

# The Grapes of Wrath: The Discretionary Function Exception of the Federal Tort Claims Act §2680(a), as Applied to the Chilean Grape Crisis of 1989

Where discretion is absolute, man has always suffered. . . . It is more destructive of freedom than any of man's other inventions. . . . It makes a tyrant out of every contracting officer. He is granted the power of a tyrant though he is stubborn, perverse, or captious. . . . He is allowed the power of a tyrant though he is incompetent or negligent. He has the power of life and death over a private business even though his decision is grossly erroneous.<sup>1</sup>

## I. INTRODUCTION

The federal Food & Drug Administration (FDA) has been responsible for protecting the American public health since 1906. Its responsibilities have grown over the years, as it regulates the introduction of new drugs, cosmetics, foods, and a host of other products,<sup>2</sup> including imported food products.<sup>3</sup> Consequently, the FDA has the authority to refuse the admission of any food products that appear adulterated or otherwise into the United States.<sup>4</sup> The objective of this authority has consistently retained the same character: protection of the public health. Yet what happens when FDA investigators purportedly conduct inappropriate scientific testing or use poor judgment in their technical analysis of food imports, which results in a nationwide embargo causing the loss of thousands of jobs, hundreds of millions of dollars, and potential economic chaos in developing nations? In March, 1989, the FDA imposed such an embargo on all Chilean fruit, after investigators allegedly discovered small traces of cyanide in two grapes. This embargo led to severe hardship in Chile and was deemed to be

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1. *United States v. Wunderlich*, 342 U.S. 98, 101 (1951) (Douglas, J., dissenting).

2. *See generally* CONGRESSIONAL QUARTERLY'S FEDERAL REGULATORY DIRECTORY, 289-321 (6th ed. 1990).

3. 21 U.S.C.A. § 331(a) (West Supp. 1993) (prohibiting the introduction of imported food products that appear to be adulterated into interstate commerce).

4. 21 U.S.C.A. § 381 (West Supp. 1993).

the result of negligent scientific testing by FDA officials. This event is now commonly referred to as the Chilean Grape Crisis.

Following the Chilean Grape Crisis, the Chilean Exporters Association brought a tort action against the United States on the grounds that the FDA did not have the discretion to impose an embargo as a result of the negligent violations of FDA laboratory procedures.<sup>5</sup> However, the court dismissed the action on the grounds that the suit fell within the "discretionary function" exception of 28 U.S.C.A. § 2680(a)<sup>6</sup> of the Federal Tort Claims Act (FTCA). This Note will examine the discretionary function exception of the FTCA as it applies to *Balmaceda v. United States*. Specifically, it will present the events surrounding the Chilean Grape Crisis, a brief history of the development of the Supreme Court's interpretations of the discretionary function exception, and the application of the two-step analysis developed by the Supreme Court. Additionally, this Note will demonstrate the application of the two-step analysis to conduct that is grounded in mathematical, scientific, and quantitative policy; describe why this conduct is an insufficient basis to shield a government agency from judicial scrutiny; and conclude with an analysis of the ramifications of such conduct on United States foreign policy and trade relations between the United States and developing nations.

## II. THE BALMACEDA DECISION

### A. *The Crisis*

On March 12, 1989, the FDA imposed a nationwide embargo on all seedless grapes imported from Chile after scientific testing allegedly revealed traces of cyanide in two grapes.<sup>7</sup> The Chilean Grape Crisis began when an anonymous telephone caller informed officials at the United States Embassy in Chile that Chilean fruit en route to the United States had allegedly been poisoned with cyanide.<sup>8</sup> The FDA detained and examined the Chilean fruit shipments, but subsequently determined that the calls had been part of a hoax and lifted the

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5. *Balmaceda v. United States*, 815 F. Supp. 823, 825 (E.D. Pa. 1992), *appeal docketed*, No. 93-1205 (3rd Cir. March 5, 1993).

6. 28 U.S.C.A. § 2680(a) (West 1965).

7. *Balmaceda*, 815 F. Supp. at 824.

8. Philip Shenon, *Chilean Fruit Pulled From Shelve As U.S Widens Inquiry on Poison*, N.Y. TIMES, March 15, 1989, at A1, A22.

temporary hold on the fruit.<sup>9</sup> A second anonymous telephone caller then informed the United States Embassy that the threats were not part of a hoax, as was indicated in the Chilean newspapers.<sup>10</sup> The FDA continued to inspect samples of all fruit imported from Chile and began to test imported fruit samples for cyanide contamination.<sup>11</sup>

During the investigation, FDA inspectors found three seedless grapes that were "suspicious-looking"<sup>12</sup> from a batch of approximately 2,000 grape-bunches sampled<sup>13</sup> aboard the *Almeria Star*.<sup>14</sup> Laboratory analysis purportedly confirmed that two of the three grapes were contaminated with cyanide.<sup>15</sup> Consequently, the FDA decided to impound all fruit imports from Chile and to impose a nationwide embargo on Chilean fruit imports.<sup>16</sup> Although disagreeing with the FDA embargo, the Chilean Government cooperated with the United States by immediately reinforcing security throughout the fruit production process and by conducting chemical tests in order to determine if other fruits had been contaminated.<sup>17</sup> The FDA asked American consumers to avoid eating seedless grapes and other fruit originating from Chile and warned them to throw away any fruit that might have come from Chile.<sup>18</sup> Subsequently, the FDA mandated that American distributors destroy all Chilean grapes in their possession and ordered the destruction of all Chilean fruit leaving the ports for distribution.<sup>19</sup>

The FDA's decision initiated a wave of panic among American distributors, grocers, wholesalers, and consumers, who hastened to

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9. *Id.*

10. *Id.*

11. David Lauter, *Cyanide Traces Lead U.S. to Seize All Chilean Fruit*, L.A. TIMES, March 14, 1989, at A1, A18.

12. Herbert Burkholz, *Killer Grapes: an FDA horror story*, NEW REPUBLIC, November 30, 1992, at 13. The FDA tightened security and inspectors then found two red grapes that were discolored and had a ring of crystalline dust around the puncture holes. Shenon, *supra* note 8, at A1.

13. Amy Callahan, *Stores remove Chilean fruit; Tons piled up as U.S. probes cyanide threat*, BOSTON GLOBE, March 15, 1989, available in LEXIS, NEWS Library, MAJPAP File.

14. The *Almeria Star* is the vessel that carried the grapes in question. The ship left Chile on February 27, 1989, and arrived in Philadelphia on March 11. Marlene Cimons, *U.S., Chile Seek Fruit Safety Plan*, L.A. TIMES, March 16, 1989, at A1, A26.

15. Shenon, *supra* note 8, at A1.

16. Lauter, *supra* note 11.

17. *Id.* at A18.

18. Warren E. Leary, *U.S. Urges Consumers Not to Eat Fruit from Chile*, N.Y. TIMES, March 14, 1989, at A15.

19. Marie Cocco, *Chilean Grapes to Make Comeback*, NEWSDAY, March 18, 1989, available in WESTLAW, PAPERSMJ Database.

destroy potentially contaminated Chilean fruit. Although the FDA commissioner initially sought to avoid panic, panic erupted as store owners frantically removed tens of thousands of pounds of grapes off of their shelves,<sup>20</sup> distributors and wholesalers hurriedly destroyed all grapes in their possession, and a mother even chased down a schoolbus for fear that she had packed contaminated grapes in her child's lunch.<sup>21</sup> Further, store-owners complained that consumers were refusing to purchase any and all fruit, in fear that everything had originated from Chile.<sup>22</sup> Additionally, the American Produce Association recommended that its participating members recall all Chilean fruit.<sup>23</sup>

The effects of the FDA's announcement were also manifested on the international front. On March 12, 1989, the Canadian Government banned all Chilean fruit imports and ordered retailers to remove existing fruit from store shelves. The Canadian ban on Chilean fruit was expected to last one week with an estimated loss of over ten million Canadian dollars in retail sales throughout the country.<sup>24</sup> Following the United States' and Canada's lead, West Germany, Hong Kong, and Denmark also stopped importing and selling Chilean fruit.<sup>25</sup> Authorities in Rio and Sao Paulo, Brazil also banned sales of Chilean grape imports.<sup>26</sup> Likewise, after receiving an anonymous telephone call at the Japanese Embassy in Chile threatening contamination, the Japanese halted shipments of Chilean fruit.<sup>27</sup> Additionally, several British supermarket chains removed all Chilean grapes from their shelves.<sup>28</sup>

The effects of the embargo were felt most harshly in Chile. As a result of the grape ban, approximately 25,000 Chilean workers were laid off and over \$300 million in total grape sales were lost.<sup>29</sup> Even

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20. Craig Wolff, *Shoppers Confront a New Food Peril*, N.Y. TIMES, March 15, 1989, at A22.

21. Margaret Carlson, *Do You Dare To Eat A Peach?*, TIME, March 27, 1989, at 24, 26.

22. *Id.*

23. Leary, *supra* note 18.

24. *Chile Should Not Compensate Canada for Contaminated Fruit, says Ambassador*, XINHUA GENERAL OVERSEAS NEWS SERVICE, March 16, 1989, available in LEXIS, NEWS Library, XINHUA File.

25. Callahan, *supra* note 13.

26. *Brazil Bans Imports of African, Asian and Pacific Fruit*, REUTER LIBRARY REPORT, March 22, 1989, available in LEXIS, Nexis Library, LBYRPT File.

27. Callahan, *supra* note 13.

28. Ian Brodie & Imogen Mark, *Chile fails to shift US ban on fruit in Poison Grape Scare*, THE DAILY TELEGRAPH (London), March 17, 1989, available in LEXIS, NEWS Library, TELEGR File.

29. George de Lama, *U.S. - Chile grape crisis withering on vine*, CHI. TRIB., September 24, 1989, at 4.

after the ban was lifted, Chilean exporters could not sell the fruit that had been withheld at port, due to the lingering fear among buyers. Chilean officials were angered by the embargo, which was described by one of Chile's financial leaders as "almost an act of war . . . an aggression against Chile" and an "incident [that] could 'frustrate or harm' Chile's transition to democracy, scheduled for an important step in December [1989] with the first presidential election in 19 years."<sup>30</sup> Moreover, United States Ambassador Charles Gillespie stated: "This is scary, . . . [t]here are a lot of little countries in the world dependent on exports."<sup>31</sup> "People will be scared for quite a while," said agricultural economist Richard Brown; "[i]t's a blow to the whole table grape industry."<sup>32</sup>

After lifting the embargo on March 17, despite receiving a third anonymous phone call threatening contamination, FDA officials were questioned extensively by Chilean authorities regarding their decision to impose the embargo.<sup>33</sup> Surprisingly, the level of cyanide allegedly found in the grapes by the FDA investigators was considered "far below a lethal dose and below the amount that would even sicken a small child."<sup>34</sup> FDA commissioner Frank Young defensively stated that "[i]t's better to be safe than sorry."<sup>35</sup> He added: "We've got to call this to the attention of the American people. I couldn't let it be on my conscience."<sup>36</sup> However, after lifting the ban, Young, contrary to his initial concerns, stated: "It is impossible to assure 100% safety," even though the United States Embassy in Chile received a third similar anonymous threat the same day that the ban was lifted.<sup>37</sup>

On December 29, 1992, the United States District Court in the Eastern District of Pennsylvania dismissed a tort action brought by Chilean grape exporters against the United States government, which alleged that "the FDA did not have the discretion to act given alleged

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30. Eugene Robinson, *Chile's Grape Growers Rage Against U.S. Ban*, Wash. Post, March 16, 1989, at A1.

31. Tom Harvey, *U.S. Fruit ban an earthquake for Chile*, UPI, March 24, 1989, available in LEXIS, NEWS Library, UPI File.

32. David C. Rudd, *Chilean Fruit Pulled in Cyanide Alert*, CHIC. TRIB., March 15, 1989, available in LEXIS, NEWS Library, MAJPAP File.

33. *USA/Canada: Canada and U.S. Lift Import bans on Chilean Fruit*, REUTER TEXTLINE FINANCIAL POST, March 20, 1989, available in LEXIS, World Library, TXTLINE File.

34. Leary, *supra* note 18.

35. Callahan, *supra* note 13.

36. Shenon, *supra* note 8.

37. Cocco, *supra* note 19.

negligent violations of a procedures manual which provides instructions on testing procedures within the FDA laboratory."<sup>38</sup> The issue before the court was whether the discretionary function exception to the FTCA bars suit against the United States for tort actions.<sup>39</sup> In applying §2680(a), the court held that the

FDA had the discretion to act during the Chilean grape crisis . . . [i]t had the discretion to test the fruit and determine whether the fruit was adulterated. . . . It also had the discretion to refuse entry into the United States. The actions taken were not violative of any regulatory or statutory provisions . . . [a]ccordingly, the FDA is protected by the discretionary function exception.<sup>40</sup>

In essence, the court determined that, in light of the FDA's responsibility to protect the public health, its actions in imposing a nationwide embargo on Chilean grapes involved judgment and choice that are grounded in policy,<sup>41</sup> regardless of the amount of negligence or abuse of discretion.<sup>42</sup> Consequently, the court refused to consider alleged violations of the FDA laboratory procedures manual, on the grounds that "[t]he proper focus under the discretionary function exception is on the discretion provided by the regulations, statutes and policies of the FDA."<sup>43</sup> Therefore, the court dismissed the case stating that "*all the acts* involved judgment and choice and were grounded in policy."<sup>44</sup> The plaintiffs in the case appealed the decision and oral arguments were heard by the Court of Appeals for the Third Circuit on September 24, 1993. Until the Third Circuit rules, the question remains whether the discretionary function exception of the FTCA precludes a suit on the grounds that the FDA negligently violated its laboratory procedures manuals and based its decision to impose a nationwide embargo on Chilean grapes on allegedly invalid and erroneous scientific analysis.

### B. *The Allegations*

Four days after the initial embargo, further analysis of the same two grapes revealed that there was actually no cyanide contamination

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38. *Balmaceda*, 815 F. Supp. at 825.

39. *Id.* at 824.

40. *Id.* at 827.

41. *Id.*

42. *Id.* at 826.

43. *Id.* (citing *United States v. Gaubert*, 111 S.Ct. 1267, 1274 (1991)).

44. *Id.* at 827 (emphasis added).

in the grapes at all.<sup>45</sup> Critics alleged that the FDA panicked as a result of questionable test data which seemed to indicate low levels of cyanide in two grapes.<sup>46</sup> However, it was claimed that cyanide injected into grapes or other fruit in Chile could not still be present in the fruit after a thirteen day trip to the United States, implying that the grapes were actually contaminated in the United States and not in Chile.<sup>47</sup> The Chilean Exporters Association alleged that the FDA "(1) used inappropriate tests to determine the presence of cyanide in the grapes, (2) inappropriately modified a test, thereby invalidating the test's results, (3) did not promptly record test results, and (4) did not exercise adequate control to protect fruit samples against contamination."<sup>48</sup>

A study commissioned by the Chilean Exporters Association, conducted at the University of California at Davis, revealed that it would have been impossible for the grapes to have been contaminated in Chile, because of the chemical effects that cyanide has on acidic fruits.<sup>49</sup> The FDA initially contended that, even though the grapes contained barely enough cyanide to make an infant ill, acidic fruits break down the chemical properties of cyanide, and therefore the grapes could have had much higher amounts of cyanide prior to discovery.<sup>50</sup> An investigation by the General Accounting Office (GAO) also reported that, although it is possible that all of the cyanide would probably have dissipated during the voyage from Chile, the effects of refrigeration would have reduced the dissipation of cyanide.<sup>51</sup> However, researchers at the University of California-Davis contended that the GAO's report was "deficient, replete with factual errors and omissions, and without a scientific basis for the conclusions reached."<sup>52</sup> The California study further indicated that the chemical reactions between acidic fruits and cyanide would have caused the grapes to shrivel and that, if there had been higher amounts of cyanide present, the contamination would have

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45. Matthew L. Wald, *This Autumn in New York, Fear of Asbestos Is in the Air*, N.Y. TIMES, September 26, 1993, at D5.

46. Burkholz, *supra* note 12.

47. *Food Tampering: FDA's Actions on Chilean Fruit Based on Sound Evidence*, UNITED STATES GENERAL ACCOUNTING OFFICE REPORT TO THE RANKING MINORITY MEMBER (hereinafter GAO), COMMITTEE ON FOREIGN RELATIONS, U.S. SENATE, September 1990, GAO/HRD-90-164, at 12.

48. *Id.*

49. *Id.* at 17.

50. Lauter, *supra* note 11, at A18.

51. GAO, *supra* note 47, at 17, 37.

52. Malcom Gladwell, *GAO Report Backs FDA in Cyanide Grape Debate*, WASH. POST, October 3, 1990, at A21.

migrated to the entire shipment of grapes and would not have remained confined in two grapes.<sup>53</sup> The California study concluded that "[t]he clinical evidence rejects virtually any possibility of contamination of the grapes in Chile or on the ship or at the port of Philadelphia . . . . On the contrary, the laboratory results only support the hypothesis that the grapes were accidentally or intentionally contaminated inside the FDA laboratory in Philadelphia."<sup>54</sup>

The first issue in the Chilean Grape Crisis concerns the discretionary conduct manifested by the FDA investigators in their laboratory procedures for detecting the cyanide in the grapes. If the Chilean Exporters Association's allegations are true, then the FDA based its decision to impose an embargo on data that is both erroneous and misleading. Recognizing that the role of the FDA is to protect the public health, to what degree do we accept rash decision-making without a rational, scientific basis for the decision? Did slits in two grapes, out of two thousand bunches, justify the assumption that the grapes were contaminated and thus hazardous to public health which, in turn, led to the destruction of Chilean grape imports and a virtual public panic? The FDA's culpability lies in its negligent testing of the grapes and in its poor scientific judgment. The FDA was aware ten days prior to the discovery of the grapes in question that cyanide was the contaminant in question. Basic cyanide experimentation would have led a scientist to observe that grapes shrivel and turn black when contaminated and that the contamination would have migrated to other grapes in the batch if they had actually been poisoned in Chile.<sup>55</sup> The U.C.-Davis study concluded that two suspect grapes were contaminated within four hours of the FDA analysis, because of their physical appearance as portrayed by the FDA pictures.<sup>56</sup> If the FDA's testing had been conducted according to its procedural guidelines, the analysis may have revealed that the grapes were not contaminated with cyanide and the embargo could have been avoided. Thus, the question remains whether the United States can be held liable for its negligence in imposing an embargo based on erroneous scientific data.

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53. GAO, *supra* note 47, at 17, 37.

54. Gladwell, *supra* note 52.

55. Shirley Christian, *Chile May Sue U.S. over Grape Ban*, N.Y. TIMES, September 12, 1990, at A13.

56. *Id.* The cyanide testing conducted by the FDA required an injection of a known quantity of cyanide into the grapes commonly referred to as "spiking." If the agent accidentally injected quantities higher than expected, the testing would have resulted in a false positive, indicating cyanide contamination when there actually is no cyanide present. GAO, *supra* note 47, at 35.



The second issue concerns the international ramifications of the FDA's decision to place the nationwide embargo on Chilean fruit. Although the alleged contamination was isolated to two grapes in the laboratory, the mass destruction of Chilean grapes far exceeded the representative sampling of these two grapes. All Chilean grapes that were not inspected by the FDA were destroyed, including those that did not come from the ship that produced the two grapes in question, even though no other Chilean fruit was found to be contaminated.<sup>57</sup> It was later alleged that the grapes could not have been contaminated in Chile, due to the chemical properties of cyanide.<sup>58</sup> The question then becomes whether the FDA, in adopting their "better safe than sorry" approach to imported foods, is appropriately considering the consequences of its actions.<sup>59</sup> Can we allow the FDA to base its decisions on "suspicious-looking" fruit, and if so, will this form of discretion be favored in the face of foreign policy?

### III. THE DISCRETIONARY FUNCTION EXCEPTION

In an effort to satisfy the growing number of claims against the United States Government, the U.S. Congress adopted the Federal Tort Claims Act in 1946,<sup>60</sup> which authorizes suits against the United States for damages "for . . . loss of property . . . caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment."<sup>61</sup> Although one of the broadest waivers of sovereign immunity ever enacted by Congress,<sup>62</sup> the FTCA is subject to thirteen exceptions.<sup>63</sup> The discretionary function exception specifically states that the FTCA will not apply to:

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57. GAO, *supra* note 47, at 34.

58. Christian, *supra* note 55.

59. Allegations of discrimination center around the California grape industry. Because the California grape season begins in April, a sharp decline in Chilean grape supply during the apex of its season would spur the California season with huge demand and high prices. Lauter, *supra* note 11.

60. Barry R. Goldman, *Can the King Do No Wrong? A New Look at the Discretionary Function Exception to the Federal Tort Claims Act*, 26 GA. L. REV. 837, 838 (1992). This note examines the discretionary function exception, its history, and the policies and argument against its expansion.

61. 28 U.S.C.A. § 1346(b) (West 1993)(prescribing a basis of jurisdiction for civil actions against the United States government).

62. Captain Bruce Clark, USAF, *Discretionary Function and Official Immunity: Judicial Forays into Sanctuaries from Tort Liability*, A.F. L. REV., Spring 1974, at 33, 35.

63. 28 U.S.C.A. § 2680(a)-(n) (West 1965 & Supp. 1993).

[A]ny claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.<sup>64</sup>

### A. *A Brief History*

To support its finding that the statutory language of the discretionary function exception of the FTCA precludes liability regardless of negligence, the court in *Balmaceda* suggested that the legislative history of the FTCA indicates that it was not designed to impose liability for acts performed by government employees or officers when acting in a discretionary manner.<sup>65</sup> However, over the past forty years, the courts have had great difficulty in determining what constitutes discretionary conduct. In 1988, the U.S. Supreme Court adopted a two-step analysis to determine whether the FTCA discretionary function exception applies to certain conduct.<sup>66</sup> First, the Court considers "whether the challenged action is a matter of choice for the acting employee: '[T]he discretionary function exception will not apply when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow'" and the employee fails to follow that course of action.<sup>67</sup> Second,

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64. 28 U.S.C.A. § 2680(a) (West 1965). For a comprehensive analysis of the discretionary function exception, see Goldman, *supra* note 60.

65. *Balmaceda*, 815 F. Supp. at 825. The court stated:

[I]n enacting the FTCA, Congress stated that this 'highly important exception' was designed to preclude application of the bill to a claim against a regulatory agency . . . based upon an alleged abuse of discretionary authority by an officer or employee, whether or not negligence is alleged to have been involved . . . The bill is not intended to authorize a suit for damages to test the validity of, or provide a remedy on account of, such discretionary acts, even though negligently performed and involving an abuse of discretion.

*Id.* (quoting H.R.REP. NO. 1287, 79th Cong., 1st Sess. 5-6 (1945)).

66. *Prescott v. United States*, 973 F.2d 696, 703 (9th Cir. 1992)(citing *Summers v. United States*, 905 F.2d 1212, 1214 (9th Cir. 1990)(citing *Berkovitz*, 486 U.S. 531 (1988))).

67. *Id.* (citing *Summers v. United States*, 905 F.2d 1212, 1214 (9th Cir. 1990)(quoting *Berkovitz*, 486 U.S. 531, 536 (1988))).

“[i]f the challenged conduct does involve an element of judgment, the [court must] determine whether that judgment ‘is of a kind that the discretionary function was designed to shield.’”<sup>68</sup> “To be shielded the judgment must be grounded in social, economic, or political policy.”<sup>69</sup> Under this analysis, “the United States must prove that each and every one of the alleged acts of negligence (1) involved an element of judgment and (2) the judgment was grounded in social, economic, or political policy.”<sup>70</sup> The following Supreme Court decisions illustrate the development of this analysis.

### 1. *Operational/Planning Distinction*

The U.S. Supreme Court first interpreted the FTCA in *Dalehite v. United States* in 1953, when the United States was sued for damages as a result of a fatal and disastrous explosion of ammonium nitrate fertilizer, which had been produced and distributed under the direction of the United States for export to devastated areas occupied by the Allied Armed Forces after World War II.<sup>71</sup> The Court broadly interpreted the discretionary function exception, suggesting that, although Congress desired to waive the Government’s immunity from liability for tortious injuries as a result of a government agent’s conduct, it did not intend that the government be liable for all damages that arise from acts of a governmental nature or function.<sup>72</sup> The Court held that the government would not be liable for initiating the fertilizer program

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68. *Id.*

69. *Id.*

70. *Id.*

71. 346 U.S. 15 (1953). Claims of negligence arose out of a catastrophic explosion of fertilizer containing ammonium nitrate in Texas City, Texas. The fertilizer was manufactured by the United States as part of its post-war effort to increase the food supply in areas under military occupation. The court held that all plaintiffs’ claims fell within the discretionary function exception, such that “‘the discretionary function or duty’ that cannot form a basis for suit under the [FTCA] includes more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications or schedules of operations. Where there is room for policy judgment and decision there is discretion.” *Id.* at 35-36.

72. *Id.* at 27-28. “The Federal Tort Claims Act was passed by the seventy-ninth Congress in 1946 . . . after nearly thirty years of congressional consideration. It was the offspring of a feeling that the Government should assume the obligation to pay damages for the misfeasance of employees in carrying out its work. And the private bill device was notoriously clumsy. Some simplified recovery procedure for the mass of claims was imperative.” *Id.* at 24-25.

because it involved an element of policy judgment.<sup>73</sup> The Court determined that the discretionary function includes the establishment of plans, specifications, or schedules of operations, stating "[w]here there is room for policy judgment and decision there is discretion."<sup>74</sup> As a result, the Court limited liability to tortious conduct arising from "operational" activities, but continued to shield the government from liability whenever tortious conduct arose from actions grounded in policy or planning activities.<sup>75</sup>

Following the *Dalehite* decision, the Supreme Court in *Indian Towing Co. v. United States*<sup>76</sup> attempted to limit *Dalehite's* interpretation of the discretionary function exception. In *Indian Towing*, the plaintiff sued the government for failing to maintain a lighthouse in good working order. The Court determined that the initial decision to undertake and to maintain lighthouse service was a discretionary judgment.<sup>77</sup> The Court held, however, that the failure to maintain the lighthouse in good condition subjected the government to suit under the FTCA.<sup>78</sup> The Court's decision focused on the broad scope of liability under the FTCA and suggested that once a government agent decides to act, that individual must act with a standard of due care because he or she is no longer shielded under the discretionary function exception.<sup>79</sup> The Court further focused on the dichotomy between discretionary functions and operational activities, holding that the government was liable because its actions were operational in nature.<sup>80</sup> Over the next thirty years, courts struggled to ascertain which acts were uniquely planning in nature versus those that were simply operational in nature and inconsistently applied the operational/planning test in determining the liability of the United States Government under the FTCA.

## 2. *Nature of Conduct*

In 1984, the Supreme Court in *United States v. Varig Airlines*<sup>81</sup> again addressed the discretionary function exception, in an effort to clarify the operational/planning test and to harmonize the lower courts' in-

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73. *Id.* at 35.

74. *Id.* at 36.

75. *Id.* at 42.

76. 350 U.S. 61 (1955).

77. *Id.* at 69.

78. *Id.*

79. *Id.* at 68-69.

80. *Id.* at 67-68.

81. 467 U.S. 797 (1984).

consistent definitions of a discretionary act.<sup>82</sup> In *Varig*, the survivors of two separate airplane accidents brought a tort action alleging that the Federal Aviation Administration (FAA) had acted negligently in certifying certain airplanes for operation. The Court found that the FAA's decision to certify planes according to a spot-check procedure without first inspecting them was a discretionary act for which the government was immune from liability.<sup>83</sup> The Court held that FAA spot-checking procedures were within the discretionary exception because the FAA balanced the burden of regulating with that of safety through these procedural mechanisms.<sup>84</sup> In an effort to limit the tort liability of the government, the Court held that it was "the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case."<sup>85</sup> The Court was concerned that tort liability had been extended to certain governmental activities that were intended to be protected from suit by private individuals.<sup>86</sup> It stated that the discretionary function exception was designed by Congress to reflect its "wish[ ] to prevent judicial 'second guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort."<sup>87</sup> The Court was attempting to clarify *Dalehite* by suggesting that, although administrative actions may involve discretionary judgment, the actions must be grounded in economic, political, or social policy before the exception will shield the government from liability.<sup>88</sup>

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82. Donald N. Zillman, *Regulatory Discretion: The Supreme Court Reexamines the Discretionary Function Exception to the Federal Tort Claims Act*, 110 *MIL. L. REV.* 115, 117 (1985).

83. *Varig*, 467 U.S. at 820. *Varig Airlines* involved two lawsuits challenging the FAA's certification for commercial use of two airplanes which later caught fire in flight. The Court held that the discretionary function exception applied to both the initial FAA decision to adopt a spot-check system of compliance review and the application of that system to the particular planes involved in the two crashes, because the two challenged FAA actions were taken within a statutory and regulatory element, leaving both the FAA and its spot-check inspectors room to make policy decisions. *Id.* at 819-20.

84. *Id.* at 820.

85. *Id.* at 813.

86. *Id.* at 808.

87. *Id.* at 814.

88. *Id.* "[T]he exception covers '[n]ot only agencies of government . . . but all employees exercising discretion.' Thus the basic inquiry . . . is whether the challenged acts of a Government employee—whatever his or her rank—are of the nature and quality that Congress intended to shield from tort liability." *Id.* at 813 (citations omitted).

### 3. *The Two-Step Analysis*

In 1988, the Supreme Court in *Berkovitz v. United States*<sup>89</sup> specified that the discretionary function exception of the FTCA does not preclude liability for any and all acts arising out of the regulatory programs of federal agencies; rather, the Court determined that the degree of discretion specifically prescribed by statute, regulation, or policy is determinative.<sup>90</sup> In *Berkovitz*, a child contracted severe polio and became paralyzed after ingesting a dose of Orimune, a polio vaccine which had been licensed and approved by the National Institute of Health's Division of Biologic Standards (DBS). The plaintiff challenged both the initial licensing of the vaccine and the approval of a particular lot for release to the public. The Court held that neither claim fell within the discretionary function exception, stating that if DBS incorrectly determined that the vaccine complied with regulatory safety standards, the crucial issue would be whether that determination "involve[d] the application of objective scientific standards . . . [or] 'policy judgment.'"<sup>91</sup>

As a result, the Court developed a two-step analysis. The Court first considered whether the action is a matter of choice for the acting employee.<sup>92</sup> If there is a federal statute, regulation, or policy specifically prescribing a course of action for the employee to follow, then the discretionary function exception will not apply.<sup>93</sup> If no regulation is involved, then the second step in the test is to "determine whether that judgment is of the kind that the discretionary function exception was designed to shield."<sup>94</sup> To be shielded from liability, the judgment must be "grounded in social, economic, and political policy."<sup>95</sup> The Court in *Berkovitz* determined that some of the claims fell outside the exception, because the agency employees had neglected to follow the specific directions contained in the applicable regulations; in those instances, there was no room for choice or judgment.<sup>96</sup> In other words, the employee had no rightful option but to adhere to the directive since his conduct cannot be the product of judgment or choice; "there is no discretion in the conduct for the discretionary function exception to protect."<sup>97</sup>

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89. 486 U.S. 531 (1988).

90. *Id.* at 538.

91. *Id.* at 544-45.

92. *Id.* at 536.

93. *Id.*

94. *Id.*

95. *Id.* at 536-37 (quoting *Varig*, 467 U.S. at 814).

96. *Id.* at 544.

97. *Id.* at 536. The Court held that the exception did not apply in *Berkovitz*

In 1991, the Supreme Court in *United States v. Gaubert*<sup>98</sup> abandoned the operational/planning distinction from *Dalehite* on the basis that all acts involve some form of discretion and that the central question is whether the act is grounded in policy. *Gaubert* involves the alleged negligent behavior on the part of federal bank regulators in their supervisory capacities over a failed savings and loan. Although the plaintiff contended that the actions fell outside the exception because the supervisory acts involved "the mere application of technical skills and business expertise," the Court held that "[i]t may be that certain decisions resting on mathematical calculations, for example, involve no choice or judgment in carrying out the calculations, but the regulatory acts alleged here are not of that genre."<sup>99</sup> The Court further held that "it is [obvious] that each of the challenged actions involved the exercise of choice and judgment."<sup>100</sup> The Court concluded that "if the routine or frequent nature of a decision were sufficient to remove an otherwise discretionary act from the scope of the exception, then countless policy-based decisions by regulators exercising day-to-day supervisory authority would be actionable."<sup>101</sup>

Although the Court in *Gaubert* rejected the operational/planning distinction that was set forth in *Dalehite*, it reaffirmed that the exception only protects those actions and decisions grounded in public policy and covers only acts that involve an element of judgment.<sup>102</sup> The Court

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at least insofar as it does not apply if the "Bureau's policy leaves no room for an official to exercise policy judgment in performing a given act, or if the act simply does not involve the exercise of such judgment, the discretionary function exception does not bar a claim that the act was negligent or wrongful." *Id.* at 546-47.

98. 111 S.Ct. 1267 (1991).

99. *Id.* at 1278.

100. *Id.*

101. *Id.* at 1279.

102. *Id.* at 1278-79. Compare *Olsen v. Government of Mexico*, 729 F.2d 641, 647 (9th Cir. 1984), *cert. denied*, 469 U.S. 917 (1984) (where a wrongful death suit was filed by the children of the deceased, who was killed in an airplane crash while being transported from Mexico to the United States. The court held that Mexico's alleged acts or omissions of negligently piloting a plane which contributed to the accident were not discretionary).

[F]irst, while Mexico's decision to enter into the Prisoner Exchange Treaty with the United States or to transfer these particular prisoners to United States custody might well be deemed discretionary, those decisions were not implicated in the [alleged negligence of maintaining, directing, and piloting of the aircraft]. Such conduct represents measures taken to implement the broader policy or plan to exchange prisoners. The acts or omissions in question involved the transportation of prisoners, an act remote

also reaffirmed its holding in *Berkovitz* that the nature of conduct will not shield the government from liability "if a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow because the employee has no rightful option but to adhere to the directive."<sup>103</sup> Secondly, the Court reaffirmed its position in *Varig* that, "'assuming the challenged conduct involves an element of judgment,' it remains to be decided 'whether that judgment is of the kind that the discretionary function exception was designed to shield.'"<sup>104</sup> The Court concluded that, "the exception 'protects only governmental actions and decisions based on considerations of public policy'."<sup>105</sup> Therefore, to overcome a motion to dismiss under the discretionary function exception, the complaint "must allege facts which would support a finding that the challenged actions are not the kind of conduct that can be said to be grounded in the policy of the regulatory regime."<sup>106</sup> Further, "[t]he focus of the inquiry is not on the agent's

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from the policy decision to transfer them. While the pilot and air controllers had considerable discretion in carrying out their assigned tasks, it is clear they acted on the operational level, far from the centers of policy judgment.

*Id.* (citations omitted).

103. *Gaubert*, 111 S.Ct. at 1273 (citing *Berkovitz*, 486 U.S. at 536).

104. *Id.* (citing *Varig*, 467 U.S. at 813). The Court gave an analogy when discretionary acts will not be shielded. The Court stated:

[T]here are obviously discretionary acts performed by a Government agent that are within the scope of his employment but not within the discretionary function exception because these acts cannot be said to be based on the purposes that the regulatory regime seeks to accomplish. If one of the officials involved in this case drove an automobile on a mission connected with his official duties and negligently collided with another car, the exception would not apply. Although driving requires the constant exercise of discretion, the official's decisions in exercising that discretion can hardly be said to be grounded in regulatory policy.

*Id.* at 1275, n.7.

105. *Id.* at 1273-74 (citing *Berkovitz*, 486 U.S. at 537).

106. *Id.* at 1274-75.

[U]nder the applicable precedents, therefore, if a regulation mandates particular conduct, and the employee obeys the direction, the Government will be protected because the action will be deemed in furtherance of the policies which led to the promulgation of the regulation. If the employee violates the mandatory regulation, there will be no shelter from liability because there is no room for choice and the action will be contrary to policy. On the other hand, if a regulation allows the employee discretion, the very existence of the regulation creates a strong presumption that a discretionary act authorized by the regulation involves consideration of the same policies which led to the promulgation of the regulations.

*Id.* at 1274 (citations omitted).



subjective intent in exercising the discretion conferred by statute or regulation, but on the nature of the actions taken and on whether they are susceptible to policy analysis.”<sup>107</sup> However, the Court recognized that “not all agencies issue comprehensive regulations . . . [rather,] . . . [s]ome establish policy on a case-by-case basis . . . or . . . rely on internal guidelines rather than on published regulations.”<sup>108</sup> The Court stated that, “[i]n any event, it will most often be true that the general aims and policies of the controlling statute will be evident from its text.”<sup>109</sup> Thus, in determining whether the discretionary function exception of the FTCA shields the government from liability, a two-step analysis must be conducted; the government must prove that the acts of negligence (1) involved an element of judgment and (2) that the judgment was grounded in social, economic, or political policy.

### B. *The Application of the Two-Step Analysis*

In granting a motion to dismiss, the U.S. District Court in *Balmaceda* determined that no inquiry into the alleged violations of the FDA laboratory procedure manual was necessary, on the grounds that negligence is not a consideration because the government is immune from liability under the discretionary function exception to the FTCA.<sup>110</sup> However, prior to dismissing an action on the basis of the discretionary function exception, the “United States bears the burden of proving the applicability of the [discretionary function exception] to the FTCA’s general waiver of immunity.”<sup>111</sup> At a minimum, the government must establish that the agent’s discretionary act involved a balancing of policy.<sup>112</sup> The following section illustrates the application of the two-step analysis to *Balmaceda*.

#### 1. *Did the FDA decision to impose an embargo involve an element of judgment?*

The first issue concerns whether the allegedly negligent acts of the FDA investigators were discretionary and thus involved an element of

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107. *Id.* at 1274-75.

108. *Id.* at 1274.

109. *Id.*

110. *Balmaceda*, 815 F. Supp. at 826.

111. *Prescott*, 973 F.2d at 702.

112. *Id.* at 703.

judgment. While the operational/planning test has been rejected, courts have not abandoned the central theme that there is no discretion in an act which violates a regulation and, therefore, the exception will not reinstate sovereign immunity. In conducting a scientific analysis of the impounded grapes, the FDA investigators decided to modify the testing procedures in violation of both the Code of Federal Regulations and the FDA Regulatory Procedures Manual.<sup>113</sup> The facts indicate that the cyanide was discovered in the Philadelphia laboratory and then sent to a specialist in cyanide contamination for additional testing.<sup>114</sup> Because of the migratory characteristics of cyanide, the surrounding grapes in the sample should have revealed traces of contamination; however, no traces were found.<sup>115</sup> In an effort to explain the discrepancy, the investigators were to retest the sample. However, as a result of their testing methods,<sup>116</sup> the sample had been destroyed in violation of FDA laboratory procedures, which require the retention of any original sample in case reexamination becomes necessary.<sup>117</sup> Although the GAO determined that the violation of FDA procedures was acceptable, the discrepancy in testing procedures rendered the grape sample useless for further testing.<sup>118</sup> Therefore, in violating FDA regulations on laboratory procedures, the agents did not engage in discretionary conduct involving an element of judgment. However, if the court finds that the scientific testing did involve an element of judgment, the second part of the two-step analysis requires an examination of whether the conduct was grounded in social, economic, or political policy.

2. *Was the FDA's judgment grounded in social, economic, or political policy?*

At the outset, the two types of conduct manifested by the FDA in the Chilean Grape Crisis must be distinguished. The court in *Balmaceda* focused on the FDA's decision to impose an embargo on Chilean fruit as the discretionary act in question. However, the Chilean Exporters Association sued for negligence on the grounds that the FDA did not have the discretion to impose the embargo, based on alleged

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113. Burkholz, *supra* note 12, at 14. *But see* GAO, *supra* note 47, at 13-14, 29-38.

114. Burkholz, *supra* note 12, at 14.

115. *Id.* *See also* GAO, *supra* note 47, at 39.

116. GAO, *supra* note 47, at 34.

117. Burkholz, *supra* note 12, at 14.

118. *Id.*

negligent violations of a procedures manual which delineates mandatory testing procedures within the FDA laboratory. Further, the findings of the GAO indicate that the violations of the FDA's laboratory testing and sampling procedures were the proximate cause of the FDA's actions in imposing the embargo on Chilean fruit imports.<sup>119</sup> Therefore, it must be determined whether both the decision to impose an embargo on Chilean fruit and the decision to modify FDA laboratory procedures were judgments grounded in social, economic, or political policy which are immune from liability under the discretionary function exception.

a. *The FDA's Decision to Impose the Embargo*

Recognizing the FDA's role as the protector of the public health, there is little question that it has the authority to refuse the admission of adulterated fruit into the United States.<sup>120</sup> The FDA's judgment to impose an embargo on Chilean fruit was grounded in policy designed to protect the public health. The question, however, is whether the actions which led to that judgment are shielded under the discretionary function exception. In *Kennewick Irrigation District v. United States*,<sup>121</sup> the court determined that the government's design of a canal was a discretionary act which was grounded in economic policy.<sup>122</sup> In *Kennewick*, the United States Bureau of Reclamation designed and constructed the canal in question in the 1950s. Once the canal was completed, the district of Kennewick assumed responsibility for its operation and maintenance. As a result of "piping" due to rodent holes, several breaks erupted in the main canal during its operation. The eruption caused a railroad right-of-way and track bed to be washed away and led to the derailment of a passenger train, which resulted in a number of personal injuries. The magistrate found that the negligence of the United States in both the design and the construction of the canal was the proximate cause of the breaks in the canal which led to the damage.<sup>123</sup> In applying the two-step analysis to determine whether the government's actions were discretionary and whether its judgment was grounded in

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119. GAO, *supra* note 47, at 6.

120. 21 U.S.C.A. § 381 (West Supp. 1993). "The FDA may refuse admission of food into the United States '[i]f it appears from the examination of such samples or otherwise that . . . such article is adulterated.' . . ." *Balmaceda*, 815 F. Supp. at 826 (quoting 21 U.S.C.A. § 381(a)(West Supp. 1993)).

121. 880 F.2d 1018 (9th Cir. 1989).

122. *Id.* at 1031-32.

123. *Id.* at 1030.

social, economic, and political policy,<sup>124</sup> the court determined that the design of the canal was grounded in policy; however, the government official's discretion in the construction of the canal was based not on policy judgments, but on technical, scientific, and engineering considerations.<sup>125</sup> Thus, the court held that the discretionary function exception did not bar a claim of negligence arising from the exercise of scientific judgment.<sup>126</sup> Similarly, the FDA's decision to impose an embargo on Chilean fruit was grounded in social policy designed to protect the public health. However, the proximate cause of the embargo was the scientific analysis conducted by the FDA investigators, which erroneously led to a finding that the grapes were contaminated with cyanide. Therefore, it must be determined whether these scientific judgments<sup>127</sup> were grounded in technical and scientific considerations such that they are not shielded by the discretionary function exception.

b. *The FDA's Scientific Testing*

Assuming that the FDA investigators were acting with discretion, the second issue concerns whether the decision to modify FDA laboratory procedures involved the weighing of social, economic, and political policy considerations.<sup>128</sup> While the predominant goal of FDA policy is the protection of the public health, the exercise of sound scientific laboratory practices is essential in determining when protection is necessary. The Supreme Court in *Berkovitz* stated that "the discretionary function exception will not apply when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow."<sup>129</sup> The Court determined that, if the conduct is "not a product of judgment or choice," then there cannot be any discretion for the exception to protect.<sup>130</sup> In *Berkovitz*, a child contracted a severe case of polio after orally ingesting a polio vaccination that was licensed and approved by the FDA. The child's parents alleged that the FDA acted wrongfully in approving the release of a particular lot of vaccine to

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124. *Id.* at 1025.

125. *Id.* at 1031.

126. *Id.* See also *Routh v. United States*, 941 F.2d 853 (9th Cir. 1991). Following Kennewick's two-step analysis, the court determined that a "contracting officer's on-site decision were not of the nature and quality that Congress intended to shield from tort liability." *Id.* at 857.

127. GAO, *supra* note 47, at 6.

128. *Berkovitz*, 486 U.S. at 536-37.

129. *Id.* at 536.

130. *Id.*

the public in violation of federal law and policy.<sup>131</sup> The Court found that the discretionary function exception did not bar suit when a specific regulation requires the employee to gather certain test data before making a determination as to whether the polio vaccine lot complies with regulatory standards.<sup>132</sup>

Conversely, in *Ayala v. United States*,<sup>133</sup> a suit was brought against the United States for alleged negligent technical advice and inspection of mining equipment by a coal mine electrical inspector employed by the Mine Safety and Health Administration (MSHA) in violation of MSHA standards. The main dispute revolved around the discretion used in giving technical advice. The district court focused on “the fact that inspectors had discretion in deciding whether or not to offer technical advice.”<sup>134</sup> However, the Court of Appeals for the Tenth Circuit stated that, “[t]he specific technical assistance (i.e. to connect the wires to the wrong terminal in violation of mandatory safety standards) is what is at issue.”<sup>135</sup> The court held that this particular decision was not grounded in any consideration of social, economic, or political policy; rather, the discretion exercised was based solely on technical considerations governed by “objective principles of electrical engineering.”<sup>136</sup> Thus, the court in *Ayala* reversed the decision that the technical assistance claim “was barred by the discretionary function exception” and concluded that scientific practices are not immune from judicial scrutiny.<sup>137</sup> Likewise, in *In re Sabin Oral Polio Vaccine Products Liability Litigation*,<sup>138</sup> the court held that scientific analysis does not immunize the government from judicial review.<sup>139</sup> The court determined that neurovirulence testing of polio vaccines “requires the exercise of sound scientific judgment” when a regulation guiding action “calls for a ‘comparative evaluation,’ not simply a comparison of numerical test scores.”<sup>140</sup> Similarly, the FDA agents’ discretion in deciding to modify the scientific procedures during the testing and inspection of the grapes

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131. *Id.* at 542-43.

132. *Id.*

133. 980 F.2d 1342 (10th Cir. 1992).

134. *Id.* at 1349.

135. *Id.*

136. *Id.* at 1349-50.

137. *Id.* at 1354.

138. 763 F.Supp. 811 (D. Md. 1991), *aff'd*, 984 F.2d 124 (4th Cir. 1993).

139. *Id.* at 821-22.

140. *Id.*

for cyanide was based on technical and scientific considerations.<sup>141</sup> In this case, no traces of cyanide could be detected after the original tests had been conducted because the remainder of the original samples was too scarce to allow retesting and a confirmation of the findings because of the alteration of testing procedures.<sup>142</sup> The policy of following the FDA laboratory procedures in retaining part of the original sample is to confirm cases of contamination when there are disparities in the findings.<sup>143</sup> Therefore, the violations of these FDA laboratory procedures are not based on social, economic, or political policy, but rather on technical and scientific considerations. Consequently, the scientific testing procedures are not immune from judicial scrutiny under the discretionary function exception to the FTCA.

### C. *Summary*

While recognizing that the FDA has discretion in its actions to protect the public health, it must also be recognized that the FDA does not have absolute discretion. The FDA is responsible for regulating and inspecting food shipments entering the United States. Shipments can be rejected after the FDA follows certain procedural guidelines. However, if those guidelines are negligently administered, then the exception should not protect the government from liability. If arbitrary guidelines are employed, then the FDA could reject any shipment of grapes for any reason. For example, the grapes may look too big, too small, slightly unripe, or just not to the inspector's liking. However, this is not an appropriate procedure to be used in refusing admission of food imports. In today's age of sophisticated scientific analysis, we expect regulators to employ sound and accurate procedures. If the testing is performed negligently, and is the proximate cause of injury, then the discretionary function exception to the FTCA should not bar suit. If the grapes had actually been contaminated and were allowed to enter the stream of commerce in the United States because the negligent testing by the FDA failed to reveal the contamination, then we would not want to deny recovery if American lives had been lost. The scrutiny must be placed upon the actors that performed the negligent analysis. If the *Balmaceda* decision is allowed to stand, then a

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141. GAO, *supra* note 47, at 6. The GAO's report stated that the modifications made in the inspecting and testing procedures were based on *scientific practices* rather than on economic considerations. *Id.*

142. *Id.* at 34.

143. Burkholz, *supra* note 12, at 14.

loophole is created for all administrative agencies to make their decisions on "other factors," essentially shielding decisions based on policy, as well as the negligent conduct that led to that decision. The general policy of protecting the public health and of granting FDA agents discretion to achieve those ends is far too broad and indefinite to insulate FDA investigators' conduct from suit.

#### IV. FOREIGN POLICY CONCERNS

"International trade in FDA-regulated products has become increasingly important to the United States economy."<sup>144</sup> Our dependence on imported foods during off-seasons has become commonplace in the fruit industry. Prior to the Chilean Grape Crisis, most Americans were unaware that certain foods would be unavailable if it were not for the antithetical seasons of the southern hemisphere providing grapes, kiwis, melons, and other non-citrus fruits that would normally be unavailable during the winter months.<sup>145</sup> Chile has also benefited from the increase in market demand for fruit and has become a "star among the new exporters,"<sup>146</sup> being "virtually the sole supplier of soft tree fruits such as peaches and plums."<sup>147</sup> Likewise, the United States and Japan are Chile's largest trading partners, together accounting for over 32 percent of all exports.<sup>148</sup> Because of Chile's increasing fruit exports<sup>149</sup> and because the Chilean agricultural industry is a major employer accounting for

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144. Paul M. Hyman, *Legal Overview of FDA Authority Over Imports and Exports*, 42 FOOD DRUG COSM. L.J. 203 (1987).

145. Leary, *supra* note 18. Because Chile is located in the Southern Hemisphere, its fruit season is opposite to that of the United States. As a result, most fruit that Americans buy during the winter and spring months come from Chile. This symbiotic relationship helps maintain a continual flow of fruit in both countries when the supply is low due to their diametrically opposing seasons.

146. Clemons P. Work & Robert E. Norton, *The Great Global Food Fright: Whether it's Grapes, Apples, or other Produce, World Food Exports are Growing. So, too, are Safety Concerns*, U.S. NEWS & WORLD REPORT, March 27, 1989, at 56, 57.

147. Lauter, *supra* note 11, at A1.

148. *Foreign Trade and External Payments and Debt, Chile Country Profile*, BUS. INT'L., May 1, 1993, available in LEXIS, NEWS Library, BUSINT File. While fruit exports do not constitute a large portion of Chile's gross domestic product, they averaged around 11 percent in 1991 of Chile's total exports. *Id.*

149. Chile's fruit exports earned a total of \$949 million in 1991, and \$704 million in 1990, with grapes accounting for 43.8 percent of total fruit exports in 1991-92. *Agriculture, Forestry, Fishing and Crops, Chile Country Profile*, BUS. INT'L., May 1, 1993, available in LEXIS, NEWS Library, BUSINT File.

over 17.5 percent of the Chilean workforce,<sup>150</sup> threats of a potential disruption in fruit shipments can have devastating effects on the Chilean economy.<sup>151</sup> Thus, when a United States agency such as the FDA takes action, its action affects not only domestic consumers and suppliers, but also the people of the nations with whom we trade.

This trend towards economic interdependence has encouraged the development of multilateral and bilateral free trade agreements throughout the world. With the European Community as a model of successful cooperation between nations, pockets of "communities" are discussing the possibilities of multilateral free trade agreements, including countries within the Pacific Basin, the continent of South America,<sup>152</sup> and the United States.<sup>153</sup> As the United States engages in free trade agreements, it must recognize the problems that are inherently associated with them, specifically the effects of absolute discretion and the perception of participating countries who, despite their dependency on American consumption, are suddenly barred from entering the American market because of the lack of due care exercised by American administrative agents. The policies of administrative agencies must also be adjusted by balancing the interests of the American public with the commercial interests of our trading partners.<sup>154</sup>

The Chilean Grape Crisis prompted Chile to ask the Council on General Agreement on Tariffs and Trade (GATT) to consider adopting directives that would require nations to balance "both the rights of contracting parties to defend the health of their populations . . . [with the interests of] . . . insur[ing] a stable climate for trade and exports."<sup>155</sup>

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150. *Chile Country Reports*, WALDEN COUNTRY REPORTS., December 18, 1992, available in LEXIS, World Library, COUREP File.

151. Shenon, *supra* note 8, at A22.

152. Don Podesta, *South Americans Give More Than Lip Service to Economic Integration*, WASH. POST, January 18, 1994, at A15.

153. On January 1, 1994, the North American Free Trade Agreement (hereinafter NAFTA) between Canada, Mexico, and the United States went into effect, making it the largest economic trading bloc in the world. *Nafta signed in 'defining moment'*, USA TODAY (Int'l Ed.), December 9, 1993, available in WESTLAW, PAPERSMJ Database.

154. See, e.g., Robinson, *supra* note 30. In spite of the United States embargo, the European Community had opted to inspect the incoming Chilean fruit rather than banning it. *Id.* But cf. William Pendergast, *Does, or Can, FDA Discriminate Against Foreign Origin Goods to the Advantage of Domestic Products?*, 42 Food Drug Cosm. L.J. 527 (1987). This article suggests that the current FDA policies and procedures governing foreign origin goods tend to illustrate a pattern of discrimination against such imports and recommends that the FDA policy on the regulation of international trade should reflect fair and equal treatment.

155. Chakravarthi Raghavan, *Trade: U.S. Blocks Panel Ruling on Section 337 Pro-*



As a result of Chile's request, the GATT Council provided guidelines to ensure that any measures taken by nations toward a third nation must bear a reasonable relationship to the conservation or public health objective.<sup>156</sup> The guidelines specifically state that "[a] measure taken by an importing contracting party should not be any more severe, and should not remain in force any longer than necessary to protect human, animal, or plant life or health involved, as provided in Article XX(b)."<sup>157</sup> The objective of this measure is to deal with the potential threats of "economic terrorism" and to avoid prejudicing the commercial interests of smaller nations when the threat is small compared to the action taken against that threat.<sup>158</sup> Therefore, under these guidelines, the FDA would have to weigh its decision to impose an embargo, after finding two grapes with scant traces of cyanide barely enough to make a small child sick, with the severe hardship inflicted upon the people, the industry, and the economy of another nation.

With the recent passage of NAFTA, administrators are seriously considering Chile as the next prospective nation to join the North American trading bloc, due to its consistent growth rate and political stability.<sup>159</sup> In May, 1992, the United States and Chile entered into free trade negotiations to enable Chile to export mineral and agricultural products to the United States and to allow the United States to export American mining, machinery, and telecommunications equipment into Chile.<sup>160</sup> The long-term goal of such an agreement is to eventually create a free-trade zone between the two countries.<sup>161</sup> The benefits for Chile are enormous, as the agreement reduces tariffs and protectionist measures after years of scrutiny by our government for violations of

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*ceedings*, INTER PRESS SERVICE, Geneva, April 12, 1989, available in LEXIS, NEWS Library, INPRES File.

156. Janet McDonald, *Greening the GATT: Harmonizing Free Trade and Environmental Protection in the New World Order*, 23 ENVTL. L. 397, 436 (1993) (citing GATT, GATT ACTIVITIES 1989, 100 (1990)).

157. *Id.* "[T]he guidelines do not provide any real guidance on the meaning of Article XX(b) but at least indicate that the measure taken must intrude as little as possible on trade policies and must bear a proportionate relationship to the policy objective being pursued." *Id.*

158. Raghavan, *supra* note 155.

159. Don Podesta, *South Americans Bank on NAFTA Trade Pact's Passage Viewed as Crucial for U.S. Ties in Region*, WASH. POST, November 13, 1993, at A20. See also Stan Hinden, *Some Favored Foreign Funds Could Be Winners in 1994*, WASH. POST, December 22, 1993, at D3.

160. Vicki Mayer, *The fever for free trade*, AMERICAS, July-August, 1992, at 2, 2-3.

161. *Id.*

human rights by the former military government.<sup>162</sup> For the United States, the tangible economic benefits are slim, as the United States only imports about \$1.3 billion in goods from Chile; however, the treaty is a symbol of the United States' support of the reinstitutionalization of democracy in Chile.<sup>163</sup> The passage of a free trade agreement will signal an era of increasing trade between the United States and Chile and will require cooperation among both nations so that free trade can prosper. Thus, the United States should analyze how its foreign policy will affect free trade agreements. It should also consider how a single act of negligence by one or two individuals in a United States regulatory agency will impact another nation, particularly a developing nation that is vulnerable to, and dependent upon, more advanced nations such as the United States. The United States must accommodate this vulnerability if it is willing to engage in free trade agreements with developing nations.

#### V. CONCLUSION

The discretionary function exception to the FTCA remains as controversial today as it was forty years ago, with the central issue being when, if ever, the government will become liable for acts arising out of a government agent's actions. The holding in *Balmaceda v. United States* suggests gross inequity, because it implies that administrative agency decisions will be shielded regardless of the negligence of government employees in exercising their power to regulate the importation of food products. The U.S. Supreme Court and lower court decisions suggest that acts prescribed by statute, regulation, or procedure, or acts that are not grounded in economic, social, or political policy, will not be shielded by the discretionary function exception, and will thus be subject to tort liability. Scientific analysis is a means to an end and merely provides the basis upon which a decision can be made. To suggest that any action towards imposing an embargo is protected, irrespective of how that decision is grounded, is to imply that both the means and the end are protected from tort action. While the final decision to impose an embargo may be protected, scientific analysis cannot be afforded that same protection.

Likewise, building a global market is important to the United States economy, as demonstrated by efforts to promote free trade and market economies throughout the world. However, with one negligent

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162. *Id.* at 2, 3.

163. *Id.*

act, the FDA has the power to destroy consumer confidence in another nation's food products and thereby to inhibit trade with that nation and economic growth within that nation. The government should be wary of the implications of providing the FDA with such broad discretionary power. Through the imposition of an embargo on Chilean grape exports, the FDA crippled a developing economy, leading to enormous capital losses, further unemployment, and overall social, political, and economic hardship. Although the protection of the public health is an important and valid concern for the United States, perceived threats to the public health which are illusory and unfounded do not justify the closing of the United States market and the destruction of consumer confidence in another nation's goods. As a world trader, the United States must restrict the scope of protection afforded to the FDA in an effort to promote free and fair trade. Therefore, the United States must adopt policies which adequately balance the interests of protecting its citizens with the interests of engaging in prosperous relationships with other people and nations of the world.

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