>42</sup> The FDA also utilizes “other enforcement tools not detailed in the FDCA,” such as issuing warning and information letters to regulated entities that note violations of the Act.<sup>43</sup>

The FDA, however, is not the only federal agency tasked with enforcing the FDCA. Indeed, while the FDA has significant authority to promote compliance with the Act and to investigate violations of the FDCA, faced with a case of noncompliance, the FDA, lacking independent litigating authority, must rely on the Department of Justice (DOJ) to enforce the Act through product seizures, injunctions, civil penalty proceedings, or criminal prosecutions.<sup>44</sup> As a consequence, when the FDA discovers a violation of the Act has occurred or continues to occur, the relevant FDA district office in consultation with the FDA’s Chief Counsel’s office will generally evaluate the nature of the violation and determine whether a violation warrants referring a matter to DOJ’s Office of Consumer Litigation.<sup>45</sup> The Office of Consumer Litigation and the DOJ’s field representative, the U.S. Attorney for the judicial district in which the FDA seeks judicial relief, in consultation with their agency client, will make the ultimate decision on whether to seek judicial relief on behalf of the FDA.<sup>46</sup>

In addition to the DOJ, several other agencies have roles in enforcing the mandates of the FDCA. The U.S. Customs and Border Protection (CBP), in administering federal laws relating to the import, export, and collection of duties, “must work in close cooperation” with the FDA when refusing to admit certain articles into the United States that fail to comply with the FDCA.<sup>47</sup> As a result, the CBP will alert the FDA when a product under its purview arrives at a port of entry, and the FDA, after determining the importation of a particular product would be in violation of the Act, will ask CBP to issue a “Notice of Refusal of Admission” to the importer and to destroy any shipment that is not exported within 90 days.<sup>48</sup>

More broadly, because of the breadth of products and subject matters regulated by the FDCA, the enforcement of the Act necessarily concerns the interests of other federal and state agencies and, accordingly, other entities besides the FDA do sometimes play discrete roles in regulating products that fall under the FDCA’s umbrella. For example, under the Act, the FDA must ensure

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<sup>40</sup> 21 U.S.C. § 372(a).

<sup>41</sup> 21 U.S.C. § 375(b).

<sup>42</sup> 21 U.S.C. § 375(a).

<sup>43</sup> See ROSEANN B. TERMINI, *FOOD AND DRUG LAW* 40 (6<sup>th</sup> ed. 2013); see also Hutt, Merrill, and Grossman, *supra* note 15, 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.”).

<sup>44</sup> See Linda Horton, *International Harmonization and Mutual Recognition Agreements*, 29 SETON HALL L. REV. 692, 698 (1998).

<sup>45</sup> Vandya Swaminathan and Matthew Avery, *FDA Enforcement of Criminal Liability for Clinical Investigator Fraud*, 4 HASTINGS SCI. & TECH. L.J. 325, 350 (Summer 2012); see also Hutt, Merrill, and Grossman, *supra* note 15, at 1217.

<sup>46</sup> See O’Reilly, *supra* note 30, at § 6.1; see generally U.S. DEP’T JUSTICE, *Monograph, Office of Consumer Litigation*, [http://www.justice.gov/civil/docs\\_forms/OCPL\\_Monograph.pdf](http://www.justice.gov/civil/docs_forms/OCPL_Monograph.pdf), at pp. 2-3.

<sup>47</sup> FOOD & DRUG ADMIN., *FDA REGULATORY PROCEDURES MANUAL*, 9-2 <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf> (April 2013).

<sup>48</sup> *Id.* at pp. 9-36.



that drug and device manufacturers properly label their products so as to not mislead consumers,<sup>49</sup> a power that has been broadly interpreted to allow the FDA to regulate any advertising associated with a drug or medical device.<sup>50</sup> However, the Federal Trade Commission (FTC), a wholly independent agency that is tasked under the Federal Trade Commission Act with promoting economic competition and consumer protection by eliminating acts or practices that are “unfair or deceptive,”<sup>51</sup> likewise has considerable discretion in regulating the advertising of goods in interstate commerce, a power that necessarily includes the regulation of the advertising of drugs or medical devices.<sup>52</sup> Because of their overlapping jurisdictions, the FDA and the FTC have entered into a memorandum of understanding (MOU) wherein the two agencies share responsibilities in overseeing the marketing of products regulated by the FDCA.<sup>53</sup> As a consequence, the FTC is the primary oversight agency with respect to over-the-counter drugs and medical device advertising.<sup>54</sup> The FDA has entered into similar MOUs with a host of different government agencies, including U.S. Department of Agriculture (USDA),<sup>55</sup> the Department of the Treasury,<sup>56</sup> and the Department of Defense.<sup>57</sup> Other “principal cooperating agencies” the FDA must interact with include the Environmental Protection Agency, the Consumer Product Safety Commission, the Drug Enforcement Agency, the National Institute of Health, the Nuclear Regulatory Commission, the Office of Management and Budget, and the Securities and Exchange Commission.<sup>58</sup> In addition to these various federal agencies, the FDCA authorizes state governments, working in conjunction with the FDA, to enforce certain aspects of the Act.<sup>59</sup> In short, while the FDA is the lead agency in enforcing the FDCA, other entities may have more minor roles in effectuating the Act’s mandates.

Importantly, the FDCA does not contain a private right of action in which members of the public can sue to enforce the Act’s provisions.<sup>60</sup> Instead, under the FDCA, generally all proceedings “for the enforcement, or to restrain violations, of” the Act must be in the name of the United States.<sup>61</sup> Put another way, as the Supreme Court recently remarked, “the FDCA and its regulations provide the United States with nearly exclusive enforcement authority,” and “[p]rivate parties may not bring enforcement suits.”<sup>62</sup> While the Supreme Court has recognized that laws with mandates

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<sup>49</sup> 21 U.S.C. § 352.

<sup>50</sup> See *Kordel v. United States*, 335 U.S. 345 (1948).

<sup>51</sup> 15 U.S.C. § 45.

<sup>52</sup> See *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965).

<sup>53</sup> FTC-FDA Memorandum of Understanding, 36 Fed. Reg. 18,539 (1971).

<sup>54</sup> See 15 U.S.C. §§ 41, 52-53; see also FTC-FDA Memorandum, 36 Fed. Reg. at 18,539 (explaining that FTC, not FDA, has the authority over over-the-counter drugs and medical devices).

<sup>55</sup> 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); see generally FOOD & DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL, 3.2.1.4, <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123506.pdf> (September 2013) (discussing the various MOUs entered between different sub-agencies within the USDA and the FDA).

<sup>56</sup> See, e.g., FDA and BATF, Memorandum of Understanding, 52 Fed. Reg. 45,502 (Nov. 30, 1987).

<sup>57</sup> See, e.g., Memorandum of Understanding Between the Department of Defense and the Food and Drug Administration, 52 Fed. Reg. 33,472 (Sept. 3, 1987).

<sup>58</sup> See O’Reilly, *supra* note 30, at § 24.1.

<sup>59</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 1369-70.

<sup>60</sup> See 21 U.S.C. § 337(a).

<sup>61</sup> *Id.*

<sup>62</sup> See *POM Wonderful LLC v. Coca-Cola Co.*,—S. Ct.—, 2014 WL 2608859, at \* 5 (June 12, 2014).

similar to those contained in the FDCA can be enforced through private lawsuits,<sup>63</sup> the onus for ensuring the Act's provisions are enforced lies almost exclusively with the federal government.

## What Limits Are There to the Enforcement Jurisdiction of the FDCA?

The limits to the FDA's jurisdiction in enforcing the Act are necessarily a product of the constitutional limits imposed upon Congress under the Commerce Clause, the source of power Congress relied upon in enacting the FDCA.<sup>64</sup> Article I, Section 8 of the U.S. Constitution grants Congress the power "[t]o regulate commerce with foreign nations, and among the several States, and with the Indian Tribes."<sup>65</sup> While early 20<sup>th</sup> century case law interpreted Congress's commerce power narrowly to prevent the regulation of local economic activity that had an "indirect" impact on interstate commerce,<sup>66</sup> beginning in 1937, the Supreme Court began to read the commerce power more expansively,<sup>67</sup> extending the power such that Congress could regulate wholly intrastate activity that was economic in nature.<sup>68</sup> This relatively broad understanding of the constitutional commerce power continues today.<sup>69</sup> Given the modern case law respecting the commerce power, there is little question with respect to Congress's constitutional power to regulate in this area. Indeed, the Supreme Court in a case predating the modern interpretation of the Commerce Clause upheld the Pure Food and Drug Act of 1908, the FDCA's predecessor, against a challenge that the law's provisions that allowed for the seizure and condemnation of adulterated goods were an illegitimate exercise of the commerce power.<sup>70</sup> This case law coupled with the later expansion of the constitutional limits to the commerce power supports the suggestion of one commentator that "Congress ... appears to retain virtually unlimited power to regulate even the wholly intrastate production and sale of food, drugs, devices, and cosmetics."<sup>71</sup>

Notwithstanding the *constitutional* limits to the FDA's enforcement jurisdiction, the ability to enforce the FDCA is also circumscribed as a *statutory* matter. The original 1938 Act, which was

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<sup>63</sup> *Id.* at \*10 (noting that the "centralization of FDCA 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 (concluding that Congress intended private state law tort claims regarding drug labeling to proceed despite the existence of the FDCA).

<sup>64</sup> *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 FDCA, rested "upon the power of Congress to regulate interstate commerce").

<sup>65</sup> U.S. Const., Art. I, § 8, cl. 3.

<sup>66</sup> *See, e.g.*, *Hammer v. Dagenhart*, 247 U.S. 251, 273 (1918); *Carter v. Carter Coal Co.*, 298 U.S. 238, 308 (1936).

<sup>67</sup> *See* *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937).

<sup>68</sup> *See* *Wickard v. Filburn*, 317 U.S. 111 (1942).

<sup>69</sup> *See* *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."); *but see* *United States v. Lopez*, 514 U.S. 549 (1995); *United States v. Morrison*, 529 U.S. 598 (2000).

<sup>70</sup> *See* *Hipolite Egg*, 220 U.S. at 58 ("The question in the case, therefore is, What power has Congress over such articles? ... The power ... is certainly appropriate to the right to bar them from interstate commerce, and completes its purpose, which is not to prevent merely the physical movement of adulterated articles, but the use of them, or rather to prevent trade in them between the States ... And appropriate means to that end, which we have seen is legitimate, are the seizure and condemnation of the articles at their point of destination ... The selection of such means is certainly within that breadth of discretion which we have said Congress possesses in the execution of the powers conferred upon it by the Constitution.")

<sup>71</sup> *See* Hutt, Merrill, and Grossman, *supra* note 15, at 1220 (citing *Raich*, 545 U.S. 1).

enacted in the immediate wake of the 1937 change in constitutional jurisprudence, was “largely limited to products that have moved, are moving, or will be moving in interstate commerce.”<sup>72</sup> Nonetheless, even as Congress has expanded the FDA’s power over intrastate activities respecting FDCA covered articles, the Act still requires that the regulated activity still have some nexus with interstate commerce.<sup>73</sup> For example, the “prohibited acts” in Section 301 of the Act are generally limited to articles that were, are, or will be interstate commerce.<sup>74</sup>

The statutory required nexus with interstate commerce can come from a host of 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.<sup>75</sup> 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.”<sup>76</sup> At the most expansive, courts have held that the fact that a product contains even a single ingredient that has been shipped in interstate commerce is sufficient to confer enforcement jurisdiction for the FDA.<sup>77</sup> Thus, the FDCA’s reach, while not coterminous with the constitutional limits of the commerce power that have the potential to reach any intrastate economic class of activities that have a substantial effect on interstate commerce,<sup>78</sup> is significant, and as a consequence, recent federal court decisions have found the interstate commerce nexus required by the FDCA to pose “no obstacle” to allowing the FDA to enforce the Act with respect to wholly intrastate activities.<sup>79</sup>

The fact that the FDA has the authority to enforce the FDCA with respect to wholly intrastate activities does not mean that the agency’s authority is limitless. Rather, while there may be no clear geographic limit to the FDA’s authority, the central statutory restriction on the agency’s powers resides in the FDCA’s defined limits with respect to the articles regulated under the Act.

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<sup>72</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 1220.

<sup>73</sup> *Id.* at 1221. Pursuant to Section 709 of the Act, the nexus with interstate commerce is presumed to exist and need not be demonstrated as an initial matter by the government. See 21 U.S.C. § 379a.

<sup>74</sup> See, e.g., 21 U.S.C. § 331(a) (prohibiting the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded food, drug, device, tobacco product, or cosmetic); *id.* § 331(b) (prohibiting the adulteration or misbranding of any covered article in interstate commerce); *id.* § 331(c) (prohibiting the receipt in interstate commerce of any adulterated or misbranded article that is then delivered or proffered for delivery for pay).

<sup>75</sup> See *United States v. 7 Barrels, etc. of Spray Dried Whole Egg*, 141 F.2d 767, 770 (7<sup>th</sup> Cir. 1944); see also *United States v. Sanders*, 196 F.2d 895, 898 (10<sup>th</sup> 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.”).

<sup>76</sup> *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

<sup>77</sup> See *Baker v. United States*, 932 F.2d 813 (9<sup>th</sup> Cir. 1991); *United States v. An Article of Food*, 752 F.2d 11, 14 (1<sup>st</sup> 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.”).

<sup>78</sup> See *Raich*, 545 U.S. at 17.

<sup>79</sup> *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1320 (D.C. Cir. 2014). It should be noted that just because the FDA likely possesses the legal power to enforce the FDCA’s provisions against many purely local activities, such as with respect to a local grocery, restaurant or vending machine, the FDA has, as a matter of its discretion, largely “ceded the regulation of such establishments to state and local governments.” See Hutt, Merrill, and Grossman, *supra* note 15, at 1234.

For example, prior to the enactment of Family Smoking Prevention and Tobacco Act of 2009,<sup>80</sup> the FDCA contained no explicit authority that allowed the FDA to regulate tobacco products. In 1996, after years of expressly disavowing the authority to regulate tobacco use, the FDA issued a host of regulations governing “access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents,” relying on the argument that nicotine is a “drug.”<sup>81</sup> The Supreme Court, in *FDA v. Brown & Williamson Tobacco Corp.*, rejected the FDA’s argument, holding that Congress had “clearly precluded the FDA from asserting jurisdiction to regulate tobacco products.”<sup>82</sup> While Congress has since provided the FDA with the explicit statutory authority to regulate tobacco products that the Court found lacking in *Brown & Williamson*,<sup>83</sup> the case illustrates that the FDA’s enforcement authority is not limitless and that the reach of the FDA’s authority, as several courts have recognized, may ultimately be circumscribed by the definition attached to a regulated article.<sup>84</sup>

## Is Every Violation of the FDCA Enforced?

Given the breadth of the articles regulated by the FDCA and the reach of the FDA’s enforcement authority, questions often arise as to the amount of discretion, if any, the agency has in choosing whether to initiate an enforcement proceeding under the Act. The Supreme Court’s decision in *Heckler v. Cheney* is the starting point for any discussion about the FDCA’s enforcement discretion.<sup>85</sup> In *Heckler*, a death row inmate sentenced to die by lethal injection petitioned the FDA to take enforcement actions against state officials who were administering the drug cocktail to be used in the execution.<sup>86</sup> The petitioner argued that the injection would constitute the 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 FDCA.<sup>87</sup> Nonetheless, the Supreme Court refused to reach the merits of the petitioner’s misbranding argument, unanimously holding that the FDA’s decision not to prosecute or enforce a matter through civil or criminal processes is generally a decision committed to the agency’s “absolute discretion.”<sup>88</sup> For the Court, the FDCA’s general provision governing enforcement, Section 702, merely “authorized” the Secretary of Health and Human Services (and through a delegation of that authority, the Commissioner of the FDA) “to conduct examinations and investigations for the purposes of” the Act, language that was “permissive” in nature and indicative of Congress’ intent to commit the

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<sup>80</sup> See P.L. 111-31, 123 Stat 1776 (2009).

<sup>81</sup> See 61 Fed. Reg. 44396, 44632-44633 (1996).

<sup>82</sup> 529 U.S. 120, 126 (2000).

<sup>83</sup> See Family Smoking Prevention and Tobacco Act, P.L. 111-31, 123 Stat 1776 (2009).

<sup>84</sup> See, e.g., *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209, 1243-44 (M.D. Fl. 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 FDCA provided the 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 (1<sup>st</sup> Cir. 1993) (holding that the FDA did not have the authority to regulate dietary supplements under its “food additive” authorities).

<sup>85</sup> The text of the FDCA does explicitly state that the Act should not be construed to require the 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 the 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).

<sup>86</sup> *Id.* at 823-24.

<sup>87</sup> *Id.*

<sup>88</sup> See at 831.

initiation of enforcement proceedings to the FDA's discretion.<sup>89</sup> *Heckler* has been described as the "high-water mark of FDA discretionary selection of remedies," as it forms the legal basis under which the FDA can select its targets for enforcement of the FDCA.<sup>90</sup>

Notwithstanding *Heckler*'s ultimate holding, it is important to note that the Supreme Court in *Heckler* did limit its ruling, as an executive agency's nonenforcement decisions are only "presumptively" unreviewable.<sup>91</sup> Put another way, the presumption providing an executive agency with enforcement discretion "may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers."<sup>92</sup> And, indeed, courts have found that other provisions of the FDCA have overcome the presumption against reviewing the FDA's enforcement decisions. For example, in *Cook v. FDA*, a case with strikingly similar facts to *Heckler*, a group of death row inmates sued the FDA for allowing several state correctional facilities to import sodium thiopental, arguing that the drug used in lethal injections was "a misbranded and unapproved new drug" and its import into the country violated Section 801 of the FDCA.<sup>93</sup> In ruling against the FDA, the D.C. Circuit Court of Appeals distinguished *Heckler*, noting that Section 801 of the FDCA mandates that when the FDA, through the CBP, examines certain imported drugs that are adulterated, misbranded, or unapproved by the FDA, the drugs "shall be refused admission," language that "unambiguously imposes mandatory duties upon the FDA" to refuse admission to the drugs.<sup>94</sup> In other words, while *Heckler* provided the FDA with significant discretion in enforcing the FDCA, as the D.C. Circuit held in *Cook* with respect to Section 801, Congress, when it speaks with sufficient clarity, can limit the FDA's exercise of its enforcement powers.<sup>95</sup>

Aside from the legal issues respecting the FDA's discretion to enforce parts of the Act, as a matter of policy, as one commentator noted, it is a "basic economic fact" that the FDA simply cannot investigate and attempt to enforce every potential violation of the Act.<sup>96</sup> Indeed, the FDA's enforcement discretion is at the heart of many of the most contentious political disputes surrounding the agency. The FDA is often faced with the difficult decision to "on the one hand" "ignore a safety issue and [potentially] precipitate deaths through nonfeasance" or "on the other hand ... shut down an entire industry within a week through maximum sanctions."<sup>97</sup> The FDA has continually set enforcement priorities through policy statements, such as choosing to take actions against drugs with safety risks before taking action against drugs that lack proof of effectiveness.<sup>98</sup> Nonetheless, the inevitable result of such policy decisions is that the agency's enforcement decisions will be of "perennial" interest to Congress.<sup>99</sup>

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<sup>89</sup> *Id.* at 835.

<sup>90</sup> See O'Reilly, *supra* note 30, at § 6.1

<sup>91</sup> 470 U.S. at 832.

<sup>92</sup> *Id.* at 833.

<sup>93</sup> *Cook v. FDA*, 733 F.3d 1, 3 (D.C. Cir. 2013).

<sup>94</sup> *Id.* at 10.

<sup>95</sup> *Id.* at 12.

<sup>96</sup> Mark Klock, *A Modest Proposal to Rename the FDA*, 36 ARIZ. ST. L.J. 1161, 1180 (Winter 2004); see generally *United States v. Thriftmart, Inc.*, 429 F.2d 1006, 1011 (9<sup>th</sup> Cir. 1970) ([The FDCA] giving the FDA discretion whether to proceed criminally or civilly is constitutional; the FDA is not required to prosecute every violation.").

<sup>97</sup> See O'Reilly, *supra* note 30, at § 6.1.

<sup>98</sup> See generally Hutt, Merrill, and Grossman, *supra* note 15, at 1197-1200

<sup>99</sup> See O'Reilly, *supra* note 30, at § 6.1.

## Civil Enforcement of the FDCA

As noted above, the FDA has several enforcement tools it may use to address violations of the FDCA. The Act provides the agency with certain administrative enforcement powers that it can exercise on its own, and the statute also contains judicial enforcement mechanisms that require the agency to go to court. Enforcement actions may be civil or criminal in nature. Civil actions include the imposition of civil monetary penalties, injunctions, and seizures.

### Civil Monetary Penalties

Under the FDCA, the FDA may impose civil monetary penalties<sup>100</sup> for certain specified violations of the Act. These include violations relating to prescription drug marketing practices,<sup>101</sup> medical devices,<sup>102</sup> electronic products,<sup>103</sup> tobacco products,<sup>104</sup> pesticide residues in food,<sup>105</sup> generic drug applications,<sup>106</sup> and improper dissemination of direct-to-consumer advertisements for approved drugs or biological products.<sup>107</sup> The maximum amount of the penalty that may be assessed by the FDA varies greatly depending on the particular prohibited act, ranging from approximately \$1,000 per violation to over \$1 million.<sup>108</sup> In determining the amount of the penalty for many of these violations, the agency is required to take into account the nature and circumstances surrounding the violation, as well as factors such as the person's ability to pay, the effect on the person's ability to continue to do business, and any history of similar prior acts.<sup>109</sup> Penalties may be assessed against both individuals and corporations.

While the agency is under no statutory obligation to provide notification, the FDA has indicated that its normal practice is to provide some form of warning to companies before seeking a civil money penalty, typically in the form of a warning letter.<sup>110</sup> Should the agency determine that a civil monetary penalty is warranted, regulations set forth procedures under which the FDA imposes civil money penalties without the involvement of the Department of Justice or the courts.<sup>111</sup> Under these regulations, a penalty proceeding is initiated that is similar to a civil suit in court, whereby the FDA serves a complaint on an individual or corporation, alleging a violation,

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<sup>100</sup> See 21 C.F.R. § 17.1 for a complete list of civil monetary penalties that may be imposed administratively by the FDA.

<sup>101</sup> 21 U.S.C. § 333(b).

<sup>102</sup> 21 U.S.C. § 333(f)(1).

<sup>103</sup> 21 U.S.C. § 360pp(b).

<sup>104</sup> 21 U.S.C. § 333(f)(9).

<sup>105</sup> 21 U.S.C. § 333(f)(2)(A).

<sup>106</sup> 21 U.S.C. § 335b.

<sup>107</sup> 21 U.S.C. § 333(g).

<sup>108</sup> The FDA is required to adjust these amounts at least once every four years, pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990. See 28 U.S.C. § 2461 note; and 21 C.F.R. § 17.2 for a table entitled "Civil Monetary Penalties Authorities Administered by FDA and Adjusted Maximum Penalty Amount."

<sup>109</sup> See 21 U.S.C. § 335b(b)(2); 21 U.S.C. § 333(f)(5)(B).

<sup>110</sup> Arthur Levine, FDA ENFORCEMENT MANUAL, Volume I, § 1071, available at <http://prod-admin1.tmg.atex.cniweb.net:8080/preview/www/2.3427/2.5267>.

<sup>111</sup> 21 C.F.R. § 17.1 et seq. However, it should be noted that under the FDCA, some provisions expressly provide that the relevant civil monetary penalty action must be imposed by a federal court, not by the FDA. See, e.g., 21 U.S.C. § 360pp (civil monetary penalties related to the distribution of electronic products).

and seeking a penalty.<sup>112</sup> This party (i.e., the respondent) is required to answer the complaint, and may request a hearing on the issue.<sup>113</sup> Following the hearing, a decision is rendered by an administrative law judge, and the decision may be appealed.<sup>114</sup>

## Seizures

In order to prevent harmful goods from reaching a consumer, the FDCA authorizes the seizure of foods, drugs, devices, cosmetics, and tobacco products that are adulterated or misbranded.<sup>115</sup> According to a House report accompanying the FDCA, a seizure is considered the harshest civil remedy under the Act, and it “should be discouraged or confined to those cases where the public protection requires such action.”<sup>116</sup> Seizures may be smaller in nature, involving only a specific lot or batch of a defective product, but they may also be large in scale, e.g., in situations where multiple seizure actions are filed simultaneously in a number of geographic locations, potentially halting the national distribution of a product.<sup>117</sup>

While the FDA itself lacks the authority to seize products, these actions may be carried out by the U.S. Attorney in a given judicial district based on the agency’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.<sup>118</sup> The FDA is under no obligation to notify a manufacturer that its products violate the FDCA before undertaking a seizure action, and the Supreme Court has found that seizing products without any prior judicial hearing does not raise due process concerns.<sup>119</sup> However, the FDA may choose to notify an owner of these products and give them an opportunity to take corrective action prior to initiating a seizure.

Under the FDCA, the point at which a product may be seized may depend on the type of product and the alleged violation.<sup>120</sup> 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.”<sup>121</sup> However, with respect to counterfeit drugs and the materials used to make them, as well as adulterated or misbranded medical devices and tobacco products, a FDA seizure may occur at any time (and before a complaint is filed).<sup>122</sup> Certain restrictions apply to seizure actions against a food that is misbranded because of its advertising, or

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<sup>112</sup> 21 C.F.R. § 17.5.

<sup>113</sup> 21 C.F.R. § 17.13.

<sup>114</sup> 21 C.F.R. § 17.51.

<sup>115</sup> 21 U.S.C. § 334. *See generally* O’Reilly, *supra* footnote 30, at § 7:3.

<sup>116</sup> *See* Erika King and Elizabeth M. Walsh, *The Authority of a Court to Order Disgorgement for Violations of the Current Good Manufacturing Practices Requirement of the Federal Food, Drug, and Cosmetic Act*, 58 FOOD DRUG L.J. 149, 158 (2003) (citing H.R. REP. NO. 75-2139, at 4 (1938)).

<sup>117</sup> *See* O’Reilly, note 30, at § 7:10.

<sup>118</sup> *See generally* FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, § 6-1, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176733.htm> (September 2011).

<sup>119</sup> *See*, *Ewing v. Casselberry*, 339 U.S. 594 (1950); *see also* *U.S. v. One Unlabeled Unit, More or Less, of an Article of Device and Promotional Brochures*, 885 F. Supp. 1025 (ND Ohio 1995).

<sup>120</sup> *See* Patrick O’Leary, *Credible Deterrence: FDA and the Park Doctrine in the 21<sup>st</sup> Century*, 68 FOOD DRUG L.J. 137, 176 n.135 (2013).

<sup>121</sup> 21 U.S.C. § 334(a)(1).

<sup>122</sup> *See* 21 U.S.C. §§ 334(a)(2) and 372(e)(5).

that is being held for sale to consumers in an establishment not owned or operated by the food's manufacturer, packer, or distributor.<sup>123</sup>

Once goods have been seized, a company with an ownership interest in the goods has at least two main options: it can do nothing and allow the products to be condemned and disposed of, or it can claim the article and contest the seizure action by filing an answer to the complaint.<sup>124</sup> It has been noted that more than 90% of FDA seizure actions are not contested.<sup>125</sup>

## Injunctions

The FDCA authorizes federal district courts to issue injunctions in order to restrain almost every violation of the Act.<sup>126</sup> Injunctions under the FDCA are designed to stem the flow of adulterated, misbranded, or otherwise violative goods in interstate commerce, and to correct the conditions that caused the violation to occur.<sup>127</sup> Injunctions can take the form of a prohibition, e.g., an order barring a company from distributing a certain product, or a command to take a certain action, such as an order to clean up a facility.<sup>128</sup> These judicial orders may be issued for the range of FDA-regulated products, and they may be temporary or permanent in nature.

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.”<sup>129</sup> The 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.<sup>130</sup>

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<sup>123</sup> 21 U.S.C. § 334(a)(3).

<sup>124</sup> 21 U.S.C. § 334(d); FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, § 6-1-9, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176733.htm> (September 2011).

<sup>125</sup> *Levine*, note 106, at § 1160. The lack of challenges generally stems from the likelihood that the FDA prevails in these actions, as well as the expense of litigation. *Id.*

<sup>126</sup> 21 U.S.C. § 332.

<sup>127</sup> FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, § 6-2, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176733.htm> (September 2011).

<sup>128</sup> 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 the required FDA approval; and (3) deviations from FDA requirements concerning labeling and promotion. *Levine*, note 106, at § 1202.

<sup>129</sup> FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, § 6-2-4, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176733.htm> (September 2011).

<sup>130</sup> *Id.* The 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.*



Similar to seizures, injunctions involve cooperation between the FDA and the Department of Justice. Based on a recommendation from the FDA, the U.S. Attorney files an injunction action in federal district court to enjoin one or more individuals and/or a company from violating the FDCA.<sup>131</sup> In general, courts have granted injunctions where it has been demonstrated that defendants violated the FDCA and there is a likelihood of recurring violations.<sup>132</sup> If the court enters the 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 FDCA are resolved through the entry of a negotiated consent decree.<sup>133</sup>

## Criminal Enforcement of the FDCA

In addition to civil enforcement mechanisms, the FDCA also subjects individuals to criminal penalties, including fines and imprisonment, for violating certain provisions of the Act.<sup>134</sup> Criminal prosecutions under the FDCA are rare: “only a miniscule fraction of 1 per cent of the [FDA’s] inspections will result in criminal prosecution”<sup>135</sup> and violations of the Act resulting from “extremely technical infractions” are very unlikely to result in criminal punishment.<sup>136</sup> In fact, according to the FDA’s enforcement manuals, criminal prosecutions rarely occur if “a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations.”<sup>137</sup> Notwithstanding the rarity of criminal prosecution under the FDCA, the threat of criminal penalties is regarded as an extremely effective tool in ensuring compliance with the statute.<sup>138</sup> 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 FDCA, criminal penalties, which threaten the liberty interests of a host of individuals such as the “factory manager, the corporate chief executive, or the researcher,” has, according to one commentator, produced the “most rapid results” for the FDA with respect to enforcing compliance with the Act.<sup>139</sup>

The FDA’s Office of Criminal Investigations (OCI) is the primary entity tasked with “investigating suspected criminal violations of the [FDCA] and other related laws.”<sup>140</sup> The OCI, which recruits experienced investigators from other government agencies, such as the Federal Bureau of Investigation or the Secret Service,<sup>141</sup> employ “customary federal law enforcement

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<sup>131</sup> *Levine*, note 106, at § 1200.

<sup>132</sup> *See, e.g., United States v. Endotec, Inc.*, No. 6:06-cv-1281, 2009 U.S. Dist. LEXIS 93985 (M.D. Fla. Sept. 28, 2009); *United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1011 (E.D. Cal. 2010).

<sup>133</sup> *Levine*, note 106, at § 1250.

<sup>134</sup> *See* 21 U.S.C. § 333.

<sup>135</sup> *See* O’Reilly, *supra* note 30, at § 8.2.

<sup>136</sup> *Id.* at § 8.1.

<sup>137</sup> *See* FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, 6-5-13, <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm> (January 2011).

<sup>138</sup> *See* O’Reilly, *supra* note 30, at § 8.1.

<sup>139</sup> *Id.*

<sup>140</sup> *See* FOOD & DRUG ADMIN., *Inspections, Compliance, Enforcement, and Criminal Investigations: Mission*, <http://www.fda.gov/ICECI/CriminalInvestigaions/ucm123027.htm> (September 10, 2013).

<sup>141</sup> *See* Steven M. Kowal, *Execution of a Criminal Search Warrant by FDA—Effective Preparation and Response*, 52 FOOD DRUG L.J. 117, 120 (1997).

methods and techniques” in conducting criminal investigations.<sup>142</sup> Upon determining that prosecution is the appropriate course of action, OCI makes a recommendation to the DOJ, as the DOJ possesses the authority to prosecute those individuals and corporations suspected of violating the FDCA.<sup>143</sup> However, pursuant to Section 305 of the Act, before any violation of the FDCA is reported to “any United States attorney for institution of a criminal proceeding,” the “person against whom such proceeding is contemplated” should be provided with notice and an opportunity to present his “views ... with regard to such contemplated proceeding.”<sup>144</sup> Notwithstanding the text of the FDCA, the Supreme Court has held that a hearing is not required,<sup>145</sup> and, while the prevailing practice is to afford a Section 305 hearing to an alleged violator, FDA regulations specify certain circumstances in which the FDA Commissioner need not provide such a hearing.<sup>146</sup> Once the FDA has recommended a criminal prosecution to the DOJ, the Justice Department, including the local U.S. Attorney’s office, will review the recommendation and, if warranted, institute criminal proceedings against the alleged violator.<sup>147</sup> While as a matter of law the DOJ has the discretion to reject the FDA’s recommendation, as a matter of course, the DOJ will typically “adhere to the recommendations of the FDA” and “act, as closely as possible, in partnership with attorneys from the FDA.”<sup>148</sup>

## Criminal Violations of the FDCA

Criminal convictions under the FDCA generally require proof of three central elements. First, the government must prove that the article at the center of the statutory violation is either a “food,” “drug,” “device,” “tobacco,” or “cosmetic.”<sup>149</sup> Second, the article at issue generally<sup>150</sup> must be “adulterated” or “misbranded.”<sup>151</sup> Third, the article at issue must have been introduced into interstate commerce.<sup>152</sup> Importantly, contrary to the typical requirement of Anglo-American criminal law, FDCA criminal provisions do not include a *mens rea* or “guilty mind” requirement.<sup>153</sup> Put another way, the standard for criminal liability under the FDCA is strict

<sup>142</sup> See FOOD & DRUG ADMIN., *Inspections, Compliance, Enforcement, and Criminal Investigations: What OCI Investigates*, <http://www.fda.gov/ICECI/CriminalInvestigations/ucm123062.htm> (August 3, 2009).

<sup>143</sup> See O’Reilly, *supra* note 30, at § 8.3.

<sup>144</sup> 21 U.S.C. § 335.

<sup>145</sup> *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.”).

<sup>146</sup> 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 Department of Justice.).

<sup>147</sup> See John W. Lundquist and Sandra L. Conroy, *Defending Against Food & Drug Prosecutions*, 21 CHAMPION 20, 21 (July 1997).

<sup>148</sup> *Id.* (internal citations omitted).

<sup>149</sup> See, e.g., 21 U.S.C. § 331(a)-(c).

<sup>150</sup> Section 301 of the FDCA, which contains the Act’s prohibited acts, generally centers its prohibitions on the concepts of adulteration and misbranding. See *supra* “Overview of the Food, Drug, and Cosmetics Act.” Nonetheless, the Act does contain several provisions where adulteration or misbranding may be irrelevant with respect to a particular prohibited act. 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 the FDA to approve a new drug application before a drug can enter interstate commerce, violates the FDCA. See 21 U.S.C. § 331(d).

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> See Hutt, Merrill, and Grossman, *supra* note 15, at 1310.

liability, such that a defendant can be held criminally liable without proof of knowledge of the event or intention to perform the act that results in a violation.<sup>154</sup>

Two Supreme Court cases established this principle. In *United States v. Dotterweich*, Justice Frankfurter, writing for a five-member majority, explained that the FDCA “dispenses with the conventional requirement for criminal conduct awareness of some wrongdoing”<sup>155</sup> and that criminal accountability extends to all those who have “a responsible share in the furtherance of the transaction which the statute outlaws.”<sup>156</sup> The Court reasoned that the strict liability standard was necessitated 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.”<sup>158</sup> Over thirty years later, in *United States v. Park*, the Supreme Court reaffirmed *Dotterweich*, holding that a showing of liability under the FDCA did not require an “awareness of wrongdoing” by the defendant, but instead merely required the defendant to be in a “position in [a] corporation” so that he had the “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.”<sup>157</sup> In so holding, the Court noted that while the strict liability standard imposed by the FDCA 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.”<sup>158</sup>

While the lack of a *mens rea* element in FDCA criminal cases could theoretically allow the FDA and the Justice Department to “bring a criminal action ... in virtually every serious case” of an FDCA violation,<sup>159</sup> two common defenses may diminish the potential reach of the FDCA’s criminal sanctions. First, an individual accused of an FDCA 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 FDCA].”<sup>160</sup> 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.<sup>161</sup> Second, under the “guaranty clause” contained in Section 303(c) of the FDCA, a person who in “good faith” merely receives and later delivers an illegal article cannot be subjected to criminal penalties under the Act.<sup>162</sup> Likewise, a person who introduced a misbranded or adulterated product into commerce is also exempt under Section 303(c) if that person received the article in “good faith” and has obtained written guaranty that the product is not in violation of the Act.<sup>163</sup> The guaranty clause has allowed pharmacists who have in

<sup>154</sup> *Id.*

<sup>155</sup> 320 U.S. 277, 281 (1943).

<sup>156</sup> *Id.* at 284.

<sup>157</sup> 421 U.S. 658, 673-74 (1975).

<sup>158</sup> *Id.* at 672.

<sup>159</sup> See O’Reilly, *supra* note 30, at § 8.2

<sup>160</sup> *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)).

<sup>161</sup> *Id.* Some commentators have raised concerns about how successful the impossibility defense is in FDCA criminal cases. See, e.g., Andrew C. Baird, *The New Park Doctrine*, 91 N.C.L. REV. 949, 978 n.179 (“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.”).

<sup>162</sup> See 21 U.S.C. § 333(c)(1).

<sup>163</sup> *Id.* § 333(c)(2). Giving a false guaranty that a product is not adulterated or misbranded is prohibited under Section 301(h) of the FDCA. See 21 U.S.C. § 331(h).

good faith distributed misbranded or adulterated drugs from a drug manufacturer or distributor to escape criminal liability.<sup>164</sup>

## **Criminal Penalties Resulting from an FDCA Violation**

Under Section 303(a)(1) of the FDCA, criminal violations of the Act are generally treated as misdemeanors,<sup>165</sup> meaning a crime that is punishable by a fine or imprisonment of a year or less.<sup>166</sup> Nonetheless, violations of the Act may constitute a felony if the act is a second offense or is done with the “intent to defraud or mislead.”<sup>167</sup> In order for a defendant to act with an “intent to defraud or mislead” under the FDCA, the defendant must “design[] his conduct to avoid the regulatory scrutiny of the FDA,”<sup>168</sup> meaning that in order to incur a felony conviction under the FDCA a defendant’s intent to defraud or mislead may be directed at not only the ultimate consumers of a product, but also state and federal government enforcement agencies.<sup>169</sup>

Section 303(a) contains the default criminal penalty provisions for individuals who commit either a misdemeanor or a felony under the Act.<sup>170</sup> Those who have committed a simple violation of the Act are, pursuant to the text of the FDCA, subject to a fine of \$1,000, imprisonment of up to one year, or both.<sup>171</sup> Subsequent convictions or convictions demonstrating an intent to defraud or mislead may, according to the text of the FDCA, result in fines of up to \$10,000, imprisonment for up to three years, or both.<sup>172</sup> However, under the Sentencing Reform Act of 1984, as amended by the Criminal Fines Improvement Act of 1987, all criminal fines are subject to certain uniform levels, modifying all fines imposed in the United States Code, including those imposed by the FDCA.<sup>173</sup> As a result of those two laws, the current maximum fine for an individual who has committed an FDCA misdemeanor that does not result in death is \$100,000,<sup>174</sup> and an individual who has committed an FDCA misdemeanor that does result in death or an FDCA felony could be subject to a fine of up to \$250,000.<sup>175</sup> Likewise, under current law, an organization could be

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<sup>164</sup> See Richard R. Abood, *Physician Dispensing: Issues of Law, Legislation and Social Policy*, 14 AM. J. L. & MED. 307, 341 n.186 (1989).

<sup>165</sup> See 21 U.S.C. § 333(a)(1).

<sup>166</sup> See generally *United States v. Graham*, 169 F.3d 787, 792 (3d Cir. 1999).

<sup>167</sup> 21 U.S.C. § 333(a)(2).

<sup>168</sup> See *United States v. Ellis*, 326 F.3d 550, 554 (4<sup>th</sup> Cir. 2003).

<sup>169</sup> See *United States v. Bradshaw*, 840 F.2d 871, 874-75 (11<sup>th</sup> Cir. 1988); see also *United States v. Cambra*, 933 F.2d 752, 755 (9<sup>th</sup> Cir. 1991); *United States v. Arlen*, 947 F.2d 139, 143 (5<sup>th</sup> Cir. 1991).

<sup>170</sup> See 21 U.S.C. § 333(a). The FDCA 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 21 U.S.C. § 333(e)(1).

<sup>171</sup> 21 U.S.C. § 333(a)(1).

<sup>172</sup> *Id.* § 333(a)(2).

<sup>173</sup> 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.

<sup>174</sup> 18 U.S.C. § 3571(b)(5).

<sup>175</sup> *Id.* § 3571(b)(3)-(4).

forced to pay a maximum fine of \$200,000 if guilty of an FDCA misdemeanor<sup>176</sup> and a maximum fine of \$500,000 for an FDCA misdemeanor resulting in death or an FDCA felony.<sup>177</sup>

Pursuant to the U.S. Sentencing Guidelines, defendants convicted of violating the Act are provided a base offense level of six,<sup>178</sup> resulting in a guideline recommendation of a final sentence of zero to eighteen months in prison, depending on the defendant's individual criminal history.<sup>179</sup> The sentence could increase considerably if the offense was committed after sustaining a prior violation of the FDCA or if the offense involved fraud.<sup>180</sup> 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."<sup>181</sup>

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<sup>176</sup> *Id.* § 3571(c)(5)

<sup>177</sup> *Id.* § 3571(c)(3)-(4). Other criminal laws may be invoked in the enforcement of the FDCA, 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 15, at 1328-29 (collecting various cases).

<sup>178</sup> *See* U.S.S.G. MANUAL § 2N2.1.

<sup>179</sup> *See* U.S.S.G. MANUAL Chapter 5, Part A.

<sup>180</sup> *See* U.S.S.G. MANUAL § 2N2.1.

<sup>181</sup> *See* U.S.S.G. MANUAL § 2N2.1, cmt. 3.

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