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## Note

### FDA Goes Loko with Warning Letters

Rebecca Boxhorn\*

#### I. INTRODUCTION

On November 17, 2010, the U.S. Food and Drug Administration (FDA) issued a Warning Letter to Phusion Projects, makers of the recently popular Four Loko malt liquor beverage.<sup>1</sup> The FDA issued this letter in the wake of several news reports detailing the potentially deadly side effects of drinking the beverage—stemming from its extremely high caffeine content.<sup>2</sup> Four Loko, also known as “black-out in-a-

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1. Letter from Joann M. Givens, Acting Dir., Office of Compliance, Ctr. for Food Safety and Applied Nutrition, to Jaisen Freeman, Chris Hunter & Jeff Wright, Phusion Projects, LLC (Nov. 17, 2010) [hereinafter Letter from Joann M. Givens], *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234023.htm>.

2. *See, e.g.*, Dash Harris, “Black-out in a Can?”, AM. MORNING (Oct. 26, 2010, 8:17 AM), <http://amfix.blogs.cnn.com/2010/10/26/black-out-in-a-can/?iref=allsearch> (“Nine Central Washington University students hospitalized this month after an off-campus party were sickened by ‘Four Loko,’ a caffeinated malt liquor also known as ‘blackout in a can’ . . .”); Collin Keefe, *Hallucinogenic Frenzies and Hospitalized College Kids: Four Loko Hysteria Reaches a Fevered Pitch*, N.Y. MAG. (Nov. 12, 2010, 11:39 AM), [http://philadelphia.grubstreet.com/2010/11/hallucinogenic\\_frenzies\\_and\\_ho.html](http://philadelphia.grubstreet.com/2010/11/hallucinogenic_frenzies_and_ho.html) (“Four Loko, the sickly fruity-sweet malt-based elixir that packs a two-fisted punch of absurd amounts of caffeine and alcohol, is perhaps the greatest scourge to society since communism, or maybe crack cocaine.”); Lance Murray, *Report: Alcoholic Energy Drink Tied to Fatal Denton Crash*, CRIME TIME (Nov. 16, 2010, 7:55 AM), [http://blogs.star-telegram.com/crime\\_time/2010/11/report-alcoholic-energy-drink-linked-to-fatal-denton-crash.html](http://blogs.star-telegram.com/crime_time/2010/11/report-alcoholic-energy-drink-linked-to-fatal-denton-crash.html) (“Four Loko has been

can,” causes drinkers to be less aware of the side effects of alcohol—leading to increased consumption and dehydration.<sup>3</sup> The FDA informed Phusion Projects that the inclusion of caffeine in the alcoholic beverage was not generally recognized as safe and that caffeine was an unsafe food additive.<sup>4</sup> As a result, under the Federal Food, Drug, and Cosmetic Act (FDCA), Four Loko was an “adulterated” drink illegal to distribute or sell.<sup>5</sup>

The FDA’s letter to Phusion Products is one of hundreds of similar letters that the FDA sends each year.<sup>6</sup> These Warning Letters generally contain: (1) a determination that the regulated party is in violation of the FDCA, (2) a demand for corrective action, (3) a request for response within fifteen days, and (4) a warning that the receipt of a Warning Letter may hinder future government contracting opportunities.<sup>7</sup> The FDA classifies Warning Letters as “informal enforcement actions” intended to obtain voluntary compliance in lieu of a formal enforcement action.<sup>8</sup> Warning Letters are an effective method

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implicated in the crash early Sunday morning that killed a 14-year-old girl in Denton.”).

3. Aina Hunter, *Four Loko: Is New Party Brew “Liquid Cocaine?”*, CBS NEWS HEALTH WATCH (June 17, 2010), <http://www.cbsnews.com/stories/2010/06/17/health/main6592444.shtml>.

4. “Generally recognized as safe” or GRAS is a term applied by the FDA to food additives that are “generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use . . . .” *Generally Recognized as Safe (GRAS)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm> (last visited Nov. 23, 2010). *See also* 21 C.F.R. § 170.3 (2010).

5. Letter from Joann M. Givens, *supra* note 1.

6. U.S. FOOD & DRUG ADMIN., THE ENFORCEMENT STORY ch. 10, at 10-9 (2009) [hereinafter ENFORCEMENT STORY]. Warning Letter totals include both district and federal offices.

7. *See, e.g.*, Letter from Diana Amador-Toro, Dist. Dir., N.J. Dist. Office, to Mark Bowden, Vice President of Global Regulatory Affairs, Johnson and Johnson Consumer Prods., Inc. (Sept. 27, 2010) [hereinafter Letter from Diana Amador-Toro] , *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm227362.htm> (“Listerine Total Anticavity mouthwash is not generally recognized as safe and effective for the antiplaque indications in its labeling, and it is, therefore, a new drug under 201(P) of the Act (21 U.S.C. § 321(P)).”).

8. State Enforcement Provisions of the Nutrition Labeling and Education Act of 1990, 58 Fed. Reg. 2457 (Jan. 6, 1993) [hereinafter State Enforcement Regulation]; Warning Letters; Regulatory Procedures Manual, Chapter 8-10; Availability, 56 Fed. Reg. 27,026 (June 7, 1991) [hereinafter Warning Letters

for coercing recipients to comply with FDA regulations without resorting to the cost and time commitment of a formal proceeding.<sup>9</sup> Many regulated parties, including Phusion Projects, change their behavior before the FDA seeks formal enforcement.<sup>10</sup> Indeed, only one day after receiving a Warning Letter from the FDA, Phusion Projects announced that it would be removing all caffeine from its products, thus effectively responding to the FDA's purported violations.<sup>11</sup>

There are few available options, however, for those regulated parties that do not wish to voluntarily comply with an FDA Warning Letter. The only courses of action available are to defy the FDA and await a potential formal enforcement action or to challenge the Warning Letter itself.<sup>12</sup> Those parties that attempt to challenge FDA Warning Letters face a nearly impossible task. The FDA and most courts will not interpret FDA Warning Letters as a final agency action and are thus not ripe for review before a court.<sup>13</sup> Even if considered final agency action, regulated parties may not be able to assert standing for failure to exhaust all available administrative options.<sup>14</sup> While the FDA considers Warning Letters to be "informal enforcement actions," very real consequences flow from their receipt.<sup>15</sup> Beyond the threat of a more "formal" enforcement action, regulated parties may lose governmental contracting rights, lose investments and sales, and be sued by consumers.<sup>16</sup>

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Regulation].

9. State Enforcement Regulation, *supra* note 8, at 2457.

10. M. Amedeo Tumolillo, *Company to Drop Caffeine From Its Alcoholic Drinks*, N.Y. TIMES, Nov. 17, 2010, at A22, available at [http://www.nytimes.com/2010/11/17/us/17drink.html?\\_r=1&emc=eta1](http://www.nytimes.com/2010/11/17/us/17drink.html?_r=1&emc=eta1); Press Release, Phusion Projects, Phusion Projects to Remove Caffeine, Guarana and Taurine from Products, (Nov. 16, 2010) [hereinafter Phusion Press Release], available at [http://www.phusionprojects.com/media\\_reformulation.html](http://www.phusionprojects.com/media_reformulation.html); see also ENFORCEMENT STORY, *supra* note 6, ch. 10, at 10-9.

11. Phusion Press Release, *supra* note 10.

12. Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 36 (D.D.C. 1995).

13. U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL ch. 4, at 4-13 (2010) [hereinafter PROCEDURES MANUAL]; Cody Labs., Inc. v. Sebelius, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118, at \*33-34 (D. Wyo. July 26, 2010).

14. See, e.g., *Cody Labs*, 2010 U.S. Dist. LEXIS 80118, at \*30.

15. State Enforcement Regulation, *supra* note 8, at 2457; Warning Letters Regulation, *supra* note 8, at 27,026.

16. See e.g., Letter from Diana Amador-Toro, *supra* note 7 (explaining that other government agencies will be alerted of the company's receipt of an FDA Warning Letter to consider in future contracting opportunities); Val Brickates Kennedy, *Boston Scientific Slides on FDA Fears*, MARKET WATCH

These consequences flow from an “informal enforcement action” which remains unreviewable by courts under current case law.<sup>17</sup>

This Note will examine the finality of FDA Warning Letters and refute the current case law that denies their justiciability. Part II will explain Warning Letters and their context in FDA enforcement actions as well as examine the current case law addressing the finality of these letters. Part III will analyze the current case law and examine Warning Letters under applicable finality standards established by the Supreme Court. Finally, this Note will conclude that, while Warning Letters serve legitimate public health and policy interests, judicial review of Warning Letters must be allowed to protect regulated parties from agency coercion and potential misapplications of the law.

## II. BACKGROUND

### A. A REVIEW OF WARNING LETTERS AND FDA ENFORCEMENT ACTIONS

Warning Letters are one of the many administrative tools that the FDA uses to address violations of federal law.<sup>18</sup> Warning Letters are correspondence sent by the FDA to firms or individuals that the Agency believes to be in violation of the FDCA.<sup>19</sup> The FDA classifies Warning Letters as “informal enforcement actions” as opposed to “formal enforcement actions” such as seizures or injunctions.<sup>20</sup> Warning Letters

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(Jan. 27, 2006, 5:58 PM), <http://www.marketwatch.com/story/boston-scientific-falls-on-fda-warning-guidant-results> (demonstrating the economic consequences of receiving a FDA Warning Letter); *Yaz FDA Warning*, BRANDI LAW FIRM, <http://www.brandilaw.com/practiceAreas/YAZ-Yasmin-Ocella-FDA-warning-letter.asp> (last visited Mar. 14, 2011) (soliciting law suits to sue Yaz after they received an FDA Warning Letter); One example of an FDA Warning Letter having a particularly negative impact on a company is the Warning Letter that Vioxx received from the FDA. See Jennifer L. Bragg & Melanie Gross, *Warning Letters: Strategies for Responding and their Impact in the Marketplace*, HEALTH CARE CONFERENCE ADMINISTRATORS, 22–23, <http://www.ehcca.com/presentations/devicecongress2/bragg.pdf> (last visited Mar. 16, 2011).

17. State Enforcement Regulation, *supra* note 8, at 2457; Warning Letters Regulation, *supra* note 8, at 27,026.

18. PETER HUTT ET AL., FOOD AND DRUG LAW 1339 (3d ed. 2007).

19. *Id.*

20. State Enforcement Regulation, *supra* note 8, at 2457; Warning Letters

“give individuals and firms an opportunity to take voluntary and prompt corrective action before [the FDA] initiates an enforcement action.”<sup>21</sup> The FDA expects that “most individuals and firms will voluntarily comply with the law” when allowed an opportunity to do so before commencing enforcement action.<sup>22</sup> This “arm twisting” allows the FDA to regulate without the expense of a full enforcement action, with reduced judicial oversight and limited, if any, procedural requirements.<sup>23</sup>

Generally, Warning Letters are issued for violations that (1) are not intentional or flagrant, (2) pose little probability of injury or death, and (3) are not part of a history of repeated or continued misconduct.<sup>24</sup> When deciding whether to issue a Warning Letter, the FDA looks to three factors: (1) if evidence shows that a firm, product or individual is in violation of the law or regulations; (2) violations are of regulatory significance and issuance of a letter is consistent with agency policy; and (3) “[t]here is a reasonable expectation that the responsible firm and persons will take prompt corrective action.”<sup>25</sup>

After the FDA issues a Warning Letter, the receiving party has fifteen business days to respond and explain the corrective actions the party has taken or plans to take.<sup>26</sup> Starting in September of 2009, the FDA instituted new procedures that allowed for “closing out” of Warning Letters that were followed by corrective action.<sup>27</sup> If the company or individual responds

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Regulation, *supra* note 8, at 27,026.

21. PROCEDURES MANUAL, *supra* note 13, ch. 4, at 4-1. Warning Letters are also issued as a way of establishing prior notice. Warning Letters Regulation, *supra* note 8, at 27,026.

22. PROCEDURES MANUAL, *supra* note 13, ch. 4, at 4-1.

23. Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 874–75 (1997).

24. PROCEDURES MANUAL, *supra* note 13, ch. 4, at 4-2.

25. *Id.* ch. 4, at 4-4.

26. *Id.* ch. 4, at 4-16. While fifteen working days are generally allowed for commencing corrective action, the Warning Letter recipient may reply with an explanation as to why fifteen days are inadequate and detail a time frame for completion of the correction. *Id.*

27. *Id.* ch. 4, at 4-11. “Warning Letter Close-out Letters” will be issued if:

- a. The firm replied to the Warning Letter with sufficient information to demonstrate that any listed violations have been adequately corrected; or
- b. A follow-up inspection shows that implementation of the corrective actions was adequate, or . . . FDA determines that the follow-up inspection is not needed; and
- c. The followup inspection . . . does not reveal other significant violations.

*Id.*

adequately to the violations listed in the Warning Letter, a close-out letter will be issued and published to the FDA Warning Letter website, if the regulated party wishes it to be published.<sup>28</sup> If a firm does not correct the violations listed in the Warning Letter to the FDA's satisfaction, the FDA considers "further administrative and/or regulatory actions."<sup>29</sup> This may include a subsequent Warning Letter.<sup>30</sup> The FDA is not obligated, however, to pursue a full enforcement after issuing a Warning Letter nor is a Warning Letter a prerequisite to any enforcement action.<sup>31</sup> The FDA maintains that Warning Letters constitute advisory actions that are "official but not final, agency action."<sup>32</sup> Because Warning Letters are not a prerequisite or commitment to enforcement actions, the FDA "does not consider Warning Letters to be final agency action on which it can be sued."<sup>33</sup>

Since 2005, a trend for issuing fewer Warning Letters has emerged.<sup>34</sup> Totals steadily decreased from 725 in 2004 to 535 in 2005, 538 in 2006, 471 in 2007 and 445 in 2008.<sup>35</sup> In 2009, total letters issued jumped to 565 and in 2010, the FDA issued 609 Warning Letters, a stark increase from previous years.<sup>36</sup> This increase followed new FDA policies that reduce oversight and review before a Warning Letter is issued.<sup>37</sup> Margaret A. Hamburg, Commissioner of Food and Drugs, recently approved

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28. *Id.* ch. 4, at 4-12.

29. *Id.* ch. 4, at 4-13.

30. *Id.*

31. *Id.* ch. 4, at 4-2.

32. *Id.* ch. 4, at 4-13.

33. *Id.* ch. 4, at 4-2.

34. ENFORCEMENT STORY, *supra* note 6, ch. 10, at 10-9.

35. *See id.* (showing total issued Warning Letters for 2004–2008); *see also* 2009 Warning Letters, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/default.htm> (last visited Mar. 16, 2011).

36. 2009 Warning Letters, *supra* note 35; 2010 Warning Letters, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/default.htm> (last visited May 12, 2011). The FDA Warning Letter websites contain several duplicates. To obtain these figures, duplicates were removed. Data on file with author.

37. *See* Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, U.S. Food & Drug Admin., Remarks at the Food and Drug Law Institute on "Effective Enforcement and Benefits to Public Health" (Aug. 6 2009), *available at* <http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm>.

a new policy proposed by the FDA's Chief Counsel to limit review of letters to "significant legal issues" in an effort to obtain a more "streamlined" process and increase the issuance speed of Warning Letters.<sup>38</sup>

The FDA reviews all letters submitted to the FDA's Office of Chief Counsel "for legal sufficiency and consistency with Agency policy."<sup>39</sup> When the Office of the Chief Counsel (OCC) receives the letter, it is required to "[r]eview the draft 'final' Warning Letter . . . within 15 working days."<sup>40</sup> The OCC must approve the Warning Letter before it is issued, unless it originates from a district office, in which case it may be released even if the OCC does not review the letter within the fifteen day time frame.<sup>41</sup>

The FDA classifies Warning Letters as "informal enforcement actions," presumably opposed to more "formal" enforcement actions such as seizure, injunction, or prosecution.<sup>42</sup> Under 21 U.S.C. § 336, the FDA has discretion in what violations it chooses to pursue with a formal or informal enforcement action.<sup>43</sup> Section 336 states that the Secretary of the FDA need not "report for prosecution . . . minor violations of [the FDCA] . . . [when] public interest will be adequately served by a suitable written notice or warning."<sup>44</sup> While Warning Letters are not formal enforcement actions by the FDA, they pose significant problems and potential costs for the regulated party.<sup>45</sup> Warning Letters expose recipients to litigation, public stigmatization, investment losses, and loss of contracting opportunities.<sup>46</sup> Warning Letters are available

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38. *Id.*; Press Release, U.S. Food & Drug Admin., FDA Commissioner Sets Out Vision on Enforcement to Support Public Health (Aug. 6, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176119.htm>. The Commissioner of Food and Drugs is the head of the FDA, in charge of agency policy formation and implementation. *About the Office of the Commissioner*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OC/default.htm> (last visited Jan. 27, 2011).

39. PROCEDURES MANUAL, *supra* note 13, ch. 4, at 4-35.

40. *Id.*

41. *Id.* ch. 4, at 4-34, 4-38.

42. *See generally id.* ch. 6.

43. 21 U.S.C. § 336 (2006) (addressing the standard for reporting and prosecuting minor violations of the FDCA).

44. *Id.*

45. Brickates Kennedy, *supra* note 16.

46. *Id.*



publicly, both at the FDA's Freedom of Information Staff office and online.<sup>47</sup> Plaintiffs' attorneys often utilize these letters to seek out potential clients and build cases.<sup>48</sup> FDA Warning Letters are also often cited in court cases as evidence of wrongdoing on the part of the defendants.<sup>49</sup> While the FDA remains adamant that Warning Letters are not final agency action,<sup>50</sup> the language used in Letters often is conclusory as to the misbranding or adulteration of various products.<sup>51</sup> Many news organizations report on companies that receive Warning Letters, often using the Warning Letter as evidence that the cited product may not be safe for use.<sup>52</sup> The publicity following a Warning Letter can also lead to losses in stock value and investment.<sup>53</sup> The FDA also advises other governmental

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47. *Warning Letters*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (last visited Oct. 20, 2010).

48. See, e.g., David Walk, *A Warning About FDA Warning Letters*, DRUG & DEVICE LAW (Apr. 20, 2010, 10:30 AM), <http://druganddevicelaw.blogspot.com/2010/04/warning-about-fda-warning-letters.html> ("Lawyers for tort plaintiffs love it every time the FDA issues a Warning Letter. To them, FDA warnings = liability . . ."); *Yaz FDA Warning*, *supra* note 16 (using a Warning Letter issued to Bayer HealthCare Pharmaceuticals, Inc. for misleading advertising for the birth control Yaz to solicit new clients that have been injured and requesting they "contact our team of birth control attorneys . . . for a free no obligation consultation.").

49. See, e.g., *Avon Pension Fund v. GlaxoSmithKline PLC*, 343 F. App'x 671, 674 (2d Cir. 2009) (unsuccessfully attempting to introduce an FDA Warning Letter as evidence to meet scienter requirement).

50. State Enforcement Regulation, *supra* note 8, at 2457; Warning Letters Regulation, *supra* note 8, at 27,026.

51. See, e.g., Letter from Jennifer Thomas, Acting Dir., Office of Compliance, Center for Food Safety and Applied Nutrition, to Dr. Ceyu Cao, Nature's Health Company (Sept. 21, 2010), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm228056.htm> ("[T]heir labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)].") (alteration in original); Letter from Diana Amador-Toro, *supra* note 7 ("Listerine Total Anticavity mouthwash is not generally recognized as safe and effective for the antiplaque indications in its labeling, and it is, therefore, a new drug under 201(P) of the Act (21 U.S.C. § 321(P)).").

52. See, e.g., Natasha Singer, *Drug Maker Cited on Quality Issues*, N.Y. TIMES, Nov. 27, 2010, at B1, *available at* [http://www.nytimes.com/2010/11/27/business/27drug.html?\\_r=1&scp=1&sq=%22FDA%20Warning%20Letter%22&st=cse](http://www.nytimes.com/2010/11/27/business/27drug.html?_r=1&scp=1&sq=%22FDA%20Warning%20Letter%22&st=cse) (quoting Karen Riley, FDA spokeswoman, that "the company continues to have serious quality control issues at its plant").

53. See, e.g., Brickates Kennedy, *supra* note 16 (documenting that Boston Scientific's stock prices dropped by 6% following the receipt of an FDA

agencies to consider the receipt of Warning Letters when awarding contracts.<sup>54</sup>

#### B. APA ADJUDICATION AND FINALITY REQUIREMENTS

The Administrative Procedure Act (APA) serves four main purposes: (1) to keep the public abreast of agency rulemaking, procedures and organization; (2) to allow the public to participate in the rulemaking process; (3) “to prescribe uniform standards” for adjudication and rulemaking; and (4) “to restate the law of judicial review” of agency action.<sup>55</sup> The APA applies to all federal agencies and serves as a common denominator for most agency action.<sup>56</sup> Section 553 of the APA controls agency rule-making while § 554 controls agency adjudication.<sup>57</sup> Agencies are also required to ensure procedural due process before depriving a regulated party of a liberty or property interest.<sup>58</sup> While the APA contains no specific provisions governing informal agency action, courts have interpreted § 706, which defines the scope of judicial review of agency action,

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Warning Letter).

54. Letter from Douglas D. Tolen, Dir., Fla. Dist., to Bill Davis, Int’l Sales Representative, Colloidal Products, Inc. (Dec. 19, 1996), *available at* <http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/1996/UCM065164.pdf> (“Other Federal Agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering awards of contracts.”); Letter from Carol S. Sanchez, Acting Dist. Dir., New Orleans Dist., to Robert H. Ketteh, President/CEO, Crothall Healthcare, Inc. (Dec. 29, 2009), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm197001.htm> (“Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts.”).

55. TOM C. CLARK, U.S. DEP’T OF JUSTICE, ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 9 (1947), *available at* <http://www.law.fsu.edu/library/admin/1947cover.html>.

56. *Id.* (“‘Agency’ means each authority (whether or not within or subject to review by another agency) of the Government of the United States other than Congress, the courts, or the governments of the possessions, Territories, or the District of Columbia.”)

57. 5 U.S.C. §§ 553–554 (2006).

58. *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976) (“Procedural due process imposes constraints on governmental decisions which deprive individuals of ‘liberty’ or ‘property’ interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.”) Procedural due process requires that the court strike a balance between “the private interest that will be affected[,] . . . the risk of an erroneous deprivation of such interest through the procedures used, . . . and finally, the Government’s interest, including . . . fiscal and administrative burdens . . .” *Id.* at 321.

to apply to informal agency adjudications.<sup>59</sup>

### C. REVIEWABILITY OF AGENCY ACTION

Agency actions are reviewable by a court only after certain criteria are met.<sup>60</sup> As with all claims, a court can only review agency action “when the facts of the case have matured into an existing substantial controversy warranting judicial intervention.”<sup>61</sup> A case is generally considered ripe for adjudication “if it presents a purely legal issue, or if further development of the facts will not render the issue more concrete.”<sup>62</sup>

Ripeness, in the context of the agency action and the APA, is defined by the characteristics of fitness, hardship to the plaintiff, and finality.<sup>63</sup> Fitness is determined by whether the claim “would benefit from further factual development” and “poses purely legal question[s] . . . not contingent on future possibilities.”<sup>64</sup> The hardship requirement is met when “plaintiffs have . . . sustained or are immediately in danger of sustaining . . . direct injury as the result of the challenged statute or official conduct.”<sup>65</sup> Courts also require that regulated parties exhaust all available agency options before resorting to the legal action.<sup>66</sup> The primary purpose of the exhaustion doctrine is the “avoidance of premature interruption of the administrative process.”<sup>67</sup>

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59. *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 337 (D.C. Cir. 1989) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971)).

60. 5 U.S.C. § 704 (2006).

61. *Ripe*, CORNELL UNIVERSITY LAW SCHOOL (Aug. 19, 2010, 5:23 PM) <http://topics.law.cornell.edu/wex/ripe>.

62. *Id.*

63. *McKart v. United States*, 395 U.S. 185, 193–94 (1969); *Pub. Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 573 (8th Cir. 2003); *Farm-to-Consumer Legal Def. Fund v. Sebelius*, 734 F. Supp. 2d 668, 695 (N.D. Iowa 2010) (citing *O’Shea v. Littleton*, 414 U.S. 488, 494 (1974)).

64. *Peculiar*, 345 F.3d at 573.

65. *Farm-to-Consumer*, 734 F.Supp.2d at 696.

66. *See, e.g., Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118, at \*33 (D. Wyo. July 26, 2010).

67. *McKart*, 395 U.S. at 193. The court reasoned that “[t]he agency, like a trial court, is created for the purpose of applying a statute in the first instance. Accordingly, it is normally desirable to let the agency develop the necessary factual background upon which decisions should be based.” *Id.* at 193–94. The Court also notes that, like most judicial doctrines, several exceptions apply to

Section 704 of the APA states that “[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.”<sup>68</sup> A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review under the final agency action rule.<sup>69</sup> A final agency action is an action that represents the “consummation’ of the agency’s decision-making process” and “by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’”<sup>70</sup> Further, the finality requirement is to be applied in a “flexible” and “pragmatic” manner keyed to whether the agency’s decision has a “direct and immediate . . . effect on the day-to-day business” of the regulated party.<sup>71</sup> Informal agency action may be interpreted as final agency action if one of four elements is present:

- (1) direct and immediate impact on regulated industries as a result of the action; (2) reliance . . . on the action; (3) agency position expressed in the action which represents the agency’s final, crystallized position on the matter in question; or (4) direct responsibility for the action in a high level official.<sup>72</sup>

#### D. WARNING LETTERS’ FAILURE TO MEET FINALITY REQUIREMENTS

Precedent has established that FDA Warning Letters do not constitute final agency action, and are thus not ripe for judicial review.<sup>73</sup> One such recent case is *Cody Labs v. Sebelius*,

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the exhaustion doctrine. *Id.* at 193. Exceptional circumstances in which the exhaustion doctrine would not be applied include: (1) agency actions outside of statutory jurisdiction; (2) “immediate and irreparable injury to [the] person or property;” (3) national interest; (4) unconstitutional action coupled with irreparable harm; or (5) first amendment violations combined with irreparable harm. Robert Layton & Ralph I. Fine, *The Draft and Exhaustion of Administrative Remedies*, 56 GEO. L.J. 315, 322–28 (1967).

68. 5 U.S.C. § 704 (2006).

69. See *McKart*, 395 U.S. at 193–94.

70. *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (quoting *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948) and *Port of Boston Marine Terminal Ass’n v. Rederiaktiebolaget Transatl.*, 400 U.S. 62, 71 (1970)).

71. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149–52 (1967).

72. 2 AM. JUR. 2D *Administrative Law* § 462 (2010).

73. See, e.g., *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1376 (9th Cir. 1983); *Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118, at \*32–33 (D. Wyo. July 26, 2010); *Summit Tech. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996). Cases

in which, the FDA accused Cody Labs of violating the FDCA by marketing a morphine sulfate solution without an approved new drug application.<sup>74</sup> Cody Labs sought declaratory judgment, restraining order, and injunctive relief to prevent the FDA from requiring Cody Labs to remove their morphine sulphate solution from the market in a future enforcement action.<sup>75</sup> The district court denied their requests.<sup>76</sup>

The court held that the Warning Letter issued to Cody Labs did not constitute final agency action.<sup>77</sup> The court cited *Biotics Research Corp. v. Heckler* for the proposition that “regulatory letters issued to [the plaintiffs do not] constitute a final decision by the FDA. The letters do contain conclusions by subordinate officials of the FDA that products offered by [the plaintiffs] are in violation of federal law . . . such letters do not commit the FDA to enforcement action.”<sup>78</sup>

The court further relied on several other opinions that state that FDA Warning Letters do not constitute final agency action because the letters do not commit the FDA to take future regulatory action.<sup>79</sup> Citing *FTC v. Standard Oil Co.*, in which the Supreme Court held that Federal Trade Commission

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prior to 1996 refer to final agency action as related to “regulatory letters” rather than “Warning Letters.” The nomenclature changed in 1996, but the letters are functionally equivalent. See HUTT ET AL., *supra* note 18, at 1339.

74. *Cody Labs*, 2010 U.S. Dist. LEXIS 80118, at \*1; Letter from Deborah M. Autor, Esq., Dir., Office of Compliance, Ctr. for Drug Evaluation and Research, to Richard E. Asherman, CEO, Cody Labs., Inc. (Mar. 30, 2009), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm131695.htm>. A new drug application, or NDA, is required for all new drugs, and are required to show whether the drug is safe and effective in its proposed use, if its benefits outweigh its risks, if the labeling meets FDA standards, and if the drug’s manufacturing process are adequate. *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last updated Aug. 20, 2010).

75. *Cody Labs*, 2010 U.S. Dist. LEXIS 80118, at \*2.

76. *Id.* at \*54.

77. *Id.* at \*32.

78. *Id.* at \*33–34 (citing *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (second alteration in original)).

79. *Id.* (citing *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1503–04 (D. Kan. 1992); *Dietary Supplemental Coal. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 4–5 (D.D.C. 1989); *IMS Ltd. v. Califano*, 453 F. Supp 157, 158–60 (C.D. Cal 1977); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985)).

administrative complaints did not constitute final agency action and that response to the complaint did not constitute irreparable injury, the *Cody Labs* court analogized FDA Warning Letters to FTC administrative complaints to determine that FDA Warning Letters do not constitute irreparable injury or final agency action.<sup>80</sup>

The finality of FDA Warning Letters has not always been so clear. In *Washington Legal Foundation v. Kessler*, Washington Legal Foundation challenged a policy of the FDA limiting the dissemination of information regarding “off-label” uses for drugs and medical devices.<sup>81</sup> In challenging the FDA policy, Washington Legal Foundation alleged that through Warning Letters and other informal agency communications the FDA established an official policy banning the distribution of information on “off-label” uses for drugs and medical devices.<sup>82</sup> The FDA argued that the Warning Letters and policies issued did not constitute final agency action and thus were not ripe for review before the court.<sup>83</sup> The court held that while the Warning Letters may be advisory, it would be unwise to “be blind to the practical effects of these letters and other statements.”<sup>84</sup> The court held that “[o]nce the agency ‘publicly articulates an unequivocal position . . . and expects regulated entities to . . . conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review.’”<sup>85</sup> The court also noted that while regulated parties “may disregard [the regulatory correspondence and] go ahead with its planned activities . . . few if any companies are willing to directly challenge the FDA in this manner.”<sup>86</sup> The court concluded that Washington Legal Foundation’s reduced ability to disseminate information about “off-label” uses is a “direct

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80. *Id.* at \*36–37 (citing *FTC v. Standard Oil Co.*, 449 U.S. 232 (1980)).

81. *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 27–28 (D.D.C. 1995). “Off-label” use of a drug occurs when a doctor prescribes a medication “in a manner different from that approved by the FDA.” Randall S. Stafford, *Regulating Off-Label Drug Use — Rethinking the Role of the FDA*, 358 *NEW ENG. J. MED.* 1427, 1427–29 (2008). Off-label prescriptions are common, but pharmaceutical companies may not promote their products for off-label use. *Id.*

82. *Wash. Legal Found.*, 880 F. Supp. at 27–30.

83. *Id.* at 34–35.

84. *Id.* at 35.

85. *Id.* (citing *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986)) (first omission in original).

86. *Id.* at 36.

and immediate effect . . . useful [in indicating] the finality of an agency position.”<sup>87</sup>

A recent decision also suggests that FDA Warning Letters constitute final agency action. In *Farm-to-Consumer Legal Defense Fund v. Sebelius*, the court considered a motion to dismiss for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.<sup>88</sup> In *Farm-to-Consumer*, the plaintiffs were individuals who purchased unpasteurized milk for personal consumption in states where it was legal to consume and then transported it to states in which it is illegal to consume.<sup>89</sup> While none of the plaintiffs received Warning Letters, the court offered analysis in dicta of the interpretation of FDA Warning Letters in the context of a motion to dismiss for lack of subject matter jurisdiction.<sup>90</sup> The court in *Farm-to-Consumer* disagreed with the decision in *Biotics Research Corp. v. Heckler*, in that it required an imminent injury to meet the hardship and ripeness requirements.<sup>91</sup> The court reasoned that “[s]uch a rule would mean that no pre-enforcement challenge to agency regulations is ever ripe . . . . The ‘hardship’ prong of the ‘ripeness’ analysis does not require the plaintiff to wait until the threatened injury occurs.”<sup>92</sup>

The court emphasized the importance of the availability of pre-enforcement action further by asserting that while judicial review may be limited in the “preliminary phases of administrative procedures to enforce regulations”<sup>93</sup> pre-enforcement declaratory judgments have not be eliminated outright.<sup>94</sup>

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87. *Id.* (citing *Ciba-Geigy Corp.*, 801 F.2d at 436).

88. *Farm-to-Consumer Legal Def. Fund v. Sebelius*, 734 F.Supp.2d 668, 675 (N.D. Iowa 2010).

89. *Id.* at 674–75.

90. *Id.* at 685.

91. *Id.* at 696 (discussing *Biotics Research Corp. v. Heckler*, 710 F.2d 1375 (9th Cir. 1983)).

92. *Id.* (emphasis in original) (citing *Pub. Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 573 (8th Cir. 2003)).

93. *Id.* at 698.

94. *Id.*

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## III. ANALYSIS

## A. COMPARING CODY LABS WITH WASHINGTON LEGAL FOUNDATION

The courts in *Cody Labs* and *Washington Legal Foundation* approached the question of finality in two distinct ways. *Cody Labs* is an opinion typical of recent decisions addressing the finality of FDA Warning Letters.<sup>95</sup> It is typical in the sense that it relies on two assumptions: (1) that previous analysis of FDA Warning Letters has been proper, and (2) that the lack of formal enforcement action by the FDA equates to a lack of finality.<sup>96</sup> Like courts before it, the court in *Cody Labs* decided that Warning Letters were not sufficiently “final” because the letter does not bind the FDA to a formal enforcement action.<sup>97</sup>

*Washington Legal Foundation*, however, took a different course. While the court recognized that Warning Letters themselves were not a full enforcement action, the policies and determinations within them did in fact constitute a final decision on the legality of the cited actions and amount to an action final enough to be challenged before the court.<sup>98</sup>

In taking this stance, the *Washington Legal Foundation* court recognized the effect of FDA Warning Letters on regulated parties.<sup>99</sup> Like many other agencies, the FDA relies upon “arm twisting” to obtain compliance without the expense of a formal enforcement action.<sup>100</sup> For this policy to be effective however, an adequate number of regulated parties must act willingly, or at least under coercion, to meet the agency’s demand.<sup>101</sup> To ensure compliance, the “arm twisting” must be significant, the demands must be real, and threat of

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95. See, e.g., *Cody Labs, Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118, at \*27–29 (D. Wyo. July 26, 2010); *Clinical Reference Lab, Inc. v. Sullivan*, 791 F. Supp. 1499, 1504 (D. Kan. 1992); *Den-Mat Corp. v. United States*, No. MJG-92-444, 1992 U.S. Dist. LEXIS 12233, at \*12–13 (D. Md. Aug. 17, 1992).

96. *Cody Labs*, 2010 U.S. Dist. LEXIS 80118, at \*27–29.

97. *Id.* at \*34 (citing *Clinical Reference Lab*, 791 F. Supp. at 1503–04).

98. *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 34 (D.D.C. 1995) (“In the context of a ripeness inquiry, it is the effect of the agency’s conduct which is most important in determining whether an agency has adopted a final policy.”).

99. See *id.* at 35.

100. See *id.* at 34–35; Noah, *supra* note 23 at 874–75.

101. See Warning Letters Regulation, *supra* note 8, at 27,026.



enforcement cannot be illusory or a far flung possibility.<sup>102</sup> FDA Warning Letters accomplish these goals by determining in precise legal language the ways in which the FDA deems the regulated parties have violated the law and demands that they must comply or face further consequences.<sup>103</sup> As a result, many regulated parties have no real choice but to comply in order to avoid further cost and inconvenience.<sup>104</sup> In this way, as the court in *Washington Legal Foundation* recognized, Warning Letters have the effect of demanding compliance and the “practical effect” is that of a formal enforcement action.<sup>105</sup>

*Cody Labs*, and other cases like it, seem unconvinced or unconcerned about the practical effect of the Warning Letter on regulated parties when determining their finality.<sup>106</sup> Much of the discussion in these cases revolves around the fact that the Letters impose no formal legal requirements upon the FDA or the regulated party.<sup>107</sup> These courts reasoned that the FDA’s position is “tentative,” and that courts should not interfere with “an ongoing agency proceeding.”<sup>108</sup> This declaration seemingly equates FDA Warning Letters as a step in a process ultimately leading to formal agency action, rather than an agency proceeding in and of itself that determines obligations and crystallizes an agency’s position on a matter.<sup>109</sup>

#### B. *BENNETT V. SPEAR* STANDARDS: CONSUMMATION AND OBLIGATION

In *Bennett v. Spear*, the United States Supreme Court summarized the finality standard in two prongs. First, the agency action must mark the “consummation of the agency’s

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102. See Noah, *supra* note 23 at 876 (“[A]dministrative agencies have numerous opportunities to pursue indirectly ends that they could not impose directly. Arm-twisting may occur during licensing, governmental contracting, and enforcement proceedings.”).

103. See Letter from Joann M. Givens, *supra* note 1.

104. See Noah, *supra* note 23, at 874–75.

105. See *Washington Legal Foundation*, 880 F. Supp. at 35–36.

106. See generally *Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118 (D. Wyo. July 26, 2010) (failing to address the practical consequences of Warning Letters in its analysis).

107. *Id.* at \*34 (citing *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1503–04 (D. Kan. 1992)).

108. *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 5 (D.D.C. 1989).

109. See *Cody Labs*, 2010 U.S. Dist. LEXIS 80118, at \*34.

decision-making process.”<sup>110</sup> Second, the agency action must determine “rights or obligations” for the regulated party “from which legal consequences will flow.”<sup>111</sup> These standards of consummation and obligation, when applied to a challenge to an FDA Warning Letter, illustrate that these letters can and should be interpreted to be final agency action.

### 1. Consummation

In order for an agency action to be final and reviewable under § 704 of the APA, the challenged agency action must be the end, or consummation, of the agency’s decision-making process.<sup>112</sup> In doing so, the test requires that a court not “step into the [agency’s] role as a formulator of . . . policy” and prevents premature review of agency decisions that may not yet be the complete or end opinion of the agency.<sup>113</sup> The consummation requirement is relevant in interpreting Warning Letters in the context of the FDA’s larger formal enforcement action scheme.

While most courts seemingly regard a Warning Letter as a mere interlocutory step in a formal enforcement action, a Warning Letter is better characterized as an independent agency action.<sup>114</sup> FDA policy neither requires a Warning Letter to be issued before a formal enforcement action nor binds the agency to commencing a formal enforcement action.<sup>115</sup> Even further, 21 U.S.C. § 336 states that minor violations of the FDCA can be fully addressed by written notice or warning where appropriate.<sup>116</sup> Because a Warning Letter is neither required, nor always used, prior to a formal enforcement action, it is not a prerequisite to a formal enforcement action.<sup>117</sup> Thus, Warning Letters are not a necessary step leading to a formal enforcement action. Rather, Warning Letters are final action undertaken by the agency to induce compliance.<sup>118</sup> Indeed, in

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110. *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal quotation marks omitted).

111. *Id.* (internal quotation marks omitted) (quoting *Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatl.*, 400 U.S. 62, 71 (1970)).

112. *See id.* at 177–78; 5 U.S.C. § 704 (2006).

113. *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 32 (D.D.C. 1995).

114. *See PROCEDURES MANUAL*, *supra* note 13, ch. 4, at 4-2.

115. *See id.*

116. 21 U.S.C. § 336 (2006).

117. *See id.*

118. *Contra PROCEDURES MANUAL*, *supra* note 13, ch. 4, at 4-13 (discussing the policy for issuing a second warning letter to the same entity).

passing 21 U.S.C. § 336, Congress passed legislation that by its own language makes a written notice or warning an action sufficient for enforcement against certain violations.<sup>119</sup> Courts that reason Warning Letters only seek to “enjoin a *possible* future FDA enforcement action” fail to recognize the operation of Warning Letters in the FDA’s overall enforcement scheme.<sup>120</sup> Just as a prosecutor can assert her discretion by choosing whom she chooses to prosecute, the FDA also has discretion to proceed to formal enforcement actions without issuing a Warning Letter at all.<sup>121</sup> While Warning Letters are not the “consummation” of the FDA’s formal enforcement action, they are the consummation of the decision to enact *informal* enforcement against a regulated party.<sup>122</sup> To characterize a Warning Letter as a tentative action is to mischaracterize its relationship to formal enforcement actions.

## 2. Obligation

The obligation requirement of the *Bennett v. Spear* test requires a final agency action to determine “rights or obligations” of the regulated party and “legal consequences [must] flow” from the agency’s determination.<sup>123</sup> In determining the obligation that an agency action has upon a regulated party, the Supreme Court has looked to the language used by agencies.<sup>124</sup> In *Bell v. New Jersey*, the Court concluded that the Department of Education established deficiencies owed, the language used in establishing the deficiency, was sufficiently “definitive” to render the order final as defined by § 704 of the APA.<sup>125</sup> In doing so, the Court adopted the “flexible”

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119. See 21 U.S.C. § 336.

120. *Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118, at \*11 (D. Wyo. July 26, 2010); PROCEDURES MANUAL, *supra* note 13, ch. 4, at 4-2.

121. 21 U.S.C. § 336.

122. *C.f.*, *Gordon v. Norton*, 322 F.3d 1213, 1220 (10th Cir. 2003) (holding that an action is not final because the agency was clear that it had not yet interpreted applicable rules and was still engaged in its decision-making process); RICHARD J. PIERCE, JR., 2 ADMINISTRATIVE LAW TREATISE 1320 (5th ed. 2010).

123. *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (quoting *Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatl.*, 400 U.S. 62, 71 (1970)).

124. *Bell v. New Jersey*, 461 U.S. 773, 779 n.4 (1983).

125. *Id.*

and “pragmatic” requirements of *Abbott Labs v. Secretary of Health, Education and Welfare*.<sup>126</sup>

From a formalistic perspective, an FDA Warning Letter imposes no binding legal obligations on the recipient.<sup>127</sup> Parties are able to disregard the directives contained in a Warning Letter and challenge “any adverse FDA action in [a formal] enforcement hearing.”<sup>128</sup> By ignoring Warning Letters, regulated parties risk “arous[ing] the ire of such a powerful agency [as the FDA],” in addition to the related hardships that accompany the receipt of a Warning Letter.<sup>129</sup> However, significant and consequential, if not legal, obligations are put upon those regulated parties that receive Warning Letters.<sup>130</sup> Beyond risking the ire of the FDA, regulated parties are vulnerable to lawsuits, loss of sales and investments, and sacrifice of contracting opportunities with the federal government.<sup>131</sup>

Another risk in receiving an FDA Warning Letter is the potential loss of government contracting opportunities. This is especially damaging to pharmaceutical companies and other health-related manufacturers. As of 2009, slightly more than 30% of the United States population received federally-funded health insurance.<sup>132</sup> The percentage of Americans covered by,

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126. *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967); *see also Bell*, 461 U.S. at 779–80 (“Our cases have interpreted pragmatically the requirement of administrative finality . . .”).

127. *See, e.g., Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 35 (D.D.C. 1995). Other courts have found, however, that where an agency issues a letter determining legally defined questions, that letter can constitute final agency action. *W. Illinois Home Health Care, Inc. v. Herman*, 150 F.3d 659, 663 (7th Cir. 1998) (holding that a letter sent by an Assistant Agency District Director was final and reviewable because it interpreted the meaning of the term “joint employer” as defined in the Fair Labor Standards Act); *PIERCE, supra* note 134, at 1330.

128. *Washington Legal Foundation*, 880 F. Supp. at 36. In reality, approximately 93% of those who receive Warning Letters respond to the FDA. State Enforcement Regulation, *supra* note 8, at 2457.

129. *Washington Legal Foundation*, 880 F. Supp. at 36.

130. Even the FDA notes that Warning Letters are not to be taken lightly and expect that a majority of parties will in fact take corrective action upon receipt. Warning Letters Regulation, *supra* note 8, at 27,026.

131. *See supra* note 16 and accompanying text.

132. U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2009, at 25 (2010), available at <http://www.census.gov/prod/2010pubs/p60-238.pdf>. Government health plans include Medicare, Medicaid, military healthcare, and plans provided to federal employees. *Id.*

and thus receiving their medications from, government sources (i.e., Medicare) is even higher for the over-sixty five population. More than 75% of Americans age sixty five and older receive their health coverage from the federal government, and thus have their prescriptions and covered health-related products paid for by the government.<sup>133</sup> Threats by the FDA to inform other government agencies, such as Medicaid and Medicare, of the presence of an outstanding Warning Letter present a real risk to those pharmaceutical companies that consistently contract with the government for the sale of their products to Medicare and Medicaid patients.<sup>134</sup> While a Warning Letter is only a threat of government action, that threat may be impossible to ignore for companies dependent on Medicare and Medicaid sales.

### C. EXHAUSTION

The issue of exhaustion is frequently raised in cases addressing the finality of FDA Warning Letters. The exhaustion doctrine, primarily a judge-made concept, states that a regulated party must utilize “all possible agency procedures . . . or levels of decision making” before an agency determination can be subject to judicial review.<sup>135</sup> The exhaustion doctrine “prevent[s] an overworked court from considering issues and remedies that [are] available through administrative channels.”<sup>136</sup> It also promotes “accuracy, efficiency, agency autonomy, and judicial economy.”<sup>137</sup> Courts have exercised discretion in applying the exhaustion doctrine, declining to enforce the requirement “where a plaintiff would be irreparably harmed by delay, where the agency lacks the power to grant effective relief, or where exhaustion would be futile.”<sup>138</sup> Exhaustion is considered futile “when there is a

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133. Elizabeth Mendes, *Nearly 30% of Insured Have Government Plans, Up from '08*, GALLUP (July 30, 2009), <http://www.gallup.com/poll/121970/nearly-insured-government-coverage-2008.aspx>.

134. This is due to the importance of reputation to repeat players. Jason Scott Johnston & Joel Waldfogel, *Does Repeat Play Elicit Cooperation? Evidence from Federal and Civil Litigation*, 31 J. LEGAL STUD. 39, 39–40 (2002).

135. WILLIAM F. FOX, UNDERSTANDING ADMINISTRATIVE LAW 282 (5th ed. 2008).

136. 2 AM. JUR. 2d *Administrative Law* § 474 (2010).

137. *Id.*

138. *Farm-to-Consumer Legal Def. Fund v. Sebelius*, 734 F.Supp.2d 668,

certainty of an adverse decision, or when the agency ‘has evidenced a strong position on the issue together with an unwillingness to reconsider.’”<sup>139</sup> Parties cannot circumvent the exhaustion requirement simply by asserting “[u]nsupported and speculative claims of futility.”<sup>140</sup> When regulated parties raise a substantial constitutional question, however, the exhaustion requirement may be excused.<sup>141</sup>

Regulated parties often confront the issue of exhaustion when challenging FDA Warning Letters. While no formal structure exists to challenge a Warning Letter, the FDA has often asserted that regulated parties have not exhausted the available remedies by failing to file a citizen petition.<sup>142</sup> A citizen petition is a procedure followed by the FDA in which any citizen can submit a request for the agency to issue, amend, or revoke any regulation or order or refrain from taking action.<sup>143</sup> After the petition is submitted, the FDA generally has 180 days to reply with a direct answer to the proposal or a response that further time is needed.<sup>144</sup> Failure to reply within the 180-day period constitutes final agency action.<sup>145</sup>

Many courts have held that even if Warning Letters were final, regulated parties had not met the requirement of exhaustion because they had not filed a citizen petition asking

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700 (N.D. Iowa 2010) (citing *McCarthy v. Madigan*, 503 U.S. 140, 146–49 (1992)).

139. *Id.* (internal citations omitted).

140. *Chorosevic v. MetLife Choices*, 600 F.3d 934, 945 (8th Cir. 2010) (quoting *Midgett v. Wash. Grp. Int’l Long Term Disability Plan*, 561 F.3d 887, 898 (8th Cir. 2009)). See also KRISTIN E. HICKMAN & RICHARD J. PIERCE, JR., *FEDERAL ADMINISTRATIVE LAW* 759 (2010) (“[C]ourts typically apply the futility exception only when the petitioner can ‘provide a clear and positive showing’ that exhaustion would be an exercise in futility.”).

141. 2 AM. JUR. 2d *Administrative Law* § 478 (2010).

142. *E.g.*, *Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 U.S. Dist. LEXIS 80118, at \*33 (D. Wyo. July 26, 2010) (“[P]laintiffs could can [sic] file a citizen petition at any time seeking FDA’s views . . . . Plaintiffs failed to exhaust this much-utilized procedure under which they could have obtained FDA’s view on an administrative record.”)

143. 21 C.F.R. § 10.30 (2010).

144. *Id.*

145. Gerald F. Masoudi, *Legal Developments in the Enforcement of Food and Drug Law*, 63 *FOOD & DRUG L.J.* 585, 588 (2008). Interestingly, while the Code of Federal Regulations does not specify that the 180-day expiration constitutes final agency action, Chief Counsel at the Food and Drug Administration, Gerald F. Masoudi stated at the 51st FDLI Annual Conference that failure to respond within the 180-day time frame in fact constituted final agency action. *Id.*

the FDA to recant the legal position taken in the received Warning Letter.<sup>146</sup> While a regulated party could submit a citizen petition and wait the requisite 180 days, the availability of this option does not necessarily thwart the justiciability of all Warning Letters.

Most clearly, those regulated parties asserting constitutional claims could likely avoid the exhaustion doctrine's implication of a citizen petition. Parties that raise constitutional questions that cannot be adequately examined by the administrative agency are generally excused from the exhaustion requirement, and thus would likely be excused from filing a citizen petition.<sup>147</sup> Regulated parties that do not assert constitutional claims may also be able to avoid the citizen petition process. Regulated parties may argue that the additional procedural hurdle of filing a citizen petition may be futile, given the clear agency position announced in the Warning Letter. Exhaustion is futile when an agency pronounces a clear position and an adverse outcome is likely. The FDA crafts Warning Letters to coerce compliance, with high specificity and a low possibility for reconsideration of the issue.<sup>148</sup> A citizen petition to exhaust agency remedies under these conditions would indeed be futile because the likelihood of reconsideration of the issue is so low as to make the process without benefit for either the regulated party or the FDA.

#### D. FDA WARNING LETTERS NEED LIMITED REVIEWABILITY

Several legal analyses support the view that FDA Warning Letters should meet the finality standard. This conclusion flows from the fact that a Warning Letter constitutes the consummation of the FDA's informal enforcement action and real obligations are placed upon regulated parties, satisfying

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146. *Cody Labs*, 2010 U.S. Dist. LEXIS 80118, at \*30–33.

147. One area of the law in which the FDA is seeing increasing number of constitutional claims is in relation to labeling and first amendment speech rights. See generally Ralph F. Hall & Elizabeth S. Sobotka, *Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review Under Greater New Orleans*, 62 FOOD & DRUG L.J. 1 (2007). A party claiming that its first amendment rights were being violated by not being able to advertise or label in a certain manner would be an example of a constitutional claim that could not be adequately addressed through a citizen petition, and thus would likely not be subject to the exhaustion requirement. See 2 AM. JUR. 2d *Administrative Law* § 478 (2010).

148. See PROCEDURES MANUAL, *supra* note 13, ch. 4, at 4-1.

the requirements outlined in *Bennett v. Spear*.<sup>149</sup> Furthermore, while not all Warning Letters may be reviewable due to the exhaustion requirement, many should be excused from that requirement by either asserting constitutional claims or that utilizing more agency procedure would be futile.

Warning Letters need to be reviewable for pragmatic and policy reasons. As a practical matter, Warning Letters have the power to seriously harm companies and researchers, causing drops in investment and purchasing, exposing these companies to liability in lawsuits, and potentially causing products to be withdrawn from the market, all with no practical recourse for those regulated parties.<sup>150</sup> While the FDA Warning Letters serve admirable purposes and undoubtedly bring offending parties into compliance at a minimal expense, the process is subject to mistakes and abuse. Even though the FDA achieves an incredible amount of regulation on a relatively limited budget and indeed many of their determinations in Warning Letters are likely accurate and sound, our judicial system rests on nothing if not the idea that parties are entitled to the opportunity to have their legal rights adjudicated before a court. By not characterizing Warning Letters as final, courts allow regulation without any of the procedural accoutrement that would normally accompany such an action if the agency proceeded in an official manner, such as notice and comment opportunities, oral or paper hearings, or judicial challenge. Failure to allow review of Warning Letters and similar agency actions could lead to agencies “effectively regulat[ing] industry without ever exposing [themselves] to judicial review,” a result that must be avoided to ensure regulatory justice.<sup>151</sup>

### III. CONCLUSION

While sympathies may run low for the makers of “black-out in-a-can”, other companies and researchers that produce life-saving drugs and devices also receive Warning Letters from the FDA. Courts have given the FDA an incredible amount of power to coerce compliance by regulated parties who may have legitimate concerns about the legal conclusions contained in the Warning Letters they receive. Failure to allow review also leaves these regulated parties open to significant consequences,

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149. *See supra* Part III.B.

150. *See supra* note 16 and accompanying text.

151. *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 34 (D.D.C. 1995).



such as loss of market share and investment as well as the risk of an onslaught of litigation costs.<sup>152</sup> Limited review of some Warning Letters can serve as a modest check on an agency that controls upwards of 25% of the United States' economy.<sup>153</sup>

Beyond policy concerns, however, the legal standards of finality stand behind the idea that Warning Letters, when sufficiently exhaustive, should be allowed review. While much case law on the subject exists, and most determines that Warning Letters are not justiciable, this case law rests on a fundamental misunderstanding of Warning Letters in the context of FDA enforcement actions. Precedent is rightly respected and followed; however, when precedent rests of false assumptions, it is improper to follow it blindly for its own sake.<sup>154</sup> When the *Bennett v. Spear* finality tests of consummation and obligation are applied to Warning Letters, it becomes clear that the precedent in this area has been incorrect, theoretically and factually. Warning Letters should be justiciable final agency action because they pass the requirements of *Bennett v. Spear* and represent a potentially crippling harm to products and companies regulated by the FDA.

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152. See *supra* note 16 and accompanying text.

153. Lisa Richwine, *FDA Chief Urges Caution on Budget Cut*, REUTERS (Nov. 9, 2010, 5:39 PM), <http://www.reuters.com/article/idUSTRE6A84QI20101109>.

154. See Oliver Wendell Holmes, Jr., *The Path of the Law*, 10 HARV. L. REV. 457, 469 (1897), available at [http://www.constitution.org/lrev/owh/path\\_law.htm](http://www.constitution.org/lrev/owh/path_law.htm) (“[History] is part of the rational study [of law], because it is the first step toward an enlightened s[k]epticism, that is, toward a deliberate reconsideration of the worth of those rules.”)