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**Protecting Our Food: A Critical Look at  
the National Uniformity for Food Act of  
2004 and Food Safety in America**

by

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# Protecting Our Food: A Critical Look at the National Uniformity for Food Act of 2004 and Food Safety in America

By Megan Danko\*

## I. Introduction

“The consumer’s interest is the American interest.”<sup>1</sup> This statement was made by President Lyndon B. Johnson in 1966 as he urged Congress to pass the Fair Packaging and Labeling Act.<sup>2</sup> He stated that “[a] new and progressive program is needed if we are to protect the American consumer’s rights in the marketplace—his right to be informed, to choose, to be protected from unsafe products and to be heard in the councils of Government.”<sup>3</sup> Today, almost forty years later, a new bill in Congress could potentially impact these same rights. The bill at issue is H.R. 2699, the National Uniformity for Food Act of 2004 (“NUFA”).<sup>4</sup> The purpose of the bill is to provide for uniformity in food warning labels by creating national standards and preventing states from enforcing requirements relating to food safety that are not identical to these standards.<sup>5</sup> But opponents of NUFA warn that, if enacted, it would disrupt the day-to-day enforcement activities of state and local governments and jeopardize

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<sup>1</sup> Fair Packaging & Labeling Act, S. REP. NO. 89-1186 (1966), reprinted in 1966 U.S.C.C.A.N 4069, 4084.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 4085.

<sup>4</sup> National Uniformity for Food Act of 2004, H.R. 2699, H.R. REP. NO. 108-770, 108th Cong., 2d Sess. (2004).

<sup>5</sup> H.R. REP. NO. 108-770, at 5 (2004).

the states' ability to protect their citizens from unsafe food.<sup>6</sup>

This article will provide a brief summary of the history of food safety in America and a review of the existing regulatory infrastructure. It will then discuss the proposed legislation in detail and its impact on the existing food safety infrastructure. Finally, it will address what effect, if any, the bill will have on consumers.

## II. Background

### A. A Brief History of Food Safety in America

Food warning labels are one aspect of a large food safety infrastructure in the United States. The system is expansive and detailed, monitoring food production and distribution at the local, state, and national levels.<sup>7</sup> Until 1906, public food safety programs were run almost exclusively by state and local governments.<sup>8</sup> The federal government became involved with food safety in the early twentieth century when Congress enacted the Federal Meat Inspection Act and the Pure Food and Drug Act of 1906.<sup>9</sup> The acts provided, in part, for uniform inspection procedures for different types of food,<sup>10</sup> however, the acts did not give the federal government the sole responsibility for food safety.<sup>11</sup> As is the case today, food safety has always depended on the collective efforts of the federal and state governments.<sup>12</sup>

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<sup>6</sup> H.R. REP. NO. 108-770, at 21 (2004).

<sup>7</sup> U.S. FOOD & DRUG ADMIN., *FDA Backgrounder: Food Safety: A Team Approach* (Sept. 24, 1998), available at <http://www.cfsan.fda.gov/~lrd/foodteam.html>.

<sup>8</sup> *A System Rued: Inspecting Food: Hearing before Subcommittee on Civil Service and Agency Organization*, 108th Cong. 8-9 (2004), available at <http://reform.house.gov/CSA/Hearings/EventSingle.aspx?EventID=930>.

<sup>9</sup> Nat'l Uniformity for Food Act of 2000, S. REP. NO. 106-504 at 1 (2000), reprinted in 2000 WL 1573351. See Pure Food & Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) repealed by Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 392(a)); Federal Meat Inspection Act, 21 U.S.C. §§ 601-80 (1907), amended by Act of Mar. 4, 1907, ch. 2907, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. §§ 601-80).

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

<sup>11</sup> *Id.*

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

The next major legislation governing food safety, the Federal Food, Drug, and Cosmetic Act (“FFDCA”), was passed in 1938.<sup>13</sup> Part of this expansive bill was to prohibit the adulteration or misbranding of any food, drug, device, or cosmetic product in interstate commerce.<sup>14</sup> The FFDCA also regulated the use of additives in food.<sup>15</sup> An additive could not be used unless it was deemed safe by the Secretary of the Department of Health, Education, and Welfare.<sup>16</sup> This provision was amended in 1958 by the Delaney Amendment, which explicitly prohibited the Secretary from finding any food additive safe which caused cancer in humans or animals, regardless of how small the risk of cancer actually was.<sup>17</sup>

While this early federal legislation dealt primarily with food inspection and quality standards, food labeling became a primary concern in the 1960s. The label’s role had become the product’s most enthusiastic advertisement, and content information suffered at the expense of this promotion.<sup>18</sup> In 1966 Congress enacted the Fair Packaging and Labeling Act (“FPLA”).<sup>19</sup> The purpose of FPLA was to adequately inform consumers of the quantity and composition of packaged consumer goods, and to enable consumers to make informed choices by providing them with relevant information on food packages listed in a coherent and uniform manner.<sup>20</sup> The bill brought uniformity to the marketplace by requiring that certain identifying information such as the identity of the commodity and the name of the manufacturer, packer, or distributor to appear on the label.<sup>21</sup> In addition, the bill required that labels include information on the weight of the product and serving sizes.<sup>22</sup> The bill also

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<sup>13</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

<sup>14</sup> 21 U.S.C. § 331(b) (1938).

<sup>15</sup> *Id.* at § 348(a).

<sup>16</sup> *Id.*

<sup>17</sup> 21 U.S.C. § 348(c)(3)(A) (1958).

<sup>18</sup> S. REP. NO. 89-1186, *reprinted in* 1966 U.S.C.C.A.N 4069, 4070.

<sup>19</sup> Fair Packaging & Labeling Act, 15 U.S.C. §§ 1451-61 (1966).

<sup>20</sup> S. REP. NO. 89-1186, *reprinted in* 1966 U.S.C.C.A.N 4069, 4071.

<sup>21</sup> *See* 15 U.S.C. § 1453(a)(1) (requiring that labels shall specify the identity of the commodity and the name and place of business of the manufacturer, packer, or distributor).

<sup>22</sup> 15 U.S.C. § 1453(2)-(4).

mandated the size and style of font used on the packaging.<sup>23</sup> While the bill listed extensively what contents must be included on a label and in what format, it did not address the use or restriction of food warning labels. This was left to the state governments to regulate.

Federal and state governments continued to be actively involved in keeping America's food supply safe and regulated. In 1990, Congress amended the FFDCFA with the Nutrition Labeling Education Act.<sup>24</sup> The act requires most foods to include uniform nutrition labeling requirements such as the total fat, cholesterol, and sodium contained in each serving size.<sup>25</sup> In addition, the act restricts the use of nutrient content claims and certain health messages unless the product complies with specific nutritional requirements.<sup>26</sup> The act also specifically preempts any state law that is not identical to the provisions of the act.<sup>27</sup>

## B. The Current System

The American food safety system today continues to be a collaborative effort among state and federal governments. The system is a complex partnership of various federal, state, and local government agencies in charge of inspecting, testing, researching, and monitoring the food supply.<sup>28</sup>

## C. Federal Agencies

In the federal arena, the Food and Drug Administration ("FDA") is primarily responsible for assuring that foods sold in the United States are safe and properly labeled.<sup>29</sup> However, given the large scope of this task, many other governmental bodies are involved and responsible for the development, implementation, and enforcement of food safety laws, including the U.S. Department of Agriculture ("USDA"), the Department of Health and Human

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<sup>23</sup> 15 U.S.C. § 1453(3)(A)(iv)(B)-(C).

<sup>24</sup> 21 U.S.C. § 343-1(a) (Supp. II 1990).

<sup>25</sup> 21 U.S.C. § 343(q)(1)(D) (1990).

<sup>26</sup> *Id.* at § 343-1(a)(4).

<sup>27</sup> *Id.* at § 343-1(a).

<sup>28</sup> S. REP. NO. 106-504 at 2 (2000).

<sup>29</sup> U.S. FOOD & DRUG ADMINISTRATION, A FOOD LABELING GUIDE, (Sept. 1994) (revised June 1999), available at <http://www.cfsan.fda.gov/~dms/flg-toc.html>.

Services (“HHS”), the Environmental Protection Agency (“EPA”), and the Food Safety Inspection Service (“FSIS”).<sup>30</sup> The FSIS, which is part of the USDA, is responsible for the safety of meat, poultry, and some egg products.<sup>31</sup> The government is also explicitly authorized to commission cooperation with any department or agency of any state in carrying out its duty to protect the national food supply.<sup>32</sup>

#### D. State and Local Governments

Under the current system, state and local governments oversee all food within their jurisdiction.<sup>33</sup> They work with the FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders.<sup>34</sup> In addition, state and local governments have the authority to stop the sale of unsafe food products made or distributed within their jurisdiction.<sup>35</sup>

The Association of Food and Drug Officials (“AFDO”), an organization which represents state and local government food safety officials, conducted a survey in 2002 of state and local food safety programs.<sup>36</sup> The survey found that, in 2001, more than eighty percent of the food safety and security activities in the United States were performed at the state or local levels.<sup>37</sup> Given this large figure, the FDA relies heavily on states to carry out food safety activities under

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<sup>30</sup> Caren A. Wilcox, Remarks at the 9th Annual European Food Law Conference, The U.S. Food Safety System, The Uses of Precautions (June 20, 2000) (transcript available at [http://www.fsis.usda.gov/OA/speeches/2000/caw\\_eulaw.htm](http://www.fsis.usda.gov/OA/speeches/2000/caw_eulaw.htm)).

<sup>31</sup> FOOD SAFETY INSPECTION SERVICE, ABOUT FSIS, available at [http://www.fsis.usda.gov/About\\_FSIS/index.asp](http://www.fsis.usda.gov/About_FSIS/index.asp) (last visited May 10, 2005).

<sup>32</sup> 15 U.S.C. § 1455(c) (2000).

<sup>33</sup> U.S. FOOD & DRUG ADMIN., *supra* note 7.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Implementation of Food Security Provisions of the Public Health Security & Bioterrorism Preparedness and Response Act: Hearing Before the House Comm. on Energy & Commerce, Subcomm. on Health*, 108th Cong. 114, 46 & 48 (June 25, 2004) [hereinafter *Hearings*] (statement of Douglas R. Saunders, Chair, Assoc. of Food and Drug Officials).

<sup>37</sup> *Id.* at 48.

state laws.<sup>38</sup> Since states have the authority to authorize food warning labels, they have enacted labels unique to their specific state's food supply and citizens' needs.<sup>39</sup>

### III. The National Uniformity for Food Act of 2004

#### A. The Proposed Legislation

NUFA was introduced in the House by Representative Richard Burr on July 10, 2003.<sup>40</sup> The purpose of the bill is to provide uniform warning notification requirements for food and to prevent states from enforcing requirements relating to food safety that are not identical to the national requirements.<sup>41</sup> The House Report accompanying NUFA states that the current multi-layer system can lead to a variety of different and sometimes inconsistent requirements under state laws.<sup>42</sup> In addition, the conflicting labeling and notification requirements between the states result in increased labeling costs to manufacturers and distributors which are then passed on to consumers.<sup>43</sup>

NUFA is designed to achieve national uniformity without affecting the safety of the nation's food supply.<sup>44</sup> If enacted, the bill would amend the Federal Food, Drug, and Cosmetic Act to require uniformity in food safety warning notification requirements.<sup>45</sup> NUFA would require states to use language identical to the federal standards.<sup>46</sup>

NUFA would establish a petition process to enable states to apply for an exemption to a uniformity standard or to petition for a

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<sup>38</sup> H.R. REP. NO. 108-770, at 21.

<sup>39</sup> See *infra* Part III (discussing examples of state specific legislation).

<sup>40</sup> H.R. 2699, 108th Cong. (2004). Rep. Richard Burr also introduced the National Uniformity for Food Act of 1998, H.R. 4383 105th Cong. (1998).

<sup>41</sup> H.R. REP. NO. 108-770, at 5.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 11.

<sup>46</sup> H.R. 2699, 108th Cong., 2d Sess. § 403B(a)(1) (2004).

new national standard.<sup>47</sup> States may petition the Secretary of HHS for an exemption to a uniformity standard to address food safety issues unique to their area;<sup>48</sup> the petitions must be filed within 180 days after the enactment of the bill.<sup>49</sup> Prior to deciding the petition, the Secretary is required to publish a notice in the Federal Register concerning the petition and provide for 180 days for public comment.<sup>50</sup> The Secretary shall make a decision no later than 360 days after the conclusion of the public hearing.<sup>51</sup>

The bill appears to give the Secretary discretion to grant exceptions but then stipulates that three requirements must be met in order to grant exceptions:

The Secretary *may* provide such an exception, under such conditions as the Secretary may impose, for such a requirement that—

protects an important public interest that would otherwise be unprotected, in the absence of the exception;

would not cause any food to be in violation of any applicable requirement or prohibition under Federal law; and

would not unduly burden interstate commerce, balancing the importance of the public interest of the State or political subdivision against the impact on interstate commerce.<sup>52</sup>

States may also petition to enact a new national standard if the state has identified a potential risk that has not been addressed in NUFA.<sup>53</sup> The FDA will examine the new national standard petition

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<sup>47</sup> *Id.* at § 403B(c).

<sup>48</sup> H.R. REP. NO. 108-770, at 5.

<sup>49</sup> H.R. 2699, 108th Cong., 2d Sess. § 403B(b)(2) (2004).

<sup>50</sup> *Id.* at § 403B(b)(3)(A).

<sup>51</sup> *Id.* at § 403B(b)(3)(B).

<sup>52</sup> *Id.* at § 403B(c)(1) (emphasis added).

<sup>53</sup> *Id.* at § 403B(c)(2); H.R. REP. NO. 108-770, at 5.

and determine whether a warning should be established to protect consumers in all states.<sup>54</sup> The Secretary must publish notice of such a petition in the Federal Register within thirty days after receiving the petition, and the Secretary shall take final action no later than sixty days after the end of the period for public comment.<sup>55</sup> While NUFA provides for the procedural requirements on how petitions for new national standards are submitted, it is silent on the Secretary's authority or discretion to grant these petitions.

NUFA does not eliminate all of the states' authority. The states will continue to have some limited authority in regard to food safety if the bill is enacted. NUFA would establish Imminent Hazard Authority, which authorizes states to establish requirements that would otherwise violate NUFA, if the requirement is needed to address an imminent hazard to health that is likely to result in serious, adverse health consequences or death.<sup>56</sup> In order to be covered under the Imminent Hazard Authority, states must follow a specific procedure. First, the state must have notified the Secretary about the situation, and the Secretary must have not already initiated any enforcement action.<sup>57</sup> Next, the state must submit a petition for either an exemption or a new national standard no later than thirty days after the state establishes the requirement under its Imminent Hazard Authority.<sup>58</sup> Then, the state must have taken enforcement action under state law within thirty days of establishing the standard.<sup>59</sup>

In addition to the Imminent Hazard Authority, states would remain primarily responsible to authorize, establish, and enforce requirements relating to food freshness and grade labeling.<sup>60</sup> NUFA exempts requirements relating to

freshness dating, open date labeling, grade labeling, a State inspection stamp, religious dietary labeling, organic or natural designation, returnable bottle labeling, unit pricing, or a statement of geographic origin; or

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<sup>54</sup> H.R. REP. NO. 108-770, at 5.

<sup>55</sup> H.R. 2699, 108th Cong., 2d Sess. § 403B(c)(3)(A)-(B) (2004).

<sup>56</sup> *Id.* at § 403B(d)(1)(A).

<sup>57</sup> *Id.* at § 403B(d)(1)(B).

<sup>58</sup> H.R. 2699, 108th Cong., 2d Sess. § 403B(d)(1)(C) (2004).

<sup>59</sup> *Id.* at § 403(B)(d)(1)(D).

<sup>60</sup> *Id.* at § 403B(g).

a consumer advisory relating to food sanitation that is imposed on a food establishment or that is recommended by the Secretary . . . <sup>61</sup>

Furthermore, NUFA does not prohibit a state from taking action regarding a mandatory recall, civil administrative order, embargo, detention order, or court proceeding involving food adulteration.<sup>62</sup>

## B. Previous Legislation

The text of NUFA is not new to Congress. In fact, the bill was introduced in 1996, 1998, and again in 1999.<sup>63</sup> The 1996 version was a small provision in a larger bill to reform, reengineer, and redesign the FDA.<sup>64</sup> The provision was not identical to NUFA, however it did operate to preempt states from establishing or enforcing laws regarding food safety that were not identical to national standards.<sup>65</sup> The 1996 bill was referred to the House Committee on Commerce, and hearings were conducted by the Subcommittee on Health and the Environment.<sup>66</sup> The hearings lasted two days and discussed many topics, including the need for uniformity in nutrition and warning labels.<sup>67</sup> After the hearings occurred, no further action was taken on the bill.<sup>68</sup>

On July 27, 1998, the National Uniformity for Food Act of 1998 (“NUFA 1998”) was introduced in the Senate.<sup>69</sup> Senator Tom Harkin highlighted two primary reasons why the bill should be enacted.<sup>70</sup> The first and perhaps the most apparent reason, according

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

<sup>62</sup> *Id.* at § 403B(a)(3).

<sup>63</sup> Food Amendments & the Animal Drug Availability Act of 1996, H.R. 3200 104th Cong. § 108 (1996); National Uniformity for Food Act of 1998, H.R. 4383, S. 2356 105th Cong. (1998); National Uniformity for Food Act of 2000, S. 1155, 107th Cong. (2000).

<sup>64</sup> 104 CONG. REC. H5632 (daily ed. May 29, 1996).

<sup>65</sup> H.R. 3200, 104th Cong. § 108D (1996).

<sup>66</sup> H.R. 3200, 104th Cong. (1996).

<sup>67</sup> *See* 104 CONG. REC. H5632 (daily ed. May 29, 1996).

<sup>68</sup> H.R. 3200, 104th Cong. (1996).

<sup>69</sup> 144 CONG. REC. S9044-02 (daily ed. July 27, 1998).

<sup>70</sup> *Id.*

to Senator Harkin, was the economic burden associated with complying with different and perhaps conflicting state requirements.<sup>71</sup> He also said that the varying labeling requirements could confuse consumers and hinder their ability to make sound purchasing decisions.<sup>72</sup> After its introduction in the Senate, the bill was read twice and referred to the Committee on Labor and Human Resources.<sup>73</sup> No further action was taken by the Senate. A companion bill was introduced in the House by Representative Richard Burr on August 3, 1998.<sup>74</sup> The bill was referred to the House Committee on Commerce on the day it was introduced, but no further action was taken by the House.<sup>75</sup>

The legislation was reintroduced in 1999 as the National Uniformity for Food Act of 1999 ("NUFA 1999").<sup>76</sup> Senator Pat Roberts, who also sponsored NUFA 1998, reintroduced the bill in the Senate on May 27, 1999.<sup>77</sup> The bill was referred to the Senate Committee on Agriculture, Nutrition, and Forestry and was reported by the Committee on October 17, 2000.<sup>78</sup> The proposed bill drew skepticism. Eleven Senators sent a letter to President Clinton urging him to reject the bill.<sup>79</sup> One of the Senators' primary concerns was that "[n]o hearings have been held on this far reaching legislation that would repeal important state and local food safety and labeling laws and drastically limit the ability of state and local governments to enact new laws to protect its citizens."<sup>80</sup> The letter continued to state that both the Reagan and the George H.W. Bush administrations

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<sup>71</sup> 144 CONG. REC. S9044-02 (daily ed. July 27, 1998).

<sup>72</sup> *Id.*

<sup>73</sup> S. 2356, 105th Cong. (1998).

<sup>74</sup> H.R. 4383, 105th Cong. (1998). Rep. Richard Burr also introduced NUFA, H.R. 2699.

<sup>75</sup> 144 CONG. REC. H6999-02 (daily ed. Aug. 3, 1998).

<sup>76</sup> S. 1155, 106th Cong. (2000). The name of the bill was revised to the National Uniformity for Food Act of 2000 when it was reported by the Senate Committee on Agriculture, Nutrition, and Forestry in 2000. *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> Letter from Barbara Boxer, United States Senator, et. al., to Bill Clinton, United States President (Oct. 26, 2000) (on file with author).

<sup>80</sup> *Id.*

opposed nearly identical legislation in the past.<sup>81</sup>

The Center for Science in the Public Interest (“CSPI”), an advocate for nutrition and health, food safety, alcohol policy, and sound science, also opposed NUFA 1999.<sup>82</sup> In a press release, the Director for Legal Affairs for the agency, said “[t]hese bills do nothing to improve food safety . . . [t]he legislation merely sets up a mechanism for the food industry to pressure the FDA to void state consumer protection laws . . . .”<sup>83</sup> The press release also questioned the process by which the bill was reported: “[w]ithout any hearings and on one day’s notice the committee passed a bill that could create a safety vacuum.”<sup>84</sup>

## IV. Benefits of NUFA

### A. A Move Towards Uniformity

Many see NUFA as the next logical step in an effort to provide uniformity in food safety laws.<sup>85</sup> The laws enacting the nation’s food safety system were developed independently of one another, each enacted in response to a specific health concern.<sup>86</sup> The result is a distribution of authority across multiple government agencies accountable for various food safety responsibilities.<sup>87</sup> There are “[a]s many as twelve different agencies . . . responsible for administering more than thirty-five food safety laws.”<sup>88</sup> In addition, there are more than fifty interagency agreements that govern food safety oversight responsibilities, as well as each state’s own statutes, regulations, and agencies.<sup>89</sup>

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<sup>81</sup> *Id.*

<sup>82</sup> Press Release, Center for Science in the Public Interest, Senate Committee Approves Bill That Could Void State Food Safety Laws (June 30, 2000), *available at* [http://www.cspinet.org/new/fs\\_lawsvoid.html](http://www.cspinet.org/new/fs_lawsvoid.html) (last visited May 10, 2005).

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> H.R. REP. NO. 108-770, at 5.

<sup>86</sup> *A System Rued*, *supra* note 8.

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

<sup>88</sup> NAT’L COMMISS’N ON THE PUB. SERV., URGENT BUSINESS FOR AMERICA, REVITALIZING THE FEDERAL GOVERNMENT FOR THE 21ST CENTURY 15 (2003).

<sup>89</sup> United States General Accounting Office (“GAO”), FEDERAL FOOD SAFETY

House Representative Jo Ann Davis, chairwoman of the Subcommittee on Civil Service and Agency Organization, highlighted some of the irregularities in the current food inspection system: “the FDA is in charge of cheese pizzas while the USDA has jurisdiction over pepperoni pizzas . . . . FDA inspects both beef soup and chicken broth—but USDA inspects chicken soup and beef broth.”<sup>90</sup> Critics of the current system argue that this patchwork system hampers efforts to adequately address existing and emerging food safety risks.<sup>91</sup>

Several government committees and task forces have reviewed the nation’s existing food safety infrastructure. Most of the reports noted areas of duplication and overlap within the system.<sup>92</sup> One report stated that the “nation’s food safety system suffers from inconsistent oversight, poor coordination, and inefficient use of staff,”<sup>93</sup> and that the fragmented food safety programs were one of the most serious management problems within the USDA.<sup>94</sup> The report continued to state that the USDA has reduced its oversight of meat and poultry below what is prudent and necessary to protect consumers.<sup>95</sup> Another report stated that the inconsistencies and inefficiencies in government oversight result in “an unacceptable level of public health protection.”<sup>96</sup>

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AND SECURITY SYSTEM, FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP 2 (Mar. 30, 2004), *available at* <http://www.gao.gov/new.items/d04588t.pdf> (last visited May 10, 2005).

<sup>90</sup> *A System Rued*, *supra* note 8 (opening statement of Jo Ann Davis, chairwoman), *available at* <http://reform.house.gov/UploadedFiles/JAD%20Opening%20Statement.pdf> (last visited May 10, 2005).

<sup>91</sup> *A System Rued*, *supra* note 8.

<sup>92</sup> NAT’L COMMISS’N ON THE PUB. SERV., URGENT BUSINESS FOR AMERICA, REVITALIZING THE FEDERAL GOVERNMENT FOR THE 21ST CENTURY 15 (Jan. 2003).

<sup>93</sup> COMM. ON GOV’TL AFFAIRS, GOVERNMENT AT THE BRINK, AN AGENCY BY AGENCY EXAMINATION OF FEDERAL GOVERNMENT MANAGEMENT PROBLEMS FACING THE BUSH ADMINISTRATION, Vol. I, 20 (June, 2001), *available at* [http://hsgac.senate.gov/\\_files/thompsongovrpt01vol1.pdf](http://hsgac.senate.gov/_files/thompsongovrpt01vol1.pdf) (last visited May 10, 2005).

<sup>94</sup> COMM. ON GOV’TL AFFAIRS, GOVERNMENT AT THE BRINK VOL. II AN AGENCY BY AGENCY EXAMINATION OF FEDERAL GOVERNMENT MANAGEMENT PROBLEMS FACING THE BUSH ADMINISTRATION, Vol. II, 6 (June, 2001), *available at* [http://hsgac.senate.gov/\\_files/thompsongovrpt01vol2.pdf](http://hsgac.senate.gov/_files/thompsongovrpt01vol2.pdf).

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

<sup>96</sup> NAT’L COMMISS’N ON THE PUB. SERV., *supra* note 92, at 15 (footnote

While all the reports and hearings acknowledged that the current system could be improved, the solutions varied. A 2004 study by the General Accounting Office (“GAO”) recommended that Congress establish a single, independent food safety agency and enact comprehensive, uniform, and risk-based food safety legislation.<sup>97</sup> However, others agencies, such as the HHS, do not think that a single food agency is the answer.<sup>98</sup> While the HHS admits there are challenges with the existing system, it contends that the current food system is stronger than ever due to enhancements made by the FDA and other agencies and the close coordination between the governmental agencies.<sup>99</sup>

The committees and reports, however, rarely address food warning labels. For example, the GAO report only discussed labels in one section which mentioned that health benefits claims may be treated inconsistently by different federal agencies.<sup>100</sup> Additionally, the hearings conducted by the Committee of Government Reform dealt solely with the food inspection system.<sup>101</sup> The only hearings that have discussed food warning labels in any detail were the hearings for the Food Amendment and the Animal Drug Availability Act of 1996.<sup>102</sup>

## **B. Reducing the Cost of Food Labels**

Another benefit of NUFA is that it will reduce manufacturers’

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omitted).

<sup>97</sup> GAO, *supra* note 89, at 1-2, 19. The Subcommittee on Oversight and Government Management requested that the GAO review and critique the existing fragmented food safety system and provide options for consolidating the system. *Id.* at 2.

<sup>98</sup> *Hearing Before Subcommittee on Civil Service and Agency Organization: House Committee on Government Reform*, 108th Cong. 1 (2004) (statement of Robert E. Brackett, Dir. Ctr. For Food Safety & Applied Nutrition, FDA), *available at* [http://reform.house.gov/UploadedFiles/Brackett\\_FDA.pdf](http://reform.house.gov/UploadedFiles/Brackett_FDA.pdf).

<sup>99</sup> *Id.* at 1-2.

<sup>100</sup> United States General Accounting Office, FEDERAL FOOD SAFETY AND SECURITY SYSTEM, FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP 2 (Mar. 30, 2004), *available at* <http://www.gao.gov/new.items/d04588t.pdf>.

<sup>101</sup> *A System Rued*, *supra* note 8.

<sup>102</sup> 142 CONG. REC. H5634 (daily ed. May 29, 1996). The 1996 hearings will be discussed in Part V.C.

and distributors' labeling costs.<sup>103</sup> Supporters of NUFA argue that the conflicting labeling and notification requirements between the states result in increased cost to manufacturers and distributors which are then passed on to consumers.<sup>104</sup> If the manufacturers' and distributors' labeling costs are reduced, then, theoretically, a portion of this savings would be passed on to consumers.

The challenge that businesses face in conforming to multiple nutrition labels was discussed during the hearings for the Food Amendments and the Animal Drug Availability Act of 1996.<sup>105</sup> Supporters argued that businesses could not afford to do business if every state, municipality, and community passed their own labeling standards.<sup>106</sup>

### C. Avoiding Consumer Confusion

Supporters of the NUFA also contend that uniformity in labeling would benefit all consumers by providing the same, clear labeling throughout the nation.<sup>107</sup> The existing system has a multitude of different labeling requirements which supporters argue can confuse consumers and hinder their ability to make sound purchasing decisions.<sup>108</sup> In addition, consumers could be misled regarding the dangers, or lack thereof, of certain food products.<sup>109</sup>

A 2000 study conducted on Proposition 65,<sup>110</sup> a California consumer protection law that requires warning labels for hundreds of different chemical agents, claimed that the bill "lists hundreds of purported carcinogens and reproductive hazards, most of which are not known to be associated with adverse health effects in humans."<sup>111</sup> The study suggested that the expansive scope of the bill "decreases

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<sup>103</sup> H.R. REP. NO. 108-770, at 5.

<sup>104</sup> *Id.*

<sup>105</sup> 104 CONG. REC. H5635 (daily ed. May 29, 1996).

<sup>106</sup> *Id.*

<sup>107</sup> Press Release, Int'l Dairy Foods Ass'n, News Center, House Committee Passes "National Uniformity" Bill of Food Safety Labeling (Oct. 4, 2004).

<sup>108</sup> 144 CONG. REC. S9044-02 (daily ed. July 27, 1998).

<sup>109</sup> *Id.*

<sup>110</sup> *See infra* Part V.A.ii (discussing California's Proposition 65).

<sup>111</sup> AM. COUNS. ON SCI. AND HEALTH, CALIFORNIA'S PROPOSITION 65 AND ITS IMPACT ON PUBLIC HEALTH, at 23 (Dec. 2000), available at [http://www.acsh.org/docLib/20040329\\_prop65.pdf](http://www.acsh.org/docLib/20040329_prop65.pdf) (lasted visited May 10, 2005).

the effectiveness of the message of known health risks and diverts attention from non-chemical lifestyle risk factors . . . that are associated with human cancer.”<sup>112</sup>

## V. Concerns about NUFA

### A. Preempting State Laws

One of the major concerns about NUFA is that it preempts all state and local food safety laws.<sup>113</sup> Opponents of NUFA argue that it recklessly eliminates the great bulk of state and local food safety laws, and that preempting and invalidating state and local food safety and security activities will lead to serious ramifications that will be difficult—if not impossible—for the nation to reverse.<sup>114</sup> Supporters contend that food safety issues unique to a particular state are not automatically preempted but can be addressed through NUFA’s petition process.<sup>115</sup> If a potential risk has been identified, the national standard petition process will allow the FDA to determine whether a national standard is required to protect consumers in all states.<sup>116</sup>

The Congressional Budget Office estimated that laws in over thirty states would be affected by NUFA.<sup>117</sup> Opponents list examples such as shellfish warning labels in California, Louisiana, and Florida; smoked fish regulations in Wisconsin and Michigan; minimum nutritional requirements for grits sold in Alabama; and numerous Florida laws regulating the labeling of citrus fruits and juices.<sup>118</sup> These laws, and others, may be preempted if NUFA is enacted and an exemption or new national standard is not created.

### B. Shellfish Regulations

According to the California Department of Health Services,

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<sup>112</sup> *Id.*

<sup>113</sup> H.R. 2699, 108th Cong. 2d Sess. § 403B(a)(1).

<sup>114</sup> *Hearings, supra* note 36, at 55 (statement of Douglas R. Saunders, Chair, Assoc. of Food and Drug Officials).

<sup>115</sup> *See* Part III.A., *infra*, for a discussion of the petition process for NUFA exemptions and new national standards.

<sup>116</sup> H.R. REP. NO. 108-770, at 5.

<sup>117</sup> *Id.* at 10-11.

<sup>118</sup> *Id.* at 22-23.

every year California citizens become seriously ill and die after consuming raw oysters harvested from the states bordering the Gulf of Mexico (Alabama, Florida, Louisiana, Mississippi, and Texas).<sup>119</sup> The Department has recorded seventy-five illnesses since 1983, and forty-nine deaths that have been associated with the consumption of raw oysters.<sup>120</sup> In order to address this problem, California has enacted strict regulations controlling the harvesting and sale of raw oysters.<sup>121</sup> Retailers are required, in part, to provide a written warning in English and Spanish to any person who orders or buys raw Gulf oysters.<sup>122</sup> If NUFA is enacted this regulation would be preempted. NUFA governs not only labels but “labeling, poster, public notice, advertising, or any other means of communications[.]”<sup>123</sup> Similar laws in Louisiana and Florida regulating the sale of shellfish would also be preempted.<sup>124</sup>

### C. Proposition 65

Another state law that would be preempted if NUFA is enacted is California’s Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986.<sup>125</sup> The act provides that “[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving *clear and reasonable warning* to such individual[.]”<sup>126</sup> The act requires that the governor of California revise and republish the list of chemicals known to the state to cause cancer or reproductive toxicity at least once a year.<sup>127</sup> The list was recently updated on December 31, 2004, and contains approximately

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<sup>119</sup> Memorandum from the State of California’s Department of Health Services to California Food Retailers (Apr. 15, 2003), *available at* <http://www.lapublichealth.org/eh/special/oyster/indnote.pdf>.

<sup>120</sup> *Id.*

<sup>121</sup> CAL. CODE REGS. tit. 17, § 13675 (2003).

<sup>122</sup> *Id.* at § 13675(b)(1).

<sup>123</sup> H.R. 2699, 108th Cong. 2d Sess. § 403B(a)(2)(A).

<sup>124</sup> LA. REV. STAT. ANN. § 40:5:3 (West 1982); FLA. ADMIN. CODE ANN. r. 5L-1.004 (1965).

<sup>125</sup> CAL. HEALTH & SAFETY CODE §§ 25249.5 – 25249.13 (West 1986).

<sup>126</sup> *Id.* § 25249.6 (emphasis added).

<sup>127</sup> *Id.* § 25249.8(a).

seventeen pages of chemicals known to cause cancer or reproductive toxicity.<sup>128</sup> Once a chemical is added to the list, food producers have one year to comply with the warning requirements under Proposition 65.<sup>129</sup> California's Office of Environmental Health and Hazard Assessment has developed safe harbor levels for each chemical on the list.<sup>130</sup> Notice is only required if the exposure exceeds the safe harbor amount, which is measured in micrograms per day.<sup>131</sup>

Proposition 65 has generated mixed reviews. The California Attorney General reported that the bill has been a useful supplement to federal standards<sup>132</sup> and California senators have stated that "Proposition 65 has successfully reduced toxic contaminants in a number of consumer products sold in California . . ."<sup>133</sup> Others have been critical of the bill. A 2000 study by the American Council on Science and Health found that there are no mechanisms for evaluating the effectiveness of Proposition 65, and that, to date, there is no evidence that Proposition 65 has been effective in reducing the incidence of cancer or adverse reproductive effects among California citizens.<sup>134</sup>

Other states, including Massachusetts and Connecticut, have considered enacting legislation modeled after California's Proposition 65, but to date no similar bill has been enacted.<sup>135</sup> During

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<sup>128</sup> CAL. EPA, OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY (Dec. 31, 2004), available at <http://www.oehha.ca.gov/prop65/pdf/P65single123104.pdf>.

<sup>129</sup> CAL. HEALTH & SAFETY CODE § 25249.10(b).

<sup>130</sup> CAL. EPA, OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, PROPOSITION 65 STATUS REPORT SAFE HARBOR LEVELS: NO SIGNIFICANT RISK LEVELS FOR CARCINOGENS AND MAXIMUM ALLOWABLE DOSE LEVELS FOR CHEMICALS CAUSING REPRODUCTIVE TOXICITY (Jan. 2005), available at <http://www.oehha.ca.gov/prop65/pdf/Jan2005StatusReport.pdf> (last visited May 10, 2005).

<sup>131</sup> *Id.*

<sup>132</sup> H.R. REP. NO. 108-770, at 23.

<sup>133</sup> 143 CONG. REC. S9811-04, S9843 (daily ed. Sept. 24, 1977).

<sup>134</sup> AM. COUNS. ON SCI. AND HEALTH, *supra* note 111, at 29.

<sup>135</sup> Mass. Citizen's Right to Know Act, H.B. 3129 (1999), Conn. Warning Label Legislation, S.B. 433 (2000), S.B. 1030 (2001). One perceived problem with Proposition 65 is that actions can be brought by any person in the public interest if a notice requirement is met and the Attorney General, district attorney, city attorney, or prosecutor is not already prosecuting the action. CAL. HEALTH &

2001 hearings on the proposed Connecticut bill opponents argued that there were significant flaws with the California law which was why no other states had adopted a similar legislation.<sup>136</sup>

Proposition 65 may have been a factor in drafting NUFA, the House Report that accompanied the bill stated that “[t]he proponents of the bill concede that one of its primary purpose is to pre-empt a specific California law, known as Proposition 65.”<sup>137</sup>

#### D. Other Examples

Other laws that may be preempted if NUFA is enacted are state laws regulating issues unique to the state’s food supply. Michigan and Wisconsin have enacted regulations controlling the sale of smoked fish.<sup>138</sup> The provisions mandate specific labeling requirements that must be included on the packaging of smoked fish.<sup>139</sup> Wisconsin has also passed a statute requiring specific information on the labels of cheese manufactured in the state.<sup>140</sup>

The Florida Citrus Code is another statute that would be affected if NUFA is enacted.<sup>141</sup> This detailed act was passed to stabilize and protect the citrus industry of Florida, its major agriculture enterprise.<sup>142</sup> The act established the Florida Department of Citrus, and authorized the Department to adopt, alter, modify or amend all rules, regulations, and orders as necessary for the exercise of its powers.<sup>143</sup> If NUFA is enacted, Florida’s Citrus Code may be preempted or reduced in scope unless an exemption is granted.

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SAFETY CODE § 25249.7(d).

<sup>136</sup> *Public Hearings on S.B. 1030 Before the Public Health Comm.* 2001 Reg. Season (Conn. Mar. 15, 2001), at 232.

<sup>137</sup> H.R. REP. NO. 108-770, at 23.

<sup>138</sup> MICH. ADMIN. CODE r. 285.569.10 (1997), WIS. ADMIN. CODE § 70.22 (1996).

<sup>139</sup> MICH. ADMIN. CODE r. 285.569.10; WIS. ADMIN. CODE § 70.22. One of these warnings, a freshness label, would be unaffected by NUFA because the act specifically exempts state laws dealing with freshness labeling. *See* H.R. 2699, 108th Cong. 2d Sess. § 403B(g) (authorizing the states to continue to enforce certain laws including freshness dating).

<sup>140</sup> WIS. STAT. § 97.177 (1983).

<sup>141</sup> FLA. STAT. ch. § 601.01 (1949).

<sup>142</sup> FLA. STAT. ch. § 601.02.

<sup>143</sup> FLA. STAT. ch. § 601.10.

### E. Bioterrorism Threats Caused by State Law Preemption

Some state officials have warned that NUFA may jeopardize the states' ability to respond to bioterrorist threats by preempting certain state laws.<sup>144</sup> Douglas R. Saunders, Chair of AFDO, raised this concern during the House Subcommittee on Health's Hearing on the Implementation of Food Security Provisions of the Public Health Security & Bioterrorism Preparedness and Response Act on June 25, 2004.<sup>145</sup> Mr. Saunders stated that

[o]ur current food safety and security system will be significantly disrupted for many years to come, and our inability to tract suspected acts of intentional adulteration will be exploited by those who seek to do harm to the nation. Passage of H.R. 2699, in its current form . . . will effectively eliminate the nation's food biosecurity shields, and will undermine our whole food safety and biosurveillance capability.<sup>146</sup>

This concern comes at a time when the security of our existing system has already been called into question. Just prior to leaving office, Tommy Thompson, former Secretary of the HHS, stated that he was surprised that terrorist had not yet attacked the nation's food supply:<sup>147</sup> "[f]or the life of me, I cannot understand why the terrorists have not attacked our food supply because it is so easy to do . . ."<sup>148</sup> The National Association of State Departments of Agriculture, which opposes NUFA, has said "it is inconceivable that the committee would consider radically altering the existing food safety system at a time when many experts agree our food supply is vulnerable."<sup>149</sup>

Supporters of NUFA do not see it as a threat to food security stating "[t]o the extent that the uniformity legislation has any bearing of food security, it will help enhance food security . . ."<sup>150</sup> In

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<sup>144</sup> *Hearings, supra* note 36, at 50 (statement of Douglas R. Saunders).

<sup>145</sup> *Id.* at 46.

<sup>146</sup> *Id.* at 50.

<sup>147</sup> ASSOC. PRESS, *Thompson Resigns From Bush's Cabinet*, (Dec. 3, 2004), available at <http://abcnews.go.com/Politics/wireStory?id=301259>.

<sup>148</sup> *Id.*

<sup>149</sup> H.R. REP. NO. 108-770, at 21-22.

<sup>150</sup> *Hearings, supra* note 36, at 67 (statement of Susan M. Stout, V.P of Fed.

addition, supporters argue that the Imminent Hazard Authority will give states the power to deal with bioterrorist threats and other emergencies.<sup>151</sup> Opponents contend, however, that the Imminent Hazard Authority is burdensome and impractical.<sup>152</sup>

[The] provision . . . requires the state facing an emergency to first enact a requirement . . . that would address the problem, [then] notify the federal government about the situation and then make a determination about whether the federal government is going to act on the threat. This is an unrealistic approach for addressing a true emergency.<sup>153</sup>

Furthermore, the Imminent Hazard Authority is only available if the threat is likely to result in serious adverse health consequences or death.<sup>154</sup> Opponents argue this is a very high standard to meet in ordinary food situations, and that the Imminent Hazard Authority is not the answer to most of the food safety problems a state or local government encounters on a daily basis.<sup>155</sup>

## VI. Implementing NUFA

Another area of debate is whether the FDA has adequate funding and resources to implement and run NUFA. Even those who support the idea of food safety consolidation recognize the challenges involved in implementing wide-spread reorganization.<sup>156</sup> Some supporters conclude that it would be nearly impossible to accomplish this type of change in the foreseeable future.<sup>157</sup>

### A. Budgetary Concerns

The Congressional Budget Office estimates that implementing NUFA would cost \$11 million in 2005 and a total of \$106 million

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Affairs, GMA).

<sup>151</sup> H.R. REP. NO. 108-770, at 22.

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

<sup>153</sup> *Id.*

<sup>154</sup> H.R. 2699, 108th Cong., 2d Sess. § 403B(d)(1)(A).

<sup>155</sup> H.R. REP. NO. 108-770, at 22.

<sup>156</sup> *Hearings, supra* note 36, at 1 (statement of Dan Glickman, former Sec'y of Agric.) available at [http://reform.house.gov/UploadedFiles/Glickman\\_IOP.pdf](http://reform.house.gov/UploadedFiles/Glickman_IOP.pdf).

<sup>157</sup> *Id.*

between 2005 to 2009—an estimate which includes an average of about one million dollars for each petition for a new national standard.<sup>158</sup> The estimate also stated that the costs would be incurred by the FDA.<sup>159</sup> Opponents of NUFA are estimating the costs to be even higher. AFDO has estimated that the “cost to the FDA to replace the infrastructure and food safety and security activities currently accomplished at the State and Local level[s] to exceed \$500 million.”<sup>160</sup> The estimate focuses on the massive scope of the restructuring: “if the States and localities lose their authority to enforce their laws and regulations, particularly with respect to adulteration . . . then the Federal Government is in a position where they may have to pick that amount of work up.”<sup>161</sup>

### **B. Lack of Resources**

Another concern is whether the FDA has the resources to implement and run the NUFA. In response to NUFA 1999, HHS stated that the legislation would be a new burden on already limited resources.<sup>162</sup> HHS also questioned the petition review process by stating that the process would require HHS to make determinations as to whether a requirement would unduly burden interstate commerce, an area that is outside the HSS’ expertise.<sup>163</sup>

### **C. Lack of Hearings**

Another area of particular concern is that NUFA was reported out of the Committee on Energy and Commerce without conducting a single hearing. Opponents argue that

[t]he implications of this bill are vast, yet no hearings have ever been held . . . and certainly no examination of the consequences of the bill since the escalation of the bioterrorist threat. We owe it to the American people to

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<sup>158</sup> H.R. REP. NO. 108-770, at 9, 11.

<sup>159</sup> *Id.* at 9.

<sup>160</sup> *Hearings, supra* note 36, at 50.

<sup>161</sup> *Id.* at 58.

<sup>162</sup> Letter from Donna E. Shalala, Sec. Of U.S. Dept. of Health and Human Servs., to Hon. Richard Lugar, Chairman Comm. on Agric., Nutrition, and Forestry (Sept. 28, 2000) (on file with author).

<sup>163</sup> *Id.*

carefully consider the consequences of such a sweeping bill, and certainly not to rush it through the legislative process at the end of session.<sup>164</sup>

A similar argument was raised with NUFA 1999, which was also reported without any hearings.<sup>165</sup> Donna Shalala, former Secretary of the HHS, shared her concern over the bill in a letter to the chairman of the Senate Committee on Agriculture, Nutrition, and Forestry, stating that "HHS has concerns about the legislation and believes its implications need to be reviewed throughout the Congressional hearing process."<sup>166</sup> The lack of hearings was also included in a letter sent to President Clinton by eleven senators who opposed NUFA 1999.<sup>167</sup>

While NUFA 1998 was never reported by a Senate or House Committee, it appears that the supporters initially welcomed conducting hearings on the bill.<sup>168</sup> One of the senators who introduced the bill said "[t]he bill being introduced today is a sound starting point for further discussion and study, and for hearings that I hope can be scheduled soon. I am sure that during this process issues and considerations will arise that will need to be addressed in the legislation."<sup>169</sup>

Hearings were held in 1996 with the Food Amendment and the Animal Drug Availability Act of 1996.<sup>170</sup> While the hearings were primarily regarding pharmaceuticals they also discussed the need for uniformity in both nutrition labeling and warning labels.<sup>171</sup>

The House Report accompanying NUFA did not elaborate why hearings were not held. The Report simply stated "The Committee of Energy and Commerce has not held hearings on the legislation."<sup>172</sup> Opponents of NUFA tried to voice their concerns regarding the bill during another hearing before the Committee on

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<sup>164</sup> H.R. REP. NO. 108-770, at 23.

<sup>165</sup> S. 1155, 106th Cong. (2000).

<sup>166</sup> Shalala, *supra* note 162, at 1.

<sup>167</sup> See Boxer, *supra* note 79 (stating "[n]o hearings have been held on this far reaching legislation . . .").

<sup>168</sup> 144 CONG. REC. S9044-02 (daily ed. July 27, 1998).

<sup>169</sup> *Id.*

<sup>170</sup> 104 CONG. REC. H5632 (daily ed. May 29, 1996).

<sup>171</sup> *Id.*

<sup>172</sup> H.R. REP. NO. 108-770, at 6.

Energy and Commerce's Subcommittee on Health.<sup>173</sup> NUFA supporters attending the hearing also shared their opinions of the bill. John Cady, President and CEO of the National Food Processors Association responded that "[f]rom the National Processors' perspective, we have reviewed the legislation pretty in depth. And we don't see the concerns that AFDO has expressed on that particular part of the issue, on that particular part of the bill."<sup>174</sup> The Grocery Manufacturers of America ("GMA") the world's largest association of food, beverage, and consumer product companies also supported the bill. The Vice President of Federal Affairs of the GMA stated that NUFA "does not have any effect at all on any State food inspection programs. It does not have any effect on any enforcement authorities

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<sup>173</sup> *Hearings, supra* note 36, at 57-58. The transcript of the relevant testimony reads, in part:

Mrs. Capps. . . . And according to your testimony, Mr. Saunders, the . . . 2699 would have quite an impact on State food and safety regulations and even on the nation's efforts to secure our food supply . . . In my home State of California, as you may well be aware, we have very vigorous food safety and labeling laws which leads me to be very concerned about this legislation, and from your testimony, it sounds like this bill, if enacted into law, would really gut California safety laws. Is that true? And would you comment briefly?

Mr. Saunders. AFDO has been following that legislation for quite some time, and we have done an awful lot with respect to trying to educate States and localities about the language in that legislation . . . . We have had numerous States—and I believe the most recent count there were 12 . . . that have had their attorneys look at the legislation. [a]nd they have all agreed that there are some very gray areas in that legislation that could have a very negative impact on these States and localities ability to operate effective food safety and security programs.

. . . .

Mrs. Capps. . . . But let me understand, that you see a direct connection to our terrorism readiness—I mean, this bill is about security. And if we enacted the law, this bill into law, and didn't make up for the cost, then we would be jeopardizing the national security in food safety.

Mr. Saunders. Yes, ma'am.

Mrs. Capps. I am going yield to the chairman.

Mr. Bilirakis. Let me just ask, Mr. Saunders, have you made an effort to communicate with the authors of that legislation.

Mr. Saunders. Yes, sir.

<sup>174</sup> *Id.* at 58 (testimony of John Cady, President and CEO of the National Food Processors Association).

enjoyed by the Federal, State or local [governments].”<sup>175</sup>

While the members of the Subcommittee on Health listened to the debate, the Chairman of the committee ultimately concluded that NUFA “is a separate piece of legislation. It will be subject to hearings. We will have the opportunity to go into the pros and cons and that sort of thing. I don’t think we need to go any further.”<sup>176</sup> But, as of yet, there have been no hearings on NUFA, and less than four months after this discussion, on October 8, 2004, NUFA was reported out of the Committee on Energy and Commerce, which never conducted a single hearing.<sup>177</sup>

#### D. Special Interest Influence on NUFA

Another question that should be raised, but is nearly impossible to answer, is what role, if any, did special interests groups have in the development and progression of NUFA? Opponents of the bill argue that special interest groups had a substantial role in the progression of the NUFA.<sup>178</sup> CSPI stated in a press release that “[i]n leading the charge for the food industry, Representative Burr is sabotaging the work of state health authorities, who are on the front lines of fighting food-borne illnesses.”<sup>179</sup>

According to documents filed with the Federal Election Commission, GMA has spent a total of \$130,500 on disbursements to federal candidates and committees in 2002 and \$134,596 in 2004.<sup>180</sup> And according to the Center for Responsive Politics, the Food Processing and Sales Political Action Committees<sup>181</sup> have contributed

<sup>175</sup> *Hearings*, *supra* note 36, at 59 (testimony of Susan Stout, VP Fed. Affairs of GMA).

<sup>176</sup> *Id.*

<sup>177</sup> H.R. REP. NO. 108-770, at 6.

<sup>178</sup> Press Release, Center for Sci. in the Public Int., House Comm. To Try to Nullify State Food Safety Laws (Sept. 30, 2004), *available at* <http://www.cspinet.org/new/200409302.html>.

<sup>179</sup> *Id.*

<sup>180</sup> FEDERAL ELECTION COMMISSION 2003–2004 Cycle, Grocery Manufacturers of America Inc. Political Action Committee, *available at* [http://herndon1.sdrdc.com/cgi-bin/cancomsrs/?\\_04+C00250068](http://herndon1.sdrdc.com/cgi-bin/cancomsrs/?_04+C00250068) (last visited Apr. 5, 2005), 2001–2002 Cycle, *available at* [http://herndon1.sdrdc.com/cgi-bin/cancomsrs/?\\_02+C00250068](http://herndon1.sdrdc.com/cgi-bin/cancomsrs/?_02+C00250068) (last visited May 10, 2005).

<sup>181</sup> “Political Action Committee (PAC)—A popular term for a political committee organized for the purpose of raising and spending money to elect and

a total of \$2,679,951 to federal candidates in 2004.<sup>182</sup> Expanding the industry further to Agribusiness,<sup>183</sup> Political Action Committees has contributed a total of \$17,202,451 to federal candidates in 2004.<sup>184</sup> While these figures are not specific to NUFA, they demonstrate that the food industry is a significant lobbying force in Congress.

### E. Misallocation of Government Resources

The efforts that Congress has taken to evaluate the nation's food safety system appear to be as disjointed as the food safety system itself. Some committees have been tasked with evaluating the food safety system as a whole,<sup>185</sup> while others have addressed individual aspects of the food safety system, such as the food inspection process and uniformity in labeling.<sup>186</sup> Moreover, it appears that no single agency has been charged with overseeing or consolidating the individual results or findings. Such a process seems problematic in reviewing a system as deeply integrated as the nation's food safety system, where one change may have unforeseen ramifications on another aspect of the system.

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defeat candidates. Most PACs represent business, labor or ideological interests." CTR. FOR RESPONSIVE POLITICS, *What is a PAC?*, available at <http://www.opensecrets.org/pacs/pacfaq.asp> (last visited May 10, 2005).

<sup>182</sup> CTR. FOR RESPONSIVE POLITICS, FOOD PROCESSING AND SALES 2003-2004 PAC CONTRIBUTIONS (based on data released from the Fed. Election Commission on Feb. 7, 2005), available at <http://www.opensecrets.org/pacs/industry.asp?txt=A09&cycle=2004> (last visited May 10, 2005).

<sup>183</sup> Agribusiness includes crop production and basic processing, tobacco, dairy, poultry and eggs, livestock, agricultural services/products, food processing and sales, and forestry and forest products. CTR. FOR RESPONSIVE POLITICS, AGRIBUSINESS 2003-2004 PAC CONTRIBUTIONS, available at <http://www.opensecrets.org/pacs/sector.asp?txt=A09&cycle=2004> (last visited May 10, 2005).

<sup>184</sup> CTR. FOR RESPONSIVE POLITICS, AGRIBUSINESS 2003-2004 PAC CONTRIBUTIONS (based on data released from the Fed. Election Commission on Mar. 28, 2005), available at <http://www.opensecrets.org/pacs/sector.asp?txt=A09&cycle=2004> (last visited May 10, 2005).

<sup>185</sup> *Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap: Hearing before Subcommittee on Civil Service and Agency Organization*, 108th Cong. 1-2 (2004).

<sup>186</sup> See *A System Rued*, *supra* note 8 (examining only the food inspection process); see *infra* Part III (discussing the National Uniformity for Food Legislation regulation of only food warning labels).

Furthermore, there appears to be inefficiencies in how the NUFA bills are being reviewed in Congress. The bills have not been referred to the same committee for review and potential referral.<sup>187</sup> Two different Senate committees have received the bill but neither held any hearings.<sup>188</sup> The House has been more consistent as all the NUFA bills were referred to the House Committee on Energy and Commerce.<sup>189</sup> Referring the bill to new committees seems redundant and inefficient. The new committee may not be aware of the entire history of the bill or any steps taken by the prior committee.

## F. Constitutional Concerns

Another question that has been raised is what are the federal and state governments' limits in regulating food safety—where does one's authority end and the others' begin? Some argue that expansive state food safety laws, such as California's Proposition 65, interfere with interstate commerce and could potentially be declared unconstitutional or drastically reduced in scope.<sup>190</sup> Others argue that acts like Proposition 65 are valid public health and safety measures that protect the citizens of the state and do not unreasonably impinge on interstate commerce.<sup>191</sup>

In addition, another constitutional question arises when there are conflicting federal and state requirements. The California Supreme Court held in 2004 that a FDA warning on a nicotine replacement therapy product pre-empted a Proposition 65 warning.<sup>192</sup> The court held that "the FDA has authority to prohibit use of the Proposition 65 warning, even though the warning is literally truthful, if the FDA concludes that it would have the effect of misleading

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<sup>187</sup> NUFA 1998 was referred to the Senate Committee on Labor and Human Resources. S. 2356, 105th Cong. (1998). NUFA 1999 was referred to the Senate Committee on Agriculture, Nutrition, and Forestry. S. 1155, 106th Cong. (2000).

<sup>188</sup> See *supra* note 187.

<sup>189</sup> H.R. 2699, 108th Cong. (2004), H.R. 4383, 105th Cong. (1998), H.R. 3200 § 108, 104th Cong. (1996).

<sup>190</sup> *FDA Restructuring: Hearing Before the Senate Labor and Human Resources Committee*, 105th Cong. 14 (Apr. 11, 1997).

<sup>191</sup> *Public Hearings on S.B. 433 Before the Public Health Comm.* 2001 Reg. Season (Conn. Feb. 29, 2000) at 11.

<sup>192</sup> *Dowhal v. Smithkline Beecham Con. Healthcare*, 88 P.3d 1, 2-4 (Cal. 2004).

consumers.”<sup>193</sup> If NUFA is enacted, the second type of constitutional question would disappear as NUFA expressly preempts all state laws that are not identical to the federal standards.<sup>194</sup> However, even if NUFA is enacted the first constitutional question remains, whether the federal or state governments have exceeded their constitutional authority by enacting certain food safety legislature.

## VII. Consumer Impact

One supporter of consolidating the nation’s food safety system said that out of all the arguments against consolidation, *reality* was the most compelling.<sup>195</sup> He argued that change is not likely to occur because it will be greatly resisted.<sup>196</sup> The real danger to consumers is if Congress moves to quickly to enact NUFA or to restructure the food safety system without carefully considering all of the potential implications and consequences. Experts already agree that the nation’s food supply is vulnerable,<sup>197</sup> drastic reform to one area of the food safety system without a thorough review and analysis of its impacts to other areas could increase this vulnerability.

Consumers may ultimately benefit from having uniform food warning label standards as proposed under NUFA.<sup>198</sup> Under this system, warning labels would only be issued if the FDA deems the risk substantial enough to inform consumers. The FDA’s process of determining whether to issue a warning label has been described as a balancing of interests, the mere existence of a risk is not always enough to justify a warning.<sup>199</sup> The FDA also takes into consideration how remote the risk is and whether the label would be potentially misleading or confusing to consumers.<sup>200</sup>

This approach acknowledges the potential dangers of over-

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<sup>193</sup> *Id.* at 3.

<sup>194</sup> H.R. 2699 § 403B(a)(1).

<sup>195</sup> Scott Bass & Alan Raul, *The Single Food Safety Agency: A Modest Dialectic Dialogue*, 59 FOOD & DRUG L.J. 453 (2004).

<sup>196</sup> *Id.*

<sup>197</sup> H.R. REP. NO. 108-770, at 21.

<sup>198</sup> H.R. 2699, 108th Cong. 2d Sess. § 403B(a)(1).

<sup>199</sup> *Dowhal*, 88 F.3d at 14.

<sup>200</sup> *Id.*

warning which may confuse or unnecessarily alarm consumers.<sup>201</sup> A position which appears to be supported by one study conducted on California's Proposition 65, "through continual expansion of the list of chemicals, Proposition 65 distracts from the more important task of increasing public awareness and understanding of how to reduce exposure to established risk factors for cancer and adverse reproductive effects."<sup>202</sup>

However, others argue that consumers are best protected under existing state and local food safety laws.<sup>203</sup> State officials have warned that NUFA would disrupt their day-to-day enforcement activities and jeopardize their ability to protect their citizens from unsafe foods.<sup>204</sup> According to a 2001 survey, more than eighty percent of the food safety and security activities in the United States were performed at the state or local levels.<sup>205</sup> If NUFA is enacted it would eliminate almost every state and local laws that provide greater consumer protection than the federal food safety laws.<sup>206</sup> Opponents also argue that if the bill is enacted, consumers will only have limited federal protection against unsafe food for a substantial period of time until the effects of the bill have been worked out.<sup>207</sup> They argue it could take years for state legislatures to reenact all of their food safety laws and that NUFA will be extensively litigated in the courts due to ambiguities within the bill.<sup>208</sup>

Until recently supporters and opponents of NUFA appeared unwilling to discuss any type of compromise with the legislation. However, AFDO, one of most vocal opponents of NUFA, has agreed to meet with the food industry to attempt to develop a compromise in the food uniformity legislation.<sup>209</sup> Hopefully, through this collaborated effort, Congress can reach a solution that best serves and protects American consumers.

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<sup>201</sup> 144 CONG. REC. S9044-02 (daily ed. July 27, 1998).

<sup>202</sup> AM. COUNS. ON SCI. AND HEALTH, *supra* note 111, at 29.

<sup>203</sup> H.R. REP. NO. 108-770, at 21.

<sup>204</sup> *Id.*

<sup>205</sup> *Hearings, supra* note 36, at 46, 48 (statement of Douglas R. Saunders).

<sup>206</sup> H.R. REP. NO. 108-770, at 21.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> FDA WEEK, *State Regulators Reach Out to Food Industry On National Uniformity* (Jan. 21, 2004).

## VIII. Conclusion

“We can re-configure the food safety system in an endless array of forms, but if food safety and public health is not improved, [then] we have failed”<sup>210</sup> Dr. Merle Pierson, Deputy Under Secretary for Food Safety at the USDA, made this statement before the Subcommittee on Civil Service and Agency Organization.<sup>211</sup> Dr. Pierson’s statement sum up what should be driving Congress’ decision as it decides whether or not to enact NUFA and consolidate the nation’s food safety system.

If there is one thing that the history of the nation’s food safety system makes clear is that shortcuts do not work. There are inefficiencies and redundancies within the existing system that are consequences of a history of enacting food safety laws independent of one another, each in response to a specific health concern, rather than part of a strategic plan as to how to best protect public health.<sup>212</sup> The result is complex system which includes twelve different agencies responsible for administering more than thirty-five food safety laws,<sup>213</sup> more than fifty interagency agreements that govern food safety oversight responsibilities, and each state’s own statutes, regulations, and agencies.<sup>214</sup> The framework of the existing system makes one agency responsible for beef soup and chicken broth but another responsible for chicken soup and beef broth.<sup>215</sup> It requires that corn dogs are inspected by FSIS daily, whereas bagel dogs are inspected by the FDA about once every five years.<sup>216</sup> The resolution of these inefficiencies and redundancies will ultimately benefit all consumers by providing them with a safer and more efficient food

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<sup>210</sup> *A System Rued*, *supra* note 8, at 8-9 (statement of Dr. Merle Pierson, Deputy Under Sec’y for Food Safety), *available at* [http://reform.house.gov/UploadedFiles/Pierson\\_USDA.pdf](http://reform.house.gov/UploadedFiles/Pierson_USDA.pdf) (last visited May 10, 2005).

<sup>211</sup> *Id.*

<sup>212</sup> GAO, *supra* note 89, at 6; *A System Rued*, *supra* note 8.

<sup>213</sup> NAT’L COMMISS’N ON THE PUB. SERV., URGENT BUSINESS FOR AMERICA, REVITALIZING THE FEDERAL GOVERNMENT FOR THE 21ST CENTURY 15 (Jan. 2003).

<sup>214</sup> GAO, *supra* note 89, at 1-2.

<sup>215</sup> *A System Rued*, *supra* note 8 (opening statement of Jo Ann Davis, chairwoman), *available at* <http://reform.house.gov/UploadedFiles/JAD%20Opening%20Statement.pdf> (last visited May 10, 2005).

<sup>216</sup> GAO, *supra* note 89, at 24.

safety system.

Congress is attempting to address the situation; however, its process seems as fragmented as the food safety system itself. Committees and governmental agencies are conducting reports,<sup>217</sup> hearings,<sup>218</sup> and issuing proposed legislature such as NUFA,<sup>219</sup> yet it does not appear that a single agency has been charged with overseeing or consolidating the individual results or findings and developing a strategic plan for the entire food safety system.

While the merits of the NUFA may, in the long run, be the right decision to best protect consumers, if enacted today it would be yet another food safety law enacted in response to a specific health concern and not part of a strategic plan as to how to best protect public health.

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<sup>217</sup> GAO, *supra* note 89, at 2, 19 (report recommending that Congress establish a single, independent food safety agency and enact a comprehensive, uniform, and risk-based food safety legislation).

<sup>218</sup> *See A System Rued*, *supra* note 8 (hearings examining the existing food inspection process).

<sup>219</sup> *See infra* Part III (discussing the National Uniformity for Food Legislature proposed legislation for regulating food warning labels).