

THE LOWEST COMMON DENOMINATOR: NATIONAL UNIFORMITY FOR FOOD ACT

“Protecting citizens from unsafe foods is a quintessential governmental function.”¹

I. INTRODUCTION

Until this past century, the regulation of domestic food in the United States (“U.S.”) has traditionally been performed by individual states.² The growth of interstate commerce and scandals in the meat industry³ and patent medicine industry⁴ led to federal intercession in 1906.⁵ Over the next eighty years, federal regulations broadened in both scope and depth. They included regulations regarding not only food adulteration and misbranding,⁶ but also food and color additives,⁷ pesticide residue,⁸ and quantity labeling.⁹ There were a particularly large number of federal consumer protection laws¹⁰ enacted during the “Consumer Decade,”¹¹ between the mid-1960s through the mid-1970s.¹²

¹ *Hearing on S. 3128: The National Uniformity for Food Act: Hearings Before the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong. (2006) [hereinafter *Hearing*] (testimony of William K. Hubbard, former Assoc. Comm’r for Policy at the FDA).

² John P. Swann, *History of the FDA: Origins*, in *THE HISTORICAL GUIDE TO AMERICAN GOVERNMENT* (George Kurian ed., 1998), available at <http://www.fda.gov/oc/history/historyoffda/default.htm>.

³ *Id.*; see also *Hearing*, *supra* note 1 (testimony of William K. Hubbard).

⁴ Swann, *supra* note 2.

⁵ Federal Food and Drugs Act of 1906 (The “Wiley Act”), Pub. L. No. 59-384, 34 Stat. 768 (1906), 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)) [hereinafter “FFDA”]; Federal Meat Inspection Act, 21 U.S.C. §§ 601et seq. (1907) [hereinafter “FMIA”].

⁶ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a)-(b) (1938) (Supp. II 1990) [hereinafter “FFDCA”].

⁷ Swann, *supra* note 2 (“... gave the FDA much tighter control . . . putting the onus on manufacturers to establish their safety.”).

⁸ *Id.*

⁹ Fair Packaging and Labeling Act, 15 U.S.C.S. §§ 1451-61, 1451 (1966) [hereinafter “FPLA”].

¹⁰ Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 895, 13 n.1 (1994) (“Of 47 federal consumer protection

State activism and state actions increased¹³ due to a domestic policy of federalism and federal deregulation ushered in during the Reagan era.¹⁴ California's Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65,¹⁵ was foremost among these state actions. The Act was broader and more stringent than existing federal regulations. It was designed to "address . . . growing concerns about exposure to toxic chemicals"¹⁶ after the federal government's deregulation. Proposition 65 has been under attack by Congressional bills intending to preempt it and other stringent state regulations in favor of uniform but less stringent federal regulations.¹⁷ The latest of these bills is H.R. 4167 / S. 3128, the National Uniformity for Food Act of 2005¹⁸ / 2006¹⁹ ("NUFA"). The NUFA and future similar bills threaten to reverse 100 years of established consumer protection under the guise of national uniformity.

This Comment will examine the history of food safety and warning notification regulation in the U.S. over the last 100 years. Discussion will include the enactments of state regulations, focusing on California's Proposition 65. This Comment will examine the history of attempts to preempt state regulations; the changes in food safety and warning notification regulations proposed by the NUFA; and why this bill, and future similar bills, should be defeated as unnecessary and unable to provide the uniformity they purport to seek.

laws enacted between 1891 and 1972, "fewer than half, or 21 statutes, were enacted in the first 75 years, and the remaining 26 were enacted [in the years from] 1966-1972").

¹¹ *Id.*

¹² *Id.*

¹³ Marina Gatti, *Proposition 65: "Shoot First, Ask Questions Later" Do the Bullets Really Work? Have We Shot the Wrong Party? Will They Call Out the Bazookas?* 47 *FOOD & DRUG L.J.* 739, 740 (1992).

¹⁴ *Id.* at 739.

¹⁵ Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE §§ 25249.5 et seq. (1986).

¹⁶ OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CAL. ENVTL. PROTECTION AGENCY, PROPOSITION 65 IN PLAIN LANGUAGE, available at <http://www.oehha.ca.gov/prop65/background/p65plain.html>.

¹⁷ ENVIRONMENTAL DEFENSE, PROP. 65 KIT: HISTORICAL CHART, <http://www.environmentaldefense.org/article.dfm?contentid=3435> (last visited July 24, 2006).

¹⁸ National Uniformity for Food Act of 2005, H.R. 4167, 109th Cong. (1st Sess. 2005).

¹⁹ National Uniformity for Food Act of 2006, S. 3128, 109th Cong. (2d Sess. 2006) [hereinafter "NUFA"] (The Senate version is materially the same as the House version. This Comment will use and refer to the Senate version (S. 3128) unless specifically noted, and will include versions of the bill likely to introduced in future Congresses).

II. A HISTORICAL OVERVIEW OF EXPANDING FOOD REGULATIONS

A. Federal Regulations

The first statutes regulating food began with the individual colonies and concerned bread and meat.²⁰ After American independence from England, the individual states continued to pass and enforce their own various regulations.²¹ Upton Sinclair's "The Jungle"²² was a well-publicized exposé of appalling conditions in the American meat packing industry. It led to public demands for government intercession at the federal level regarding the safety of foods for the American consumer.²³ The Federal Food and Drugs Act of 1906 ("FFDA")²⁴ and its companion, the Federal Meat Inspection Act,²⁵ were the result. The FFDA prohibited "the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors."²⁶ Even this relatively weak regulation was opposed; arguments that the Federal government had no business interfering in what had traditionally been regulated by the individual states were prevalent.²⁷ In 1914, the Supreme Court interpreted these regulations as a means to assure the consumer that what he thought he bought and what he actually bought were the same.²⁸ The FFDA was superseded by the Federal Food, Drug, and Cosmetic Act ("FFDCA")²⁹ in 1938. This takeover was partly due to the vacuum within the FFDA: an absence of food quality regulation and standardized labeling.³⁰ The FFDCA prohibited the introduction, adulteration or misbranding of any food in interstate commerce.³¹ It provided that safe tolerances be set for additives³² and poisonous substances.³³ The

²⁰ James Harvey Young, *The Long Struggle For The 1906 Law*, FDA CONSUMER (June 1981), <http://www.cfsan.fda.gov/~lrd/history2.html> (last visited July 27, 2006).

²¹ Wallace F. Janssen, *The Story Of The Laws Behind The Labels: Part I 1906 Food and Drugs Act*, FDA CONSUMER (June 1981), <http://www.cfsan.fda.gov/~lrd/history1.html> (last visited July 24, 2006).

²² UPTON SINCLAIR, *THE JUNGLE* (1906).

²³ Young, *supra* note 20.

²⁴ FFDA, *supra* note 5.

²⁵ FMIA, *supra* note 5.

²⁶ FFDA, *supra* note 5.

²⁷ Janssen, *supra* note 21.

²⁸ *U.S. v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914).

²⁹ FFDCA, *supra* note 6, § 301 et seq.

³⁰ FOOD AND DRUG ADMINISTRATION, *FDA'S ROLE IN PROTECTING AND PROMOTING PUBLIC HEALTH: LIMITATIONS OF THE 1906 ACT*, FDA CENTENNIAL (2006), http://www.fda.gov/centennial/centennial_files/textonly/slide12.html (last visited July 27, 2006).

³¹ FFDCA, *supra* note 6, § 331(a)-(b).

³² *Id.* § 348(a).

FFDCA also prohibited the factories from refusing inspections³⁴ and added injunctions as enforcement tools³⁵ of the renamed the Food and Drug Administration (“FDA”).

After six decades of working to ensure the safety of the American consumer’s food, the focus of Congressional policy shifted. The focus became assisting consumers and manufacturers in obtaining accurate information of the quantity of the food and the packaging, but *still* not the quality of the contents.³⁶ The concern of the 1966 Fair Packaging and Labeling Act (“FPLA”)³⁷ was limited only to quantity accuracy and placement of labels for all consumer products in interstate commerce.³⁸ The FPLA was intended, “to prevent deception of consumers and allow consumers to facilitate value comparisons.”³⁹ Products were to be honestly and informatively labeled with the identity of the product; name and place of business of the manufacturer, packer, or distributor; and net quantity of contents.⁴⁰ Though the FPLA sought the greatest practicable uniformity in state and federal labeling regulations, it also sought to not interfere with state programs.⁴¹ It expressly preempted only less-stringent or different state regulations⁴² dealing only and specifically with packaging labeling of the net quantity of the contents.⁴³ The individual States retained the right to require other “supplemental statements”⁴⁴ provided they did not include “any term qualifying . . . the amount of the commodity.”⁴⁵

This focus on labeling continued in 1990 with the Nutrition Labeling Education Act (“NLEA”),⁴⁶ an amendment to the FFDCA. The NLEA required nutrition labeling⁴⁷ for all packaged foods⁴⁸ and preempted state

³³ *Id.* § 346.

³⁴ *Id.* § 331(f).

³⁵ *Id.* § 332.

³⁶ FPLA, *supra* note 9, § 1451.

³⁷ *Id.* §§ 1451-61.

³⁸ *Id.* § 1453.

³⁹ *Id.* § 1454(c).

⁴⁰ *Id.* § 1453(a)(1)-(2).

⁴¹ *Id.* § 1458.

⁴² *Id.* § 1461.

⁴³ *Id.*

⁴⁴ *Id.* § 1453(b).

⁴⁵ *Id.*

⁴⁶ Nutrition Labeling and Education Act of 1990, 101 Pub. L. No. 535 [hereinafter NLEA].

⁴⁷ *Id.* § 2(a) (adding FFDCA § 403(q)).

⁴⁸ Food and Drug Administration, *Milestones in U.S. Food and Drug Law History*, FDA BACKGROUNDER (May 3, 1999), <http://www.fda.gov/opacom/backgrounders/miles.html> (last visited July 30, 2006) [hereinafter *Milestones*].

requirements regarding food standards, nutrition labeling, and health claims.⁴⁹ Like the FPLA, the NLEA did not include regulations for food label warning notifications.⁵⁰ Opposition at the Federal level now uses the U.S. Constitution's Supremacy Clause⁵¹ as a means to preempt state food warning regulations with the less-stringent federal regulations, such as the proposed National Uniformity for Food Act for 2006.⁵² Some critics believe the NUFA would result in a less-protected food supply for American consumers.⁵³

B. The Rise Of State Food And Warning Regulations

Since the formation of the U.S., the individual states traditionally have held primary responsibility for food safety regulations⁵⁴ by passing their own laws.⁵⁵ Interstate commerce and the need to protect the public from food dangers and fraud required federal input and control.⁵⁶ During the 1980s, President Reagan's New Federalism had the philosophy of restoring local control to local units of government.⁵⁷ This led to a return of regulatory authority at the local level.⁵⁸ During this time, there were no major federal regulations regarding food safety.⁵⁹ This encouraged consumer activism at the state level,⁶⁰ which the federal government allowed despite the risks of non-uniform state actions.⁶¹

⁴⁹ *Id.*

⁵⁰ JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION, SECOND EDITION, FDA2D §25:4 (June 2006) (Congress declined to preempt state food label warning requirements). See also Gatti, *supra* note 13, at 750.

⁵¹ U.S. CONST. art. VI, cl. 2 (Supremacy Clause) ("This Constitution, and the laws of the United States which shall be made in Pursuance thereof . . . under the authority of the United States, shall be Supreme Law of the land; and the Judges in every state shall be bound thereby, any thing in the Constitution or Laws of any state to the contrary notwithstanding.").

⁵² NUFA, *supra* note 19.

⁵³ Letter from Tommy Irvin, Comm'r Ga. Dep't of Agric., to Representative Jack Kingston, U.S. House of Representatives (February 7, 2006), available at http://www.net.org/health/GA_Ag%20DeptLetter.pdf.

⁵⁴ Thomas J. Billy, Adm'r, Food Safety Inspection Serv., at the Third Annual Federal-State Conference on Food Safety: The Future of Federal-State Cooperation in Food Safety (Nov. 21, 1997), available at <http://www.fsis.usda.gov/OA/speeches/1997/fedstat2.htm>.

⁵⁵ Janssen, *supra* note 21.

⁵⁶ O'Reilly, *supra* note 50, §25:1.

⁵⁷ C. Boyden Gray, *Regulation and Federalism*, 1 YALE J. ON REG. 93, 94 (Fall, 1983).

⁵⁸ *Id.*

⁵⁹ *Milestones*, *supra* note 48.

⁶⁰ Gatti, *supra* note 13, at 739-740.

⁶¹ Gray, *supra* note 57 at 94.

C. California's Proposition 65

The threat of hazardous substances to human life became a greater concern, and public fears about toxic dangers⁶² increased due to a California study of the pesticide toxicity.⁶³ Environmentalists took advantage of these concerns and drafted California's Proposition 65.⁶⁴ Proposition 65 was a ballot initiative that California voters passed in November 1986 by a sixty-three percent majority.⁶⁵ It is the first and only such law in the U.S.⁶⁶ Proposition 65 requires that manufacturers give a "clear and reasonable warning" notification before knowingly and intentionally exposing a person to a significant risk of *any* chemical known by the state to cause cancer or reproductive harm.⁶⁷ "No significant risk" requires that exposure to the toxic substance will have no observable effect at one thousand times the level in question.⁶⁸ This is contrasted with the FFDCA's tolerance: a yearly exposure that is no more than ten times what is considered safe, no harm from aggregate exposure, or a lifetime risk no more than twice what is considered safe.⁶⁹ This is exactly why Proposition 65 was enacted: the question is what amount of pesticide chemical residue is considered acceptable, the more stringent California level or the less stringent federal level.⁷⁰ Critics charge it is the preemption of this and other state laws that proponents of the NUFA desire, seen by their focusing on preempting Proposition 65,⁷¹ not national uniformity in labeling as they maintain.⁷¹

California is not the only state enacting regulations to protect its citizens.⁷² Attorneys General from thirty-seven states⁷³ as well as the Asso-

⁶² CALIFORNIA EPA, HISTORY OF THE CAL. ENVTL. PROTECTION AGENCY: OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, <http://calepa.ca.gov/About/History01/oehha.htm> (last visited Aug. 7, 2006) [hereinafter OEHHHA].

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Press Release, Organic Consumers Association, *Governor Schwarzenegger Opposes Food Uniformity Bill* (Apr. 18, 2006), available at <http://www.organicconsumers.org/foodsafety/gov060420.cfm>.

⁶⁶ See OEHHHA, *supra* note 62.

⁶⁷ Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE § 25249.6 (1986).

⁶⁸ *Id.* § 25249.10(c).

⁶⁹ FFDCA, *supra* note 6, § 346a(b)(2)(B)(iv).

⁷⁰ *Hearing, supra* note 1 (testimony of Peter Barton Hutt, Senior Counsel at Covington and Burling, a Washington DC law firm, and former chief counsel for the FDA).

⁷¹ Cal Dooley, *Uniformity for Food Act Should be Passed*, FRESNO BEE, at B9.

⁷² CONGRESSIONAL BUDGET OFFICE, CONGRESSIONAL BUDGET OFFICE COST ESTIMATE H.R. 4167, 3 (February 27, 2006), available at <http://www.cbo.gov/ftpdocs/70xx/doc7050/hr4167.pdf> [hereinafter "CBO"] ("CBO as-

ciation of Food and Drug Officials⁷⁴ are voicing their objections to the NUFA's preempting of their own states' regulations. Despite these numerous, multi-state regulations, California's Proposition 65 appears to be a primary target of federal preemption.⁷⁵ Even the NUFA's proponents, publicly stating that the NUFA would preempt only a limited number of states' laws, agree that Proposition 65 would be completely preempted.⁷⁶

III. ATTEMPTED PREEMPTIONS OF STATE FOOD AND WARNING REGULATIONS

A. *Prior Attempts*

The battle to diffuse or defeat Proposition 65 began at the federal level soon after its 1986 enactment.⁷⁷ Trade associations arranged for the Commissioner of the FDA to testify that FDA regulations were more stringent than Proposition 65 required.⁷⁸ Two years after Proposition 65 was enacted, an Executive Office Working Group⁷⁹ issued a report in

sumes that *states* would submit roughly 200 petitions to the FDA . . . ”) (emphasis added); *compare with* CENTER FOR SCIENCE IN THE PUBLIC INTEREST, SHREDDING THE FOOD SAFETY NET 1-xvii (March 2006), *available at* <http://www.cspinet.org/new/pdf/shredding.pdf> (listing the states' laws referenced by the CBO); *contra* JOHN BODE & STUART PAPE, NATIONAL UNIFORMITY FOR FOOD COALITION, ANALYSIS OF STATE LAWS CITED IN CSPI REPORT “SHREDDING THE FOOD SAFETY NET” (April 24, 2006) *available at* <http://www.uniformityforfood.org/StateLawAnalysisSummaryDetails.pdf> (NUFA proponents listing eleven state laws from nine states would be affected by NUFA--this is more than “only” a single state's laws).

⁷³ Letter from National Association of Attorneys General to members of Congress (Mar. 1, 2006), *available at* <http://www.net.org/health/AG%20Letter-FoodSafety-3-1-06.pdf>.

⁷⁴ Letter from Association of Food and Drug Officials to Congressional Representatives (Jan. 16, 2006), *available at* <http://www.afdo.org/afdo/upload/AFDO%20HR%204167%20Letter%20to%20Congress%201-16-06.pdf>.

⁷⁵ NATIONAL UNIFORMITY FOR FOOD COALITION, “WHAT S. 3128 WILL REALLY ELIMINATE” (Apr. 24, 2006), *available at* <http://www.uniformityforfood.org/RealProp65Costs.pdf> (chart showing the coalition's primary concerns are related to California's Proposition 65). *See also* *Hearing, supra* note 1 (testimony of Peter Barton Hutt).

⁷⁶ BODE & PAPE, *supra* note 72.

⁷⁷ Letter from Fred Altshuler, Att'y & David Roe, Att'y, to Dr. Joan Denton, Dir. Office of Env'tl. Health Hazard Assessment 5 (June 6, 2005), *available at* http://www.oehha.ca.gov/prop65/pdf/Altshuler%20Roe%20comments_.pdf [hereinafter Altshuler].

⁷⁸ *Id.*

⁷⁹ *Id.*

1988.⁸⁰ This report evaluated claims by representatives from trade associations, companies, and the Environmental Defense Fund.⁸¹ The Working Group assumed that food producers would prefer to continue selling their goods in California, despite the costs of reformulating or relabeling,⁸² as would be required by Proposition 65. However, the Working Group noted that the quality control improvements required by Proposition 65 should be minimal, provided the products met federal standards, so little relabeling would be required.⁸³ Also, regardless of relabeling costs, they believed that these costs were more likely to be borne by California consumers through higher priced products.⁸⁴ The Working Group concluded that if the costs of this statute became unduly burdensome on producers, the ability to preempt Proposition 65 was required.⁸⁵ In 1988, opponents of Proposition 65 appealed to various government officials, including White House counsel.⁸⁶ This counsel, S. Jay Plager, made clear there would be no preemptive action and continued appeals would be considered undermining, and potentially embarrassing the Administration.⁸⁷ Thus, strategically, opponents of Proposition 65 sought to amend the FFDCFA, *expressly* prohibiting conflicting or inconsistent state laws regarding food safety and warning notifications. With such a clear amendment, no court in the U.S. could misinterpret Congressional intent. Proposition 65 would then be preempted per the U.S. Constitution's Supremacy Clause.⁸⁸

⁸⁰ *Id.* at Exhibit C: Economic Analysis of Proposition 65, Working Group on the Economic Costs of Proposition 65 to Working Group on Federal Preemption 1 (December 5, 1988) (this Working Group on Federal Preemption submitted an economic study to a Cabinet-level review).

⁸¹ *Id.* at 2.

⁸² *Id.* at 3-4 (the choice for re-labeling was to either label all products to comply with California law or re-label and segregate only those products to be sold in California).

⁸³ *Id.* at 4, 7.

⁸⁴ *Id.* at 7.

⁸⁵ *Id.* at 9.

⁸⁶ *Id.* at 6; and *Id.* at Exhibit D: Letter from S. Jay Plager, Admin. Office of Info. Regulatory Affairs to Dr. Frank Young, Comm'r Food & Drug Admin. (May 17, 1989).

⁸⁷ *Id.* at Exhibit D: Letter from S. Jay Plager, Admin. Office of Info. Regulatory Affairs to Dr. Frank Young, Comm'r Food & Drug Admin. (May 17, 1989).

⁸⁸ *English v. General Electric Company* 496 U.S. 72, 78-79 (1990) (" . . . state law is pre-empted under the Supremacy Clause U.S. Constitution, art. VI, cl. 2, in three circumstances: First, Congress can define explicitly the extent to which its enactments pre-empt state law. . . . Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. . . . Finally, state law is pre-empted to the extent that it actually conflicts with federal law.").

The focus of the battle turned to Congress and a succession of bills was introduced beginning in 1989.⁸⁹ There were two years when bills were introduced almost simultaneously into each house.⁹⁰ Each bill sought to amend the FFDCa to preempt Proposition 65 and similar states' laws. Each bill included words effectively saying that no state or local government could establish or continue any food safety, warning notification, or pesticide tolerance, which was not identical to that issued by the FDA.⁹¹ None of these bills passed. Three bills *were* enacted during this period: 1990's Nutrition Labeling and Education Act,⁹² preempting state requirements regarding food identity and nutrition but not preempting state requirements regarding foods containing poisonous or deleterious substances.⁹³ The Food Quality Protection Act of 1996,⁹⁴ *specifically rejected* preemption of state requirements regarding warning statements for foods containing pesticide chemical residue.⁹⁵ Finally, the Food and Drug Administration Modernization Act of 1997,⁹⁶ preempting state requirements regarding nonprescription drugs,⁹⁷ but specifically *not* preempting state requirements adopted by public initiative enacted prior

⁸⁹ S. 1505, 101st Cong. § 5 (to replace FFDCa § 710, 1989); S. 1166, 104th Cong. § 305 (to amend FFDCa § 408(1)(4), 1995); H.R. 3200, 104th Cong. § 108 (to add FFDCa ch. VII, subch. D, §741(2)(b), 1996); H.R. 2649, 107th Cong. § 2(b)(2) (to add FFDCa §403B, 2001); H.R. 2699, 108th Cong. § 2(b)(2) (to add FFDCa §403B, 2003).

⁹⁰ H.R. 4383, 105th Cong. § 2(b)(2) (to add FFDCa §403B, 1998); S. 2356, 105th Cong. § 2(b)(2) (to add FFDCa §403B, 1998); H.R. 2129, 106th Cong. § 2(b)(2) (to add FFDCa §403B, 1999); S. 1155, 106th Cong. § 2(b)(2) (to add FFDCa §403B, 1999).

⁹¹ S. 1505, 101st Cong. § 5 (to replace FFDCa § 710, 1989); S. 1166, 104th Cong. § 305 (to amend FFDCa § 408(1)(4), 1995); H.R. 3200, 104th Cong. § 108 (to add FFDCa ch. VII, subch. D, §741(2)(b), 1996); H.R. 4383, 105th Cong. § 2(b)(2) (to add FFDCa §403B, 1998); S. 2356, 105th Cong. § 2(b)(2) (to add FFDCa §403B, 1998); H.R. 2129, 106th Cong. § 2(b)(2) (to add FFDCa §403B, 1999); S. 1155, 106th Cong. § 2(b)(2) (to add FFDCa §403B, 1999); H.R. 2649, 107th Cong. § 2(b)(2) (to add FFDCa §403B, 2001); H.R. 2699, 108th Cong. § 2(b)(2) (to add FFDCa §403B, 2003).

⁹² NLEA, *supra* note 46.

⁹³ O'REILLY, *supra* note 50 §25:4.

⁹⁴ Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 [hereinafter FQPA].

⁹⁵ *Id.* § 405, §408(n)(8).

⁹⁶ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, S. 830, 105th Cong. (1997).

⁹⁷ *Id.* at §412(a) (adding subch. F(a) to ch. VII of 21 U.S.C. § 371 et seq.; preempting non-identical state requirements).

to September 1, 1997,⁹⁸ effectively excluding 1986's Proposition 65 from preemption.⁹⁹

B. *The National Uniformity For Food Act For 2006*

Representative Mike Rogers of Michigan¹⁰⁰ sponsored the National Uniformity for Food Act for 2005, H.R. 4167¹⁰¹ to the House of Representatives on October 27, 2005.¹⁰² It was passed by the House and introduced in the Senate on May 25, 2006¹⁰³ as the National Uniformity for Food Act of 2006, S. 3128.¹⁰⁴ Sponsored by Senator Richard Burr of North Carolina,¹⁰⁵ it was referred to the Senate's Committee on Health, Education, Labor, and Pensions, which held a hearing regarding it on July 27, 2006.¹⁰⁶ The bill never left committee when Congress adjourned. Based on recent history, it is likely a "new" version will be introduced in the next Congress.

1. Preempts State Laws

The NUFA proposes amending 1938's FFDCa "to provide for uniform safety warning notification requirements, and for other purposes."¹⁰⁷ The NUFA will accomplish this by expanding the federal government's preemption of state laws. It will expressly prohibit any state or local government from establishing *or continuing*, for any food in interstate commerce, all state and local food safety regulations that are not identical to those within this Act,¹⁰⁸ unless specifically excepted per this Act.¹⁰⁹

⁹⁸ *Id.* (adding subch. F(d)(2) to ch. VII of 21 U.S.C. § 371 et seq.; exempting State requirements adopted by State public initiative prior to Sept. 1, 1997--Proposition 65 was the only such State requirement).

⁹⁹ *Id.* See also O'REILLY, *supra* note 50 §25:5.

¹⁰⁰ National Uniformity for Food Act of 2005, H.R. 4167, 109th Cong. (2005).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ NUFA, *supra* note 19.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* (while a member of the House of Representatives, Mr. Burr also sponsored or co-sponsored H.R. 3200 in 1996, H.R. 4383 in 1998, H.R. 2129 in 1999, H.R. 2649 in 2001, and H.R. 2699 in 2004. Each of these bills would preempt state food safety warnings and notification requirements).

¹⁰⁶ *Hearing, supra* note 1.

¹⁰⁷ NUFA, *supra* note 19.

¹⁰⁸ *Id.* at § 2(b)(2) (amending FFDCa by adding § 403B(a)(1): "... no State . . . may, directly or indirectly, establish or continue . . . any notification requirement . . . unless such . . . has been prescribed under the authority of this Act . . .").

State requirements preempted would include all foods that are injurious to health, or unsafe as defined by the FFDCA. Unsafe foods are those: that contain, unless unavoidable or not added to the food, poisonous or deleterious substances that are injurious to health;¹¹⁰ that have added poisonous or deleterious substances that are unsafe per the FFDCA's section 406;¹¹¹ that contain any pesticide chemical residue that is unsafe per the FFDCA's section 408(a);¹¹² that contain any food additive that is unsafe per the FFDCA's section 409;¹¹³ that contain any color additives unsafe per FFDCA's section 721(a);¹¹⁴ whose containers have poisonous or deleterious substances that are injurious to health;¹¹⁵ and those that have been radiated, unless radiation was to conform to the FFDCA's section 409.¹¹⁶ The NUFA would "allow" the states to enforce only those state requirements which are *identical* to the FFDCA provisions.¹¹⁷ The non-identical state requirements will be preempted even if there is no existing federal regulation relating to the requirement,¹¹⁸ or if the Secretary rejects a proposed regulation from a state's petition.¹¹⁹

Dr. Elsa Murano,¹²⁰ a NUFA proponent testifying before the Senate committee assured the committee that the NUFA was designed *not* to impact fundamental Federal or State food safety and warning requirements or enforcement.¹²¹ Peter Hutt¹²² testified that the NUFA *does* preempt state requirements where the FDA has an established regulation.¹²³

¹⁰⁹ *Id.* (amending FFDCA by adding § 403B(a)(1): "Except as provided in subsections (c) and (d), no State . . . may . . . establish or continue . . . any notification requirement . . . unless such . . . has been prescribed under the authority of this Act . . .").

¹¹⁰ *Id.* at § 2(a)(3) (amending FFDCA by adding § 403A(a)(6), referring to § 402(a)(1)).

¹¹¹ *Id.* (amending FFDCA by adding § 403A(a)(6), referring to § 402(a)(2)(A)).

¹¹² *Id.* (amending FFDCA by adding § 403A(a)(6), referring to § 402(a)(2)(B)).

¹¹³ *Id.* (amending FFDCA by adding § 403A(a)(6), referring to § 402(a)(2)(C)(i)).

¹¹⁴ *Id.* (amending FFDCA by adding § 403A(a)(6), referring to § 402(c)).

¹¹⁵ *Id.* (amending FFDCA by adding § 403A(a)(6), referring to § 402(a)(6)).

¹¹⁶ *Id.* (amending FFDCA by adding § 403A(a)(6), referring to § 402(a)(7)).

¹¹⁷ *Id.* at § 2(a)(4) (amending FFDCA by adding § 403A(c)(2), where § 403A(c)(1) states "identical means that the language under the laws of a State . . . is substantially the same language as the comparable provision under this Act and that any differences in language do not result in the imposition of materially different requirements").

¹¹⁸ *Id.* (amending FFDCA by adding § 403A(c)(3), "If the Secretary has not promulgated a regulation . . . a State may enforce a policy . . . that contains a requirement that is identical to a requirement in a section of Federal law . . .").

¹¹⁹ *Id.* (amending FFDCA by adding § 403A(c)(4), "If the Secretary has . . . made a determination not to promulgate such regulation . . . a State . . . may not enforce any requirements in State law that are policies rejected by the Secretary . . .").

¹²⁰ *Hearing, supra* note 1.

¹²¹ *Id.* (testimony of Dr. Elsa Murano).

¹²² *Id.*

¹²³ *Id.* (testimony of Peter Barton Hutt).

William Hubbard,¹²⁴ opposing the NUFA, testified that concern about how much preemption would occur cannot be disregarded,¹²⁵ as evidenced by disputes between the NUFA's proponents and state officials,¹²⁶ and by the contradictions by those testifying before this committee.¹²⁷ Even the Congressional Budget Office ("CBO") asserts that the scope of preemption by the NUFA is ambiguous.¹²⁸ The CBO assumes this scope will be determined after enactment, through the number of petitions submitted by the states.¹²⁹ Other national acts for uniformity regarding food allow more stringent state regulations to remain intact, and preemption is limited only to state or local regulations which are less stringent.¹³⁰ The NUFA—past, current, and likely future versions—specifically forbids that, requiring the regulations be identical even if the federal regulations are less stringent.¹³¹

Congress specifically exempted acts such as Proposition 65 from a 1996 national uniformity law regarding food safety.¹³² This makes clear that, for at least the last ten years, Congress has refused to preempt Proposition 65 and other states' more stringent requirements. As the NUFA would clearly express Congressional intent to preempt state requirements, the Supremacy Clause may be directly applied.¹³³ This clear federal expression will also result in Proposition 65 being automatically preempted per its own clause.¹³⁴

¹²⁴ *Id.*

¹²⁵ *Id.* (testimony of William K. Hubbard) (commenting on the states' uncertainty regarding preemption).

¹²⁶ *Id.* (testimony of William K. Hubbard) (" . . . the dispute between the food industry and others--whether state Attorneys General, state food safety officials, or the Center for Science in the Public Interest . . . about the number of law preempted is a good indicator of that ambiguity.").

¹²⁷ *Id.* (testimony of Dr. Elsa Murano), *contrast with Hearing, supra* note 1 (testimony of Peter Barton Hutt) (one witness stating that NUFA will not impact fundamental state food laws, the other stating that any non-identical state law will be preempted).

¹²⁸ CBO, *supra* note 72.

¹²⁹ *Id.*

¹³⁰ FPLA, *supra* note 9, § 1461.

¹³¹ NUFA, *supra* note 19, § 2(b)(2) (amending FFDCa by adding § 403A(a)(6)).

¹³² FQPA, *supra* note 94, § 405 (amending FFDCa §408(n)(8)).

¹³³ *English v. General Electric Company, supra* note 88 at 78-79 (" . . . state law is preempted under the Supremacy Clause, U.S. Constitution, art. VI, cl. 2, in three circumstances: First, Congress can define explicitly the extent to which its enactments pre-empt state law. . . .").

¹³⁴ Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE § 25249.10(a) (1986) (Section 25249.6 shall not apply to . . . an exposure for which federal law governs warning in a manner that preempts state authority).

The NUFA's proponents stress that the NUFA's opponents are overly concerned regarding preemption of state requirements.¹³⁵ They point out that the NUFA allows states the right to petition for an exemption or to make their requirement the national standard.¹³⁶ These proponents gloss over the fact that this process could take as long as two years.¹³⁷ This would occupy the resources of both the federal and state agencies. Though the state requirement would remain in effect during this process,¹³⁸ each state must petition for *each* specific food or food component.¹³⁹ This is a process potentially very costly for the states, therefore less likely to be financially feasible. Another drawback not often mentioned by the NUFA's proponents is that, absent the state's filing of a petition, states may enforce only those regulations whose state law-basis is identical to federal law.¹⁴⁰ If there is no federal law on that particular requirement, the state laws remain preempted, resulting in the states being unable to protect their own citizens.

Very often, state and even local actions have led the way in protecting the public's health.¹⁴¹ When federal and state regulations concerning the health and safety of its citizens overlap, more stringent state regulations are not always preempted.¹⁴² For example, California pioneered mobile-

¹³⁵ *Hearing, supra* note 1 (testimony of Dr. Elsa Murano); and *Hearing, supra* note 1 (testimony of Peter Barton Hutt).

¹³⁶ NUFA, *supra* note 19, § 2(b)(2) (amending FFDCA by adding § 403B(b)(2)).

¹³⁷ *Id.* (amending FFDCA by adding § 403B(b)(3)). (If a state files its petition for exemption within 180 days after NUFA's enactment, §403B (b)(3)(A) allows the Secretary up to 270 days to publish a notice for public comment and up to 180 days for public comment, and §403B (b)(3)(B) allows the Secretary up to 360 days for the Secretary to take final action, totaling up to 810 days (approximately 116 weeks) from petition filing until final action. If a state files its petition for exemption more than 180 days after enactment, §403B (c)(3)(A) allows the Secretary up to 30 days to publish a notice for public comment and §403B (b)(3)(B) allows the Secretary up to 60 days for public comment and up to 120 days for the Secretary to take final action, totaling up to 210 days (approximately 30 weeks) from petition filing until final action.)

¹³⁸ *Id.* (amending FFDCA by adding § 403B(b)(3)(C)).

¹³⁹ *Id.* (amending FFDCA by adding § 403B(b)(1)(A)(i)).

¹⁴⁰ *Id.* at § 2(a)(4) (amending FFDCA by adding § 403A(c)(3-4)).

¹⁴¹ CALIFORNIA EPA - AIR RESOURCES BOARD, CALIFORNIA'S AIR QUALITY HISTORY KEY EVENTS, <http://www.arb.ca.gov/html/brochure/history.htm> (last visited May, 28, 2004) (the first air pollution control program in the nation began at the *city* level [City of Los Angeles, 1945] and the first pollution control district in the nation was established at the *county* level [Los Angeles County, 1947]).

¹⁴² COMMITTEE ON STATE PRACTICES IN SETTING MOBILE SOURCE EMISSION STANDARDS, NATIONAL RESEARCH COUNCIL, STATE AND FEDERAL STANDARDS FOR MOBILE SOURCE EMISSIONS 2, http://newton.nap.edu/execsumm_pdf/11586 (last visited Aug. 11, 2006) [hereinafter COMMITTEE].

source emission standards¹⁴³ in 1964,⁴⁴ requiring minimal control systems for 1966 model cars sold in California.¹⁴⁵ Federal action authorized a study of air quality in 1963's Clean Air Act,¹⁴⁶ but there was no direct regulating of emissions controls until 1965.¹⁴⁷ A 1967 amendment¹⁴⁸ preempted all state and local standards,¹⁴⁹ *with one notable exception*: California's regulation was specifically *not* preempted even though it was more stringent than Federal standards.¹⁵⁰ A 1990 amendment¹⁵¹ allowed other states to adopt California's standards instead of federal standards.¹⁵² This created a two-tiered standard for emission control laws in the U.S. States are allowed stronger pollution controls than federal regulations require,¹⁵³ making federal pollutant limits the minimal tolerances. To date, seven states have adopted California's more stringent emissions controls and more are considering adopting them.¹⁵⁴ California led the way in pollution control on light-duty vehicles¹⁵⁵ using a program exceeding federal standards¹⁵⁶ but generally beneficial.¹⁵⁷ This is despite the auto industry's arguments that these requirements were cost prohibi-

¹⁴³ *Id.*

¹⁴⁴ OFFICE OF MOBILE SOURCES, ENVIRONMENTAL PROTECTION AGENCY, MILESTONES IN AUTO EMISSIONS CONTROL 1 (EPA 400-F-92-014) (Fact Sheet OMS-12) (August, 1994), available at <http://www.epa.gov/otaq/consumer/12-miles.pdf>.

¹⁴⁵ *Id.*

¹⁴⁶ Clean Air Act, Pub. L. No. 88-206, 77 Stat. 392; See also CALIFORNIA EPA - AIR RESOURCES BOARD, CALIFORNIA'S AIR QUALITY HISTORY KEY EVENTS, available at <http://www.arb.ca.gov/html/brochure/history.htm> (last visited May, 28, 2004).

¹⁴⁷ CALIFORNIA EPA - AIR RESOURCES BOARD, *supra* note 146.

¹⁴⁸ Air Quality Act of 1967, Pub. L. No. 90-148, § 208(a) (1967) (amended 1963's Clean Air Act, 42 U.S.C. 1857-1857l, adding § 208(a); redesignated as § 209 [42 U.S.C. 1857f-5 to 1857f-7] by the Clean Air Amendments of 1970, Pub. L. No. 94-604, 81 Stat. 486 §8(a); the entire Act was later reclassified as 42 U.S.C. 7401 et seq., by the Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685).

¹⁴⁹ *Id.* (amended 1963's Clean Air Act, 42 U.S.C. 1857-1857l, preempting State standards).

¹⁵⁰ *Id.* § 208(b) (amended 1963's Clean Air Act, 42 U.S.C. 1857-1857l, providing the first exemption for California); see also COMMITTEE, *supra* note 142, at 2.

¹⁵¹ Clean Air Act Amendments, Pub. L. No. 101-549, 104 Stat. 2399 (1990).

¹⁵² *Id.* § 222(b) (adding § 209(e)(2)(B)(i) to Clean Air Act, 42 U.S.C. 7543; where other States may adopt standards identical to California standards).

¹⁵³ ENVIRONMENTAL PROTECTION AGENCY, THE PLAIN ENGLISH GUIDE TO THE CLEAN AIR ACT: FEATURES OF THE 1990 CLEAN AIR ACT, available at http://www.epa.gov/air/oaqps/peg_caa/pegcaa02.html.

¹⁵⁴ COMMUNITY RIGHTS COUNSEL, REDEFINING FEDERALISM: TOP 10 STATE AND LOCAL ENVIRONMENTAL SOLUTIONS, <http://redefiningfederalism.org/SLES/Sol1.asp> (last visited Aug. 10, 2006).

¹⁵⁵ COMMITTEE, *supra* note 142, at 3.

¹⁵⁶ *Id.* at 15.

¹⁵⁷ *Id.* at 16.

tive and technically impossible.¹⁵⁸ Not only did California receive an exemption from preemption despite industry arguments,¹⁵⁹ both California and the EPA have since enacted even more stringent requirements.¹⁶⁰ These waivers from federal preemption continue,¹⁶¹ despite their effects extending beyond a single state's borders.¹⁶² Pre-existing and stronger state laws regarding vehicle emissions have been exempted from federal preemption; California and other states' pre-existing efforts in food safety and warning notification warrant similar exemptions from preemption.

2. The NUFA's Supposed Benefits

a. Uniformity

The NUFA's proponents decry the lack of nationally uniform food safety and warning notification requirements.¹⁶³ Such uniformity would likely simplify regulation enforcement in the U.S. and save the food industry money from reformulating their products.¹⁶⁴ At the Senate committee hearing on the NUFA,¹⁶⁵ Mr. Hutt testified that under the NUFA, only those state requirements that were identical could be enforced by the states, and that enforcement must also conform to FDA standards.¹⁶⁶ Proponents believe such uniformity may be achieved through the NUFA.¹⁶⁷ Proponents allege that allowing California's Proposition 65 warnings to be "imposed" on the forty-nine other states have led to consumer confusion and complaints across the nation.¹⁶⁸

¹⁵⁸ AIR QUALITY MANAGEMENT DISTRICT, THE SOUTHLAND'S WAR ON SMOG: FIFTY YEARS OF PROGRESS TOWARD CLEAN AIR (May 1997), available at <http://aqmd.gov/news1/Archives/History/marchcov.html>.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ Federal Register, California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption--Notice of Within-the-Scope Determination (AMS-FRL-6937-2), 66 Fed. Reg. 17,7751 (Jan. 25, 2001), available at <http://www.epa.gov/fedrgstr/EPA-AIR/2001/January/Day-25/a2174.htm>.

¹⁶² *Id.* (recognition that the decision would "affect not only persons in California but also the manufacturers outside the state who must comply with California's requirements in order to produce motor vehicles for sale in California.").

¹⁶³ *Hearing, supra* note 1 (testimony of Dr. Elsa Murano).

¹⁶⁴ GREATEST HERBS ON EARTH, SPECIAL SECTION: CALIFORNIA'S PROPOSITION 65 AND HOW IT AFFECTS SUPPLEMENT MAKERS (2005), available at http://greatestherbsonearth.com/prop_65.htm.

¹⁶⁵ *Hearing, supra* note 1.

¹⁶⁶ *Id.* (testimony of Peter Barton Hutt).

¹⁶⁷ *Id.* (testimony of Dr. Elsa Murano).

¹⁶⁸ NATIONAL UNIFORMITY FOR FOOD COALITION, *supra* note 75.

The NUFA's proponents observe that Congress has established nationally uniform requirements regarding food labeling in the past,¹⁶⁹ omitting that there have been none for food safety warnings.¹⁷⁰ Although Congress has refused to pass bills preempting state safety warning requirements in the past,¹⁷¹ proponents cite that the high amount of interstate commerce¹⁷² requires such uniformity to promote efficiency in commerce.¹⁷³

b. *Protects The Public Health*

Proponents of the NUFA contend that the NUFA "balances the need for a strong national law to assure safe food for all our citizens . . . with the right and duty of each State to protect its citizens from harm."¹⁷⁴ Cal Dooley, the CEO-elect of the Grocery Manufacturer's Association, wrote that the NUFA will "strengthen America's food safety net and raise consumer protection to an even higher level."¹⁷⁵ Proponents believe federal oversight of these uniform safety standards will maintain consumer confidence about food safety no matter which government level is responsible for the actual inspections.¹⁷⁶

3. Rebuttal Of Benefits

a. *Uniformity As A Practical Matter Already Exists*

Many manufacturers are already applying a single warning for the entire country rather than separating those products with Proposition 65 warnings for distribution to California alone.¹⁷⁷ Most manufacturers de-

¹⁶⁹ NLEA, *supra* note 46, § 6(a) (adding § 403A (a)(1)-(2)(d)); *see also* *Hearing, supra* note 1 (testimony of William K. Hubbard).

¹⁷⁰ *Hearing, supra* note 1 (testimony of William K. Hubbard).

¹⁷¹ O'Reilly, *supra* note 50, §25:4 (Congress declined to include safety warning preemptions in 1990's NLEA).

¹⁷² Letter from Jay Timmons, Senior Vice-President for Policy and Government Relations for the National Association of Manufacturers to members of the U.S. House of Representatives (Mar. 1, 2006), *available at* http://222.nam.org/s_nam/doc1.asp?CID=202509&DID=236490&rcss=print (approximately 70% of all products move across state lines).

¹⁷³ *Id.*

¹⁷⁴ *Hearing, supra* note 1 (testimony of Peter Barton Hutt).

¹⁷⁵ Dooley, *supra* note 71.

¹⁷⁶ Thomas J. Billy, Adm'r, Food Safety Inspection Serv., before the Third Annual Federal-State Conference on Food Safety (Nov. 21, 1997), *available at* <http://www.fsis.usda.gov/OA/speeches/1997/fedstat2.htm>.

¹⁷⁷ NATIONAL UNIFORMITY FOR FOOD COALITION, *supra* note 75 ("states outside California receive products" with California labels).

cided that continuing to sell their goods in California was in their best interests and chose to either reformulate their products or attach the required warnings.¹⁷⁸ In essence, a de facto national uniformity may already be in process through Proposition 65,¹⁷⁹ just not the one desired by the NUFA's proponents.

In addition to the public benefits from manufacturers reducing the toxins for which Proposition 65 was enacted,¹⁸⁰ manufacturers have also benefited¹⁸¹ despite a general unwillingness to comply. Some manufacturers consider Proposition 65 to be a major step towards "environmental enlightenment."¹⁸² One manufacturer of food supplements, though displeased with having to comply with Proposition 65 requirements, chose to remove non-complying products from distribution in California.¹⁸³ Reformulating its remaining line of products resulted in more powerful products it has been able to advertise to its benefit.¹⁸⁴

National food safety and warning notifications can have a similar structure as the two-tiered standards used for emission control. Federal requirements would be the first-tier minimum warnings, while the optional second tier requires stronger warnings. In this manner, national distributors would likely comply with the stronger warnings, passing any costs onto the consumers in those states, but local distributors would still be able to retain the federal requirements.

b. *The NUFA Would Lower State Standards*

The FDA regulates foods linked to two-thirds of documented outbreaks of foodborne illnesses.¹⁸⁵ Proposition 65 is a direct response to the federal government essentially abandoning food safety regulation in

¹⁷⁸ Rick R. Rothman et al., *California's Prop 65 and the Boy who Cried Wolf*, 14 SPG Nat. Resources & Env't 227, 227 (2000).

¹⁷⁹ Dooley, *supra* note 71 ("Food companies are forced to reformulate products or put unjustified warnings on products *not just in California, but in every state in the Union . . .*") (emphasis added).

¹⁸⁰ Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 367.

¹⁸¹ GREATEST HERBS ON EARTH, *supra* note 164.

¹⁸² MARTIN J. VAN DER BURGT, SR. PROD. ENG'G PROJECT MANAGER, BELDEN CABLE, RESTRICTION OF HAZARDOUS SUBSTANCES 2 (2005), available at <http://bwccom.belden.com/College/Techpprs/RoHS.pdf>.

¹⁸³ GREATEST HERBS ON EARTH, *supra* note 164.

¹⁸⁴ *Id.* (reformulation brought compliance with Proposition 65 and resulted in more-concentrated extracts, which are therefore more powerful—and may be advertised as such).

¹⁸⁵ CENTER FOR SCIENCE IN THE PUBLIC INTEREST, FDA: THE SLEEPING WATCHDOG, http://spinet.org/new/pdf/sleeping_watchdog.pdf (last visited July 27, 2006).

the 1980s.¹⁸⁶ Federal laws are the minimum standards.¹⁸⁷ State laws have been used to enhance the FDA's objective in protecting the American public.¹⁸⁸ States even have power to detain products violating State food regulations that federal inspectors do not have.¹⁸⁹ Congress specifically limited such federal action to medical devices, excluding food safety.¹⁹⁰

4. Other Problems With The NUFA

a. *Financial Impracticability Of Implementation*

The Congressional Budget Office's ("CBO") Cost Estimate for the NUFA states that, if the NUFA were enacted, as many as 200 state petitions for regulation exemptions are expected to be filed early in the enactment.¹⁹¹ Proponents of the NUFA deride this number as an error and gross overestimate made by opponents.¹⁹² They ignore the fact that the FDA and the states' existing safety and warning requirements were the sources of the information for that determination.¹⁹³ Based on this number, the CBO estimates that the FDA would spend an average of \$400,000 per petition during the first five years,¹⁹⁴ totaling \$100 million during this time.¹⁹⁵ The total budget for the Center for Food Safety and Applied Nutrition ("CFSAN") for 2006 was approximately \$179.5 million,¹⁹⁶ \$100 million of which is required for existing salaries.¹⁹⁷ A large number of these FDA employees would be required to handle petition reviews¹⁹⁸ due to the time constraint on petition evaluations written into the NUFA.

¹⁸⁶ O'REILLY, *supra* note 50, §10:1.

¹⁸⁷ *Id.* §25:4.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* §25:2.

¹⁹⁰ *Id.* §25:2 (by the 1976 Medical Device Amendments to the FFDCFA).

¹⁹¹ CBO, *supra* note 72.

¹⁹² Press Release, Grocery Manufacturer's Assoc., *GMA Corrects the Record on the National Uniformity for Food Act* (March 7, 2006), available at http://www.gma-brands.com/news/docs/newsrelease_p.cfm?DocID=1630.

¹⁹³ CBO, *supra* note 72.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ OFFICE OF FINANCIAL MANAGEMENT, FDA, FY 2006 BUDGET SUMMARY AND BUDGET IN BRIEF, available at <http://www.fda.gov/oc/oms/ofm/budget/2006> (that portion of the FDA overseeing food defense).

¹⁹⁷ Telephone Interview with William K. Hubbard, former Assoc. Comm'r for Policy, FDA, in Washington, D.C. (Aug. 3, 2006).

¹⁹⁸ E-mail from William K. Hubbard, former Assoc. Comm'r for Policy, FDA, to Wendy Aguilar (Sep. 24, 2006, 21:59:45 EST) (on file with author).

Currently, state and local agencies perform over eighty percent of food safety inspections in the U.S.¹⁹⁹ A likely result of requiring states to enforce national requirements in lieu of their own is that some states are likely to turn over the enforcement of federal requirements to the federal government and re-budget state money elsewhere. Concurrently, the FDA has approximately the same number of inspectors as in the 1970s²⁰⁰ to handle this expected increased enforcement workload. Without a significant increase in the FDA's budget, there simply are insufficient funds to implement *either* the NUFA's petition process or the likely increase in inspections formerly performed by the States.

The FDA simply cannot implement this bill without large amounts of additional money if it were to now be largely responsible for enforcement of food safety in the U.S.

b. *No Guarantee That The NUFA Would Be Science-Based*

Proponents claim that the NUFA would provide "science-based" regulation,²⁰¹ as opposed to Proposition 65 and other state regulations. One of the reasons for Proposition 65's enactment was there were no federal regulations for over one-third of the carcinogenic chemicals already recognized by National Toxicology Program testing.²⁰² Proposition 65 supporters wanted science-based regulation,²⁰³ and determined four²⁰⁴ methods for a chemical to be listed: 1) those already identified as toxic by national or international toxicology and cancer research organizations;²⁰⁵ 2) those listed by authoritative regulatory agency and scientific organizations;²⁰⁶ 3) those nominated by the state's experts;²⁰⁷ and 4) those already

¹⁹⁹ Letter from National Association of Attorneys General to members of Congress (March 1, 2006), available at <http://www.net.org/health/AG%20Letter-FoodSafety-3-1-06.pdf>. See also Letter from J. Carlton Courter III, President of the Nat'l Ass'n of State Dep'ts of Agric. to members of the U.S. Senate Health, Education, Labor & Pensions Committee (October 17, 2005), available at <http://www2.nasda.org/NR/exeres/64195D1F-4A1D-4959-9D0A-DE0EE4CB909F.htm?NRORIGINAL>.

²⁰⁰ *Hearing, supra* note 1 (testimony of William K. Hubbard).

²⁰¹ *Id.* (testimony of Senator Saxby Chambliss), and *Id.* (testimony of Dr. Elsa Murano).

²⁰² William S. Pease, *Identifying Chemical Hazards for Regulation: The Scientific Basis and Regulatory Scope of California's Proposition 65 List of Carcinogens and Reproductive Toxicants*, 13 FRANKLIN PIERCE LAW CENTER RISK (Spring), available at <http://www.piercelaw.edu/Risk/Vol3/spring/Pease.htm>.

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

regulated.²⁰⁸ Though the listing was based on sufficiency of scientific evidence, this was not a perfect system. California's governor was accused of pandering to special interests by restricting the list of chemicals, against the advice of California's own Department of Health Services.²⁰⁹

The NUFA's proponents deride Proposition 65 as not being science-based. However, the FDA cannot guarantee it would use science-based research in determining food safety and warning notification requirements. A former commissioner of food and drugs was questioned by Congress²¹⁰ regarding the amount of science versus financial or political influence in his decision-making.²¹¹ This commissioner refused to comment and his attorney indicated he would plead the Fifth Amendment in court.²¹² When the FDA opens itself to accusations from consumer groups and Congress²¹³—and even their own scientists²¹⁴—for putting politics ahead of scientific research, it seems that the NUFA's proponents cannot ensure that the FDA would itself use science-based regulations.

IV. CONCLUSION

The NUFA should not be enacted into law as it unnecessarily preempts stronger state, and even city, laws in favor of a weaker federal law.²¹⁵ National uniformity in labeling is already in progress through California's Proposition 65. This makes the NUFA unnecessary, particularly if a two-tiered system is implemented for food safety and warning require-

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ Gardiner Harris, *Ex-Head of F.D.A. Faces Criminal Inquiry*, NEW YORK TIMES, Apr. 29, 2006, available at http://www.ahrp.org/cms/index2.php?option=com_content&task=view&id=155&Itemid=29&pop=1&page=0.

²¹¹ *Id.*

²¹² *Id.*

²¹³ Press Release, FDAnews Drug Daily Bulletin, *FDA Approves Plan B OTC, Gets Sued Again* (Aug. 28, 2006), available at http://web.lexis-nexis.com.htmlproxy.lib.csufresno.edu/universe/document?_m=d600585db878b26a08dbdf46457a134e&_docnum=45&wchp=dGLbVlz-zSkVb&_md5=fb3c6a8d737394fca77f15c29d4125ed.

²¹⁴ Press Release, FDAnews Drug Daily Bulletin, *FDA Chief Meets With Scientist Group to Discuss Political Interference* (Aug. 11, 2006), available at http://web.lexis-nexis.com.htmlproxy.lib.csufresno.edu/universe/document?_m=b0bb9c386d5bb7ce01672e140bd293c6&_docnum=58&wchp=dGLbVlz-zSkVb&_md5=0e1031ab2d5d47329eb2658853ad7e5b.

²¹⁵ *Hearing, supra* note 1 (testimony of Senator Barbara Boxer, member of United States Senate) (example of state laws in California, Illinois and New York City regarding lead in children's candy which would be threatened by NUFA).

ments similar to emission control requirements. The NUFA is also financially impracticable to implement due to costs and its own time constrictions. Finally, there is no guarantee that the NUFA requirements would be as science-based as proponents tout. How the NUFA can protect America's citizens from harm by imposing federal requirements less stringent than many existing states' requirements is decidedly unclear.

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