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Prop. 65: Putting California's Labeling Horse Back into the Federal Labeling Barn

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Putting California's Labeling Horse Back Into the Federal Labeling Barn

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I. Introduction

The California Attorney General's office acknowledges "that 20 percent of all notices of intent to sue under [the Safe Drinking Water and Toxic Enforcement Act of 1986] are frivolous."[1] Furthermore, the office believes private enforcers target small businesses. "The problem is that if you're a small business, the pressure is on you to settle. You don't have the luxury of acting as a crusader against frivolous suits. The pressure is on you to meet a payroll."[2] However, the California Attorney General's office remains impotent to eliminate frivolous lawsuits.[3] The Consumer Product Safety Commission could empower the Attorney General's office to eliminate these suits by harmonizing "Prop. 65," California's labeling horse, with the Federal Hazardous Substances Act, the federal labeling barn.

In 1986, the citizens of California approved the Safe Drinking Water and Toxic Enforcement Act of 1986.[4] Commonly known as "Prop. 65," the statute generally requires warnings for environmental, consumer and occupational exposure to particular chemicals.[5] In June 1997, the Occupational Safety and Health Administration ("OSHA") limited Prop. 65's requirements for work place exposure to California manufacturers.[6] OSHA's ruling expressly excluded "consumer products."[7] In

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1. Jack McCarthy, *Toxic Showdown*, THE PRESS-ENTERPRISE (Riverside, Cal.), Feb. 16, 1998, at A1.

2. *Id.*

3. *See id.* In 1996, the California Attorney General's office "sought legislation that would give it oversight of Prop. 65 cases and authority to screen any deemed frivolous. The measure failed to get the two-thirds majority required to reconsider an initiative." *Id.*

4. CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (West 2000).

5. *See id.*

6. *See* Supplement to California Plan, 62 Fed. Reg. 31159 (June 6, 1997).

7. *See id.* "Proposition 65 also is applicable to non-occupational (i.e. consumer and environmental) exposures. OSHA has no authority to address Proposition 65's non-occupational applications; consequently, they are not at issue in this decision and will be unaffected by it." *Id.*

1992 and 1997, the Ninth Circuit Court of Appeals and the California Court of Appeal rejected industry arguments that the Federal Hazardous Substances Act ("FHSA") preempts Prop. 65.[8]

This article concludes the Ninth Circuit Court of Appeals and the California Court of Appeal erred. First, the article reviews the statutes and their purposes. Second, the article reviews key Supreme Court decisions and their implementation by California courts. Finally, the article suggests a method by which the Consumer Product Safety Commission ("CPSC"), by exercising its congressionally mandated power, can clarify Congress's intent to preempt "right-to-know" statutes such as Prop. 65, and harmonize Prop. 65 with the FHSA.

II. The Statutes

A. The Federal Hazardous Substances Act.

Congress has designed various "labeling" statutes to protect consumers by requiring producers to label their products in a specific manner.[9] In 1960, Congress recognized advancements in the field of applied chemistry necessitated specific legislation for household consumer products.

> At the time of passage of the Federal Caustic Poison Act in 1927 the number of household chemical compounds in use was extremely limited. The act called for the labeling of only 12 caustic and corrosive alkalis and acids. Other laws—the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act—include requirements for certain descriptive labeling, but, in the aggregate, the scope of these acts is not sufficient today. There are numerous hazardous chemicals used in the household which are not subject to any of the above-mentioned laws.[10]

Moreover, annual statistics demonstrated that inadequate labeling harmed children.

> The U.S. Public Health Service estimates that every year some 600,000 children swallow household acids and that about 500 children die each year as a result of such accidents. In addition, many adults are injured or killed each year by household substances that do not bear adequate cautionary labels.
>
> For example, a number of household silver polishes contain deadly cyanide, and over the years a number of deaths have been caused by the ingestion of such polish by children. A number of household dry cleaning preparations contain carbon tetrachloride, a potent liver poison that may cause serious injury or even death if used without adequate ventilation. Numerous other chemicals not covered by the Federal Caustic Poison Act are capable of causing, and have caused, tragic accidents, when used in the home improperly. The bill is intended to require a cautionary labeling of such hazardous articles, to provide householders and their families with adequate instructions for safe use of the materials, and to provide when necessary, adequate first-aid instructions for treatment of such injuries as occur.[11]

Congress determined that federal legislation requiring labeling would minimize these tragedies. Congress enacted the Federal Hazardous Substances Act ("FHSA") to

8. *See* Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992); People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368 (1997).

9. *See, e.g.*, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136(p)(2) (2000); Poison Prevention Packaging Act of 1970 (PPPIA), 15 U.S.C. § 5 1471(5) (2000); Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 321(m) (2000); Poultry and Poultry Products Inspection Act, 21 U.S.C. § 453(s) (2000); Meat Inspection Act, 21 U.S.C. § 601(p) (2000).

10. H.R. REP. NO. 1861 (1960), *reprinted in* 1960 U.S.C.C.A.N. 2833, 2834-35.

11. *Id.*

> provide for nationally uniform requirements for adequate cautionary labeling of hazardous substances which are sold in interstate commerce and are intended or suitable for household use. . . .
>
> . . . .
>
> . . . This bill covers substances which are toxicants, corrosives, irritants, strong sensitizers, flammable, and also substances which generate pressure. It also covers any radioactive substance (other than those mentioned below) if, with respect to such substance as used in a particular class of article or as packaged, the Secretary of Health, Education, and Welfare determines by regulation that it is sufficiently hazardous to require labeling in order to protect the public health. The Secretary also may, by regulation, declare to be a hazardous substance any substance which he finds meets the requirements of the basic definition of this term in the bill, if such action would promote the objectives of this legislation by avoiding or resolving uncertainty as to its application.
>
> Excluded from the proposed legislation are economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act and food, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act (which for purposes of cautionary labeling would remain subject to the provisions of the Federal Caustic Poison Act), substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house, and any source material, special nuclear material, or by-product material as defined in the Atomic Energy Act of 1954, as amended, and regulations pursuant thereto by the Atomic Energy Commission.[12]

In passing the FHSA, Congress recognized uniform labeling benefits both children and adults:

> The nationwide uniformity in the labeling of potentially hazardous chemicals would be advantageous to everybody. Such a labeling program would facilitate the education of the public in the cautionary use of these products. Informative, uniform labeling would enable physicians to administer antidotes immediately rather than waste precious time in determining the active ingredients of the products.[13]

Absent federal legislation, Congress feared states would enact their own labeling statutes, "leading to a multiplicity of requirements and creating unnecessary confusion in labeling, to the detriment of the public."[14] For example, multiple state warning requirements, as Congress noted concerning minor hazard warning requirements, would create a situation where

> hardly. . . any substance going into the household . . . would not have to bear cautionary labeling, so that consumers would tend more and more to disregard label warnings, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness.[15]

The FHSA requires a label for "hazardous substances"[16]—"including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted" that is packaged to be used in a household or by a child—to contain the following information:

12. *Id.* at 2833-34.
13. *Id.* at 2835.
14. *Id.*
15. *Id.* at 2837.
16. *See* 15 U.S.C. § 1261(f) (defining hazardous substance).

> (1) (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Commission by regulation permits or requires the use of a recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as "Flammable," "Combustible," "Vapor Harmful," "Causes Burns," "Absorbed Through Skin," or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Commission pursuant to section 1262 of this title; (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as "highly toxic" by subsection (h) of this section; (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or (ii) if the article is intended for use by children and not a banned hazardous substance, adequate directions for the protection of children from the hazard.[17]

Congress patterned the FHSA, including its definitions, after its companion statute, the Food, Drug and Cosmetic Act.[18] The FHSA defines "label" to mean

> a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto.[19]

Congress also imposes additional requirements:

> a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to comply with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise.[20]

Although Congress did not define "labeling" in the FHSA, it vested the FHSA's regulatory body with "[t]he authority to promulgate regulations for the efficient enforcement of this chapter."[21] Exercising this authority, the FHSA regulatory bodies define necessary terms.

As originally drafted, the FHSA did not expressly preempt state labeling requirements. However, the FHSA's legislative history demonstrates a clear intent to preempt state labeling requirements.[22] In 1966, Congress amended the FHSA to formally recognize the statute's preemptive effect.[23] Moreover, the FHSA's original regulatory body, the Food and Drug

17. 5 U.S.C. § 1261.

18. *See* H.R. Rep. No. 1861, *supra* note 11, at 2839.

19. 15 U.S.C. § 1261(n). "'Label' is defined, as in the Federal Food, Drug, and Cosmetic Act, as a display of written, printed, or graphic matter upon the immediate container of any substance." H.R. Rep. No. 1861, *supra* note 11, at 2839.

20. H.R. Rep. No. 1861, *supra* note 11, at 2839.

21. 15 U.S.C. § 1269(a). Originally, the Food and Drug Administration, through the Secretary of Health, Education, and Welfare, presided over the FHSA. Congress subsequently transferred the regulatory authority to the Consumer Product Safety Commission ("CPSC"). *See* 15 U.S.C. § 2079(a).

22. *See* H.R. Rep. No. 1861, *supra* note 11.

23. 1966 U.S.C.C.A.N. 1521, 1524.

Administration ("FDA"), recognized Congress's preemptive intent and, exercising its regulatory authority, drafted the necessary regulation.[24] The FDA also defined "precautionary labeling" in the regulation as labeling that includes such information as warnings, registration or identification numbers, disclosure of hazards, antidote information, ingredient statements, and other similar labeling requirements.[25] When Congress transferred regulatory authority to the Consumer Product Safety Commission ("CPSC"), CPSC also promulgated a "preemption" regulation[26] and adopted the FDA's "precautionary labeling" definition.[27]

In 1976, Congress amended the FHSA to reflect CPSC's preemption regulation:

> With regard to the Federal Hazardous Substances Act, that legislation does not contain a preemption clause applicable to regulations used to determine when a hazardous substance or article shall be a banned hazardous substance or article. While the promulgation of such standards under the Hazardous Substances Act will assist manufacturers in complying with the Act and will assist the Commission in enforcing its provisions, the Committee action will clarify the preemptive effect of these regulations.[28]

The FHSA preemption clause provides:

> (b)(1)(A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a *cautionary labeling* requirement under section 2(p) or 3(b) designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a *cautionary labeling* requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such *cautionary* labeling requirement is identical to the labeling requirement under section 2(p) or 3(b).[29]

Congress's 1976 amendment limited the FHSA's preemptive effect, but it did not eliminate the FHSA's preemptive authority.[30] Therefore, CPSC revoked its preemption regulation:

> In May 1976 Congress amended the FHSA preemption provision, section 18(b). . . . The regulation that implemented the 1966 version . . . became incompatible with the new statutory provision. Therefore, the Commission is now revoking this regulation. . . .

24. "Federal preemption applies both to household substances and articles required to be labeled in accordance with the act, and to household substances and articles not required to be labeled in accordance with the act because they are not 'hazardous substances' as defined in section 2(f) of the act or because they have been exempt from labeling pursuant to a regulation promulgated by the Commissioner. Federal preemption applies to any nonuniform labeling requirements, regardless of whether it conflicts with or is incompatible with the Federal requirement." 37 Fed. Reg. 18,628, 18,629 (1972).

25. *Id.*

26. *See* 16 C.F.R. § 1500.7(b). "Federal preemption applies (1) to household substances and articles required to be labeled in accordance with the act and (2) to household substances and articles not required to be labeled in accordance with the act because they (i) are not 'hazardous substances' as defined by section 2(f) of the act (repeated in section 1500.3(b)(4)) or (ii) are exempt from labeling under a regulation promulgated by the Commission. Federal preemption applies to any nonuniform labeling requirement, regardless of whether it conflicts with or is incompatible with the Federal Requirement." 38 Fed. Reg. 27,012, 27,016 (1973).

27. S*ee* supra note 24 and accompanying text.

28. 1976 U.S.C.C.A.N. 1003.

29. Consumer Product Safety Commission Improvements Act of 1976, Pub. L. No. 94-284, § 17, 90 Stat. 510 (1976) (emphasis added). Sections 2(p) (15 U.S.C. Sec. 1261(p)) and 3(b) (15 U.S.C. Sec. 1262(b)) dictate label and labeling's content.

30. "The original FHSA 'limited preemption amendment,' adopted in 1966, declared Congress's intent to 'supersede any and all laws of the States . . . insofar as they may . . . provide for cautionary labeling of any substance or article intended for household use . . . which differs from the requirements or exemptions of this Act.' In 1976, Congress amended the provision and limited preemption to instances where there is a federal labeling requirement in effect and a State imposes a different labeling requirement that seeks to warn about the same hazards." Chemical Specialties Mfrs. Ass'n v. Allenby, 744 F. Supp. 934, 937 n.4 (N.D. Cal. 1990), *aff'd*, 958 F.2d 941 (9th Cir. 1992).

> [T]he Commission finds that a notice and comment rulemaking procedure is unnecessary because the statutory *basis of the existing* FHSA *preemption regulation no longer exists*.[31]

However, CPSC simultaneously revoked its "precautionary labeling" definition.[32] Therefore, "precautionary labeling" or its nomenclature "cautionary labeling" remains undefined.

B. Proposition 65.

In December 1984, a Union Carbide plant producing pesticides released methyl isocyanate, a toxic gas, near Bhopal, India, killing and injuring thousands.[33] In response, federal and state governments enacted "right-to-know" statutes.[34] Typically, these statutes require an administrative authority, such as the Environmental Protection Agency ("EPA"), to identify and publish a list of "extremely hazardous substances."[35] A facility releasing certain quantities of the substances must warn various agencies of the release.[36]

In 1986, California voters approved their own "right-to-know" statute. The purpose of the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Prop. 65") was "to identify chemicals known to cause cancer or birth defects, and to prevent exposure to those chemicals through our water supplies, in the workplace, and by other means."[37] Prop. 65 mimics many features found in "right-to-know" statutes. For example, it requires the Governor "to publish a list of those chemicals known to the state to cause cancer or reproductive toxicity. . . and cause such list to be revised in light of additional knowledge at least once per year thereafter."[38] Furthermore, Prop. 65 also contains a warning provision. Prop. 65 provides that

> no 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.[39]

Prop. 65 fails to define "warning," but explains:

> "warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided the warning accomplished is clear and reasonable.[40]

This emulates the Emergency Planning and Community Right-to-Know Act of 1986, which requires the owner or operator of a facility that releases a listed substance to notify the public "by such means as telephone, radio, or in person."[41] Prop. 65 also contains a citizen enforcement provision. This provision states that

31. 47 Fed. Reg. 57,489 (1982) (emphasis added).

32. *See id*.

33. *See Anniversaries*, THE TIMES (London), Dec. 3, 1997 ("More than 3,000 people were killed as a result of a chemical spillage at the Union Carbide pesticide factory in Bhopal, India, [December, 1984.").

34. *See, e.g.*, Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. §§ 1101–05 (2000). The "Right-to-Know" "provisions were developed in large part as a result of the terrible disaster in Bhopal, India, at which deadly fumes of methyl isocyanate, a pesticide, intermediate, were released accidentally into a sleeping community, resulting in death or injury to thousands of people." 132 CONG. REC. 14,895 (1986).

35. *See, e.g.*, 42 U.S.C. § 11002 (2000).

36. *See, e.g.*, 42 U.S.C. § 11004 (2000).

37. Nicolle-Wagner v. Deukmejian, 230 Cal. App. 3d 652, 655 (1991).

38. CAL. HEALTH & SAFETY CODE § 25249.8 (West 2000).

39. *Id*. § 25249.6 (emphasis added). The statute also exempts persons employing fewer than ten persons. *See id*. § 25249.11(b).

40. *Id*. § 25249.11(f). *See also* Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941, 944 (9th Cir. 1992); People *ex rel*. Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 377 (1997). Furthermore, Prop. 65's regulations "describe four types of 'safe harbor' warnings for consumer products: product labeling, 'shelf labeling, signs, menus, or a combination thereof.'" *Cotter*, 62 Cal. Rptr. 2d at 372 (citing CAL. CODE REGS. tit. 22, § 12601(b)(1)(B)).

41. 42 U.S.C. § 11004(b).

> [a]ctions pursuant to this section may be brought by any person in the public interest if (1) the action is commenced more than sixty days after the person has given notice of the violation which is the subject of the action to the Attorney General and the district attorney and any city attorney in whose jurisdiction the violation is alleged to occur and to the alleged violator, and (2) neither the Attorney General nor any district attorney nor any city attorney or prosecutor has commenced and is diligently prosecuting an action against such violation.[42]

Since June 1997—when OSHA ruled that Prop. 65 does not apply to manufacturers outside of California—the California Attorney General has received more than 500 pages of Prop. 65-required 60-day notices.[43] From this list, it appears that Prop. 65 "bounty hunters," i.e., private enforcers, prey upon out of state companies.

III. The California Courts Avoid Preemption

Subsequent to Prop. 65's enactment, various industries claimed federal statutes preempted Prop. 65's requirements.[44] In P*eople ex rel. Lungren v. Cotter and Company*[45] and C*hemical Specialties Manufacturers Association v. Allenby*,[46] the courts rejected industry claims that the FHSA preempts Prop. 65's labeling requirements.

In C*hemical Specialties*, plaintiff Chemical Specialties Manufacturers Association, Inc. ("CSMA"), filed a declaratory judgment action seeking a ruling that the FHSA preempted Prop. 65.[47] CSMA argued Prop. 65 frustrates Congress's purpose for passing the FHSA, i.e., to set nationwide uniformity in labeling of potentially hazardous chemicals.[48] Furthermore, CSMA argued the FHSA preempts "all state mandated precautionary labeling that is not identical" to the FHSA's requirements.[49] The court, however, held Prop. 65 complemented, rather than contradicted, the FHSA warnings: "A retail outlet can comply with Proposition 65 by posting a sign in a visible place specifying the products that are known to the state to cause cancer or that are reproductive toxic."[50] This is known as a "point-of-sale" warning.[51]

The court held three reasons precluded the FHSA from preempting Prop. 65. First, the court defined "cautionary labeling" to include "directions for use"; however, Prop. 65's "point-of-sale" warnings contained no "directions for use."[52] The point-of-sale warnings do not

> tell you whether it's going to cause defects if you pour it on your feet, or if you drink it, or if you poke it in your ear, it just says that it may cause birth defects. How is that a direction for use?[53]

Second, the court held Prop. 65 warnings are not identical as required by the FHSA's preemption clause:

> FHSA does not require any specific language in its warnings. The Act merely requires (1) that labels contain the signal word "WARNING" or "CAUTION" and (2) words which describe the potential hazard. Consequently, a message such as the following could comply with both Proposition 65 and the FHSA: "Warning, this product contains

42. CAL. HEALTH & SAFETY CODE § 25249.7.

43. Proposition 65 Notice Report, list of 60-day notices (on file with the California Attorney General and the United States House of Representatives Committee on Small Business).

44. S*ee, e.g.*, D-Con Co., Inc. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989) (Federal Insecticide, Fungicide, and Rodenticide Act); Committee of Dental Amalgam Mfrs. & Distrib. v. Stratton, 92 F.3d 807 (9th Cir. 1996) (Medical Device Amendments to the Food, Drug and Cosmetics Act); Industrial Truck Ass'n v. Henry, 125 F.3d 1305 (9th Cir. 1996).

45. 62 Cal. Rptr. 2d 368.

46. 958 F.2d 941 (9th Cir. 1992).

47. I*d.* at 942.

48. I*d.* at 945.

49. I*d.* at 949.

50. I*d.* at 944.

51. I*d.* at 945.

52. I*d.* at 949.

53. I*d.*

> materials known to the State of California to cause cancer."[54]

Finally, the court held Prop. 65 did not frustrate any congressional purpose:

> On the one hand, a national safety standard would ease the burden of compliance for chemical product manufacturers by relieving them from the burden of complying with fifty-one separate regulatory schemes promulgated by each state and the federal government. On the other hand, such a standard would take police powers away from the state who best knows how to service the interests of their citizenry. The preemption clause in FHSA balances these competing concerns by leaving cautionary labeling requirements to the federal government while allowing states to regulate the sale and use of hazardous chemicals. Proposition 65 warnings do not constitute cautionary labeling preempted by FHSA.[55]

California refined these arguments in *Cotter*.[56] In *Cotter*, defendant Cotter & Company ("Cotter") challenged a lower court decision that the FHSA did not preempt Prop. 65. Cotter argued *Cipollone*,[57] a case in which the United States Supreme Court held statutorily required cigarette warnings preempted failure to warn claims, rendered Chemical Specialties' analysis no longer good law. The *Cotter* court, however, disagreed.

First, the court found that *Medtronic*,[58] decided after *Cipollone*, held that federal labeling statutes with general applicability do not preempt state labeling requirements that "are unlikely to interfere with the federal government's objective."[59] The court reasoned that the "predicate duty" analysis used in *Cipollone* used to preempt the failure to warn claims "does not apply when both the federal and state statutes require a general warning for a variety of products and do not target specific products." [60] Therefore, the court concluded, *Medtronic* supported *Allenby's* holdings that Prop. 65 and the FHSA's warnings are "nonidentical" and Prop. 65 does not frustrate any congressional purpose.[61]

Second, the *Cotter* court sustained Allenby's conclusion that "point-of-sale" signs do not constitute "cautionary labeling" under the FHSA:

> The act defines label as a "display of written, printed, or graphic matter upon the immediate container of any substance . . . and (2) on all accompanying literature where there are directions for use or otherwise." . . . .
>
> Congress chose to restrict the definition of a label to include accompanying literature only when that material contains "directions for use." . . . These words indicate the warning must tell the user how to use the product. This situation resembles the one in Medtronic, where the court refused to interpret "requirement" in the preemption provision of the MDA to mean "remedy" because ". . . if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it." . . . Similarly, if Congress wanted preemption under the FHSA to apply to all accompanying literature with "implied" directions for use, as Cotter argues, Congress could have specified that.[62]

Therefore, California courts hold the FHSA does not preempt Prop. 65 because (1) Prop. 65, a general warning statute, does not interfere with a specific federal interest found in a

54. *Id.*
55. *Id.* at 950.
56. 62 Cal. Rptr. 2d 368 (1997).
57. 505 U.S. 504 (1992).
58. 518 U.S. 470 (1996).
59. 62 Cal. Rptr. 2d at 379.
60. *Id.* at 1386.
61. *See id.*
62. *Id.* at 1387.

general warning statute; and (2) "cautionary labeling" includes "directions for use," and Prop. 65 requires no directions for use. Analyzing the Supreme Court cases identified by *Allenby* and *Cotter*, subsequent case law, the FHSA's legislative history, and Congress's usage of "labeling" in similar statutes clearly demonstrates the Allenby and Cotter courts erred. First, the analysis demonstrates Prop. 65 requires a specific warning for a discernible product class and interferes with a particular federal interest. Second, the analysis finds no current "cautionary labeling" definition, but previous definitions did not include a "directions for use" element. Therefore, the California courts erred in refusing to recognize the FHSA preempts Prop. 65.

A. The FHSA Preempts State Court Actions.

1. Preemption.

The Supremacy Clause of the United States Constitution provides:

> This Constitution and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the 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.[63]

Federal law preempts state law in three circumstances:

> (1) express preemption, where Congress explicitly defines the extent to which its enactments preempt state law; (2) field preemption, where state law attempts to regulate conduct in a field that Congress intended the federal law exclusively to occupy; and (3) conflict preemption, where it is impossible to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress.[64]

These categories are not "inflexible" as "[a] state law that falls within a pre-empted field conflicts with Congress's [sic] intent (either expressly or plainly implied) to exclude state regulations."[65] When Congress preempts a field, "state law that conflicts with federal law is 'without effect.'"[66]

States "traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."[67] Generally, "the historic police powers of the State are not to be superseded by Federal law unless that is the 'clear and manifest purpose of Congress.'"[68] Courts discern Congress's purpose from "the language of the pre-emption statute and the 'statutory framework' surrounding it."[69] However, courts also find the "'structure and purpose of the statute as a whole,' as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law."[70]

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and

63. U.S. CONST. art. VI, cl. 2.

64. Industrial Truck Ass'n v. Henry, 125 F.3d 1305, 1309 (9th Cir. 1997) (citing English v. General Elec. Co., 496 U.S. 72, 78-80 (1990); Southern Pac. Transp. Co. v. Public Util. Comm'n, 9 F.3d 807 (9th Cir. 1993)).

65. *Id.* (citing *English*, 496 U.S. at 79 n.5).

66. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).

67. Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996) (quoting Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756 (1985)).

68. Busch v. Graphic Color Corp., 644 N.E.2d 839, 842 (Ill. App. Ct. 1995) (citing Farner v. Brunswick Corp., 607 N.E.2d 562, 565 (Ill. App. Ct. 1992)). *See also Industrial Truck Ass'n*, 125 F.3d at 1309 (citing Law v. General Motors Corp., 114 F.3d 908, 909-10 (9th Cir. 1997)).

69. *Medtronic*, 518 U.S. at 486.

70. *Id.*

> when that provision provides a 'reliable indicium of congressional intent with respect to state authority,' 'there is no need to infer congressional intent to pre-empt state laws from the substantive provisions' of the legislation. Such reasoning is a variant of the familiar principle of expressio unius est exclusio alterius: Congress's enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.[71]

"Since the FHSA does have a specific pre-emption clause, we need to determine 'the domain expressly pre-empted.'"[72]

2. The FHSA preempts "failure to warn" claims.

Prop. 65 bars businesses from exposing an individual "to a chemical known to the state to cause cancer or reproductive toxicity *without first giving clear and reasonable warning to such individual*."[73] At its core, Prop. 65 codifies a particular "duty to warn." Prior to the 1976 amendments, courts recognized the FHSA preempted a statutorily imposed "duty to warn," *e.g.*, a "right-to-know" statute. [74] Subsequently, courts recognized the FHSA preempts a common law "duty to warn" claim.

Like a common law-imposed "duty to warn," Prop. 65 imposes upon businesses a duty to warn when California's government determines that a consumer product contains a chemical believed to cause cancer or birth defects.[75] Unlike a typical common law claim, a typical Prop. 65 claim rests upon a business's failure to satisfy a specific "duty to warn." A court's inquiry into whether the FHSA preempts a "failure to warn" claim is straightforward: courts ask whether the legal duty that is the claim's predicate meets "cautionary labeling requirements for hazardous substances which are different from and are designed to protect against the same risk of illness or injury as those imposed by the FHSA."[76] Courts routinely hold the FHSA preempts common law "failure to warn" claims that impose cautionary labeling requirements; Prop. 65 is no exception.

Medtronic, Inc. v. Lohr[77] and *Cipollone v. Liggett Group, Inc.*[78] are the seminal cases "that address the issue of federal preemption inadequate labeling and failure-to-warn claims brought under state law."[79] Together, these cases hold that a federal labeling statute preempts a "failure to warn" claim predicated upon "additional [or] more clearly-stated warnings" within the preemptive scope, while claims predicated upon a "general duty to inform users and purchasers of potentially dangerous items of the risks involved" are not preempted.[80] The California courts, however, ignore the Cipollone and Medtronic directions.

The California courts hold both the FHSA and Prop. 65 are general warning statutes that apply to a non-identifiable product class. The court in *Cotter*, cites *Medtronic* for the proposition that "courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability."[81]

71. *Cipollone*, 505 U.S. at 517 (citations omitted).

72. People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 378 (citing *Cipollone*, 505 U.S. at 517). Notwithstanding the court's holding, the FHSA appears to expressly preempt state cautionary labeling. *See* Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976).

73. CAL. HEALTH & SAFETY CODE § 25249.6 (West 2000) (emphasis added).

74. Chemical Specialties Mfrs. Ass'n v. Clark, 482 F.2d 325, 328 (5th Cir. 1973); Chemical Specialties Mfrs. Ass'n v. Lowery, 452 F.2d 431, 440 (2d Cir. 1971).

75. CAL. HEALTH & SAFETY CODE § 25249.6.

76. Busch v. Graphic Color Corp., 662 N.E.2d 397, 341 (Ill. 1996). *See also* Gurrieri v. William Zinsser & Co., 728 A.2d 832 (N.J. Super. Ct. App. Div. 1999); Canty v. Ever-Last Supply Co., 685 A.2d 1365 (N.J. Super. Ct. Law Div. 1996). *Cf. Cipollone*, 505 U.S. at 523-24 (1992) ("The central inquiry in each case is straightforward: we ask whether the legal duty that is the predicate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion,' giving that clause a fair but narrow reading.").

77. 518 U.S. 470 (1996).

78. 505 U.S. 504.

79. *Gurrieri*, 728 A.2d at 836.

80. *Cipollone*, 505 U.S. 504; Medtronic v. Lohr, 518 U.S. 470 (1996); *Gurrieri*, 728 A.2d 832.

81. People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 375 (1997).

Applying this rationale, *Cotter* assumes

> predicate duty analysis does not apply when the federal statute merely requires a general duty to inform users and purchasers of potentially dangerous items. When the predicate for the plaintiff's claims is the general duty to inform users and purchasers of potentially dangerous items and the federal government has not implemented or enforced specific federal requirements, general obligations imposed by the state do not threaten the federal requirements.[82]

Therefore, *Cotter* concludes *Cipollone* and *Medtronic* preclude Prop. 65's preemption. Neither case, however, supports *Cotter's* analysis.

In *Cipollone*, plaintiff, Thomas Cipollone [83] ("Cipollone"), claimed defendants caused Rose Cipollone's death because, among other things, "they failed to warn consumers about the hazards of smoking [and] . . . they fraudulently misrepresented those hazards to consumers."[84] Defendants argued the Federal Cigarette Labeling and Advertising Act of 1965 and its successor, the Public Health Cigarette Smoking Act of 1969, preempted Cipollone's claim and the Court agreed.

The Court analyzed several statutes. In 1965, Congress passed the Federal Labeling and Advertising Act ("1965 Act"):

> Section 2 of the Act declares the statute's two purposes: (1) adequately informing the public that cigarette smoking may be hazardous to health, and (2) protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations.[85]

The 1965 Act defined "cigarette" as:

> (A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and
>
> (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchase by, consumers as a cigarette described in subparagraph (A).[86]

In order to maintain nationally uniform cigarette labeling standards, Congress enacted a "preemption" provision. Section 5, in pertinent part, provided the following:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
>
> (b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.[87]

In 1969, Congress enacted the Public Health Cigarette Smoking Act of 1969 ("1969 Act"), which amended the 1965 Act, section 5(b). The 1969 Act, section 5(b), provided the following:

> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.[88]

82. *Id.* at 385 (citations omitted).

83. Rose Cipollone and her husband filed suit. Subsequently, both died and Thomas Cipollone, their son and executor, maintained the action. *See Cipollone*, 505 U.S. at 509.

84. *Id.* at 508.

85. *Id.* at 514.

86. 15 U.S.C. § 1332(1) (2000).

87. *Cipollone*, 505 U.S. at 514.

88. *Id.* at 515.

The 1965 Act prohibited state and federal rulemaking bodies "from mandating particular cautionary statements on cigarette labels or in cigarette advertisements."[89] Cipollone's claims involved common law duties, not state mandated action. Therefore, the 1965 Act did not preempt Cipollone's claim.

The 1969 Act, however, broadened the preemption clause. The 1969 Act barred all "requirements or prohibitions" regarding the "advertising or promotion" of cigarettes[90] The "requirements or prohibitions" language included common-law damages actions:

> The phrase "no requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed, is designed to be, a potent method of governing conduct and controlling policy."[91]

Furthermore, the existence of a legal duty, necessary for Cipollone's common law damages claim, imposes a "requirement or prohibition":

> It is in this way that the 1969 version of Sec. 5(b) differs from its predecessor: Whereas the common law would not normally require a vendor to use any specific statement on its packages or in its advertisements, it is the essence of the common law to enforce duties that are either affirmative requirements or negative prohibitions. We therefore reject petitioner's argument that the phrase "requirement or prohibition" limits the 1969 Act's pre-emptive scope to positive enactments by legislature and agencies.[92]

To determine whether Section 5(b) preempted Cipollone's "failure to warn" and fraud claims, "[t]he central inquiry in each case is straightforward: we ask whether the legal duty that is the predicate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion,' giving that clause a fair but narrow reading."[93]

A "failure to warn" claim requires, among other things, evidence that "a warning is necessary to make a product . . . reasonably safe, suitable and fit for its intended use."[94] Cipollone claimed defendants failed "to provide 'adequate warnings of the health consequences of cigarette smoking.'"[95] In other words, Cipollone claimed the law required defendants to include additional label language that highlighted smoking's dangers. The 1969 Act, the Court found, preempted Cipollone's "failure to warn" claim to the extent the claim required "a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings."[96]

Likewise, the 1969 Act preempted Cipollone's fraud claims. Cipollone claimed defendants, through advertising, minimized smoking's health effects and failed to disclose its dangers. Cipollone's "minimization" claim "is merely the converse of a state-law requirement that warnings be included in advertising and promotion materials."[97] The 1969 Act partially preempted Cipollone's "fraudulent concealment" claim.

89. I*d*. at 518.

90. I*d*. at 520.

91. I*d*. at 521 (citing San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)).

92. I*d*. at 522 (emphasis omitted).

93. C*ipollone*, 505 U.S. at 523-24.

94. I*d*. at 524.

95. I*d*.

96. I*d*.

97. I*d*. at 527 (emphasis omitted).

> The predicate of this claim is a state-law duty not to make false statements of material fact or to conceal such facts. Our pre-emption analysis requires us to determine whether such a duty is the sort of requirement or prohibition proscribed by sec. 5(b).
>
> Section 5(b) pre-empts only the imposition of state-law obligations "with respect to the advertising or promotion" of cigarettes. [Cipollone's] claims that [defendants] concealed material facts are therefore not pre-empted insofar as those claims rely on a state-law to disclose such facts through channels of communication other than advertising or promotion. Thus, for example, if state law obliged [defendants] to disclose material facts about smoking and health to an administrative agency, sec. 5(b) would not pre-empt a state-law claim based on a failure to fulfill that obligation.[98]

In short, the 1969 Act preempted Cipollone's claims to the extent they sought to add, detract or clarify a "requirement or prohibition" concerning cigarette "advertising or promotion," but did not preempt other claims.

Medtronic, Inc. v. Lohr applies *Cipollone's* reasoning to instances when a federal statute does not preempt a state cause of action. In *Medtronic*, Medtronic, Inc. ("Medtronic"), manufactured a pacemaker lead.[99] Lora Lohr depended on a pacemaker for proper heart function. In 1990, Lora Lohr's Medtronic pacemaker failed. The Lohrs[100] sued, claiming Medtronic "failed to warn" of the pacemaker's tendency to fail. Medtronic claimed the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act ("MDA") preempted her claims. The Court, however, disagreed.

Congress passed the MDA "to provide for the safety and effectiveness of medical devices intended for human use."[101] Generally, the MDA establishes a system by which the FDA approves medical devices for consumer use. The FDA approves some products, such as Medtronic's lead, absent review because a "substantially equivalent" medical device is already marketed. The MDA requires labeling regulations

> that require manufacturers of every medical device with a few limited exceptions, to include with the device a label containing "information for use, . . . and any relevant hazards, contraindications, side effects and precautions."[102]

Congress also enacted a MDA preemption provision. 21 U.S.C. § 360k(a) states:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[103]

Contrary to *Cipollone*, *Medtronic* held the MDA did not preempt Lohrs' "failure to warn" claim.

> The pre-emptive statute in Cipollone was targeted at a limited set of state

98. *Id.* at 528.

99. "The lead is the portion of a pacemaker that transmits the heartbeat-steadying electrical signal from the 'pulse generator' to the heart itself." 518 U.S. 470, 480 (1996).

100. Lora Lohr's husband also joined the suit.

101. *Id.* at 474.

102. *Id.* at 497 (citing 21 C.F.R. §§ 801.109(b), (c) (1995)).

103. *Id.* at 481.

> requirements—those "based on smoking and health"—and then only at a limited subset of the possible applications of those requirements—those involving the "advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of" the federal statute.[104]

By contrast,

> [t]he legal duty that is the predicate for the Lohrs' failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements, therefore, escape pre-emption not because of the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that sec. 360k envisioned to be "with respect to" specific devices such as pacemakers.[105]

Preemption, the Court continued, occurs "only where a particular state requirement threatens to interfere with a specific federal interest."[106] The MDA regulations require medical device manufacturers to include on a product's label information for use, any relevant hazards, contraindications, side effects and precautions as well as to comply with the Good Manufacturing Practices.[107] Furthermore, the MDA regulations exclude from preemption

> State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices. The regulations specifically provide, as examples of permissible general requirements, that general electrical codes and the Uniform Commercial Code warranty of fitness would not be pre-empted. The regulations even go so far as to state that sec. 360k(a) generally "does not preempt a state or local requirement prohibiting the manufacture of adulterated or misbranded devices" unless "such a prohibition has the effect of establishing a substantive requirement for a specific device."[108]

The MDA's general nature, the Court concluded, and the requirement's generality,

> make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implement that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field device regulation that the statute or regulations were designed to protect from contradictory state requirements.[109]

Therefore, the Court found the MDA did not preempt Lohrs' claims.

Assuming the California courts correctly analyzed C*ipollone* and M*edtronic*, the FHSA never

104. 518 U.S. at 488 (citing Cipollone v. Liggett, 505 U.S. 504, 515 (1992)).

105. I*d*. at 501 (emphasis added).

106. I*d*. at 500.

107. I*d*. at 497.

108. I*d*. at 499.

109. I*d*. at 501.

preempts a state "failure to warn" claim. The *Cotter* court's analysis renders the *Cipollone* "predicate duty" analysis inapplicable because both the FHSA and a state duty to warn "require a general warning for a variety of products and do not target specific products."[110] This means "failure to warn" claims would "escape pre-emption not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements [the federal statute] envisioned to be [preempted]."[111] In other words, the duty is too general to identify a specific product category to which it would apply. No "predicate duty" analysis appears fatal to federal preemption clauses. However, in *Etcheverry v. Tri-Ag Service, Inc.*, the California Supreme Court rejected such an analysis with respect to FIFRA.[112] Furthermore, courts subsequent to *Medtronic* routinely hold the FHSA preempts "failure to warn" cases to the extent plaintiffs propose "additional, different, or more clearly-stated warnings."[113] *Gurrieri v. William Zinsser and Co.*[114] is the most recent case analyzing the FHSA's preemptive clause.[115]

In *Gurrieri*, plaintiff Dolores Gurrieri ("Gurrieri") suffered inhalation injuries from exposure to a stain blocker manufactured by defendant William Zinsser & Co., Inc. ("William Zinsser").[116] Gurrieri sued William Zinsser claiming its product label failed to warn consumers that a particular chemical in the product presented fatal risks.[117] William Zinsser moved for summary judgment on the grounds that the FHSA preempted Gurrieri's claim.[118] The court agreed and granted the motion.[119]

The court examined the FHSA's preemptive clause, *Cipollone*, and *Medtronic*, recognizing both cases applied the "predicate" analysis *Cotter* avoided,[120] and *Canty v. Ever-Last Supply Co.*[121] The court held that

> [i]n the present case, the 1966 preemption amendment to the FHSA interpreted in light of the intent of Congress to provide "nationally uniform requirements for adequate cautionary labeling," as expressed with the passage of the FHSA in 1960, demonstrates Congress's specific design to preempt state failure-to-warn labeling claims. H.R. Rep. No. 86-1861, at 1 (1960), reprinted in 1960 U.S.C.C.A.N. 2833. This conclusion is also supported by the Supreme Court's reasoning in *Cipollone* which is doctrinally similar to the present case. Both situations demonstrate strong Congressional lan-

110. People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 377 (1997).

111. *Medtronic*, 518 U.S. at 502.

112. 993 P.2d 366 (Cal. 2000).

113. Gurrieri v. William Zinsser & Co., 728 A.2d 832, 841(N.J. Super. Ct. App. Div. 1999). *See also* Torres-Rios v. LPS Labs., Inc., 152 F.3d 11 (1st Cir. 1998); Sabbatino v. Rosin & Sons Hardware & Paint, Inc., 676 N.Y.S.2d 633 (N.Y. App. Div. 1998); Litz v. William Zinsser & Co., 676 N.Y.S.2d 619 (N.Y. App. Div. 1998); Beyrle v. Finneron, 645 N.Y.S.2d 192 (N.Y. App. Div. 1996); Canty v. Ever-Last Supply Co., 685 A.2d 1365 (N.J. Super. Ct. Law Div. 1996).

114. 728 A.2d 832.

115. Interestingly, *Cotter* appears to ignore its own holding. *Cotter* held "courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability." 62 Cal. Rptr. 2d at 375. Accordingly, *Cotter* claimed the FHSA, as a general statute, did not preempt Prop. 65. Similarly, *Cotter* would appear to recognize that a federal warning for specific chemicals, i.e., one of limited applicability, preempts Prop. 65. *See, e.g.*, Papike v. Tambrands, Inc., 107 F.3d 737, 741-43 (9th Cir. 1997) ("In this case, the FDA has promulgated a regulation mandating the specific substantive content of the T[oxic] S[hock] S[yndrome] warnings on tampon boxes and/or tampon package inserts. [Citation omitted.] The regulation is not only device-specific (tampons), but also disease-specific (TSS). This fact distinguishes Papike's case from prior relevant MDA preemption cases."). *Cotter* involved the chemical "toluene." The FHSA provides toluene specific warnings. 16 C.F.R. § 1500.14 (2000). Nevertheless, *Cotter* failed to hold that the FHSA toluene specific warnings preempt Prop. 65. Therefore, the *Cotter* analysis appears to bar any federal labeling statute, whether limited or broad, from preempting Prop. 65.

116. 728 A.2d at 833-34.

117. *See id.* at 833.

118. *See id.* at 834.

119. *See id.*

120. *See id.* at 839.

121. Canty v. Ever-Last Supply Co., 685 A.2d 1365, 1373 (N.J. Super. Ct. Law Div. 1996) (holding that "[w]here a plaintiff's claim seeks to hold a manufacturer responsible for failing to provide warning labels which are not identical to [but stronger than] those required under the FHSA, the claim is preempted [and fails]"). However, "[where] a plaintiff does not seek more elaborate labeling requirements, but rather asserts an alleged failure to comply with the FHSA, such a claim would not impose a 'labeling requirement' and would not be preempted." *Id.* at 1373. As a result, "[the court], based on [its] perception of the 'weight of authority,' concluded that a failure-to-warn claim could be brought only for failure to comply with the FHSA's labeling provisions." *Gurrieri*, 728 A.2d at 840 (citations omitted).

> guage supporting a policy of federal labeling preemption. Similar to the circumstances . . . in the present case, [plaintiff] proposes additional label warnings not "identical" to the labeling requirements under the federal act. . . . [T]o the extent that the plaintiff proposes additional, different, or more clearly-stated warnings, these claims are preempted by the FHSA.[122]

Requiring companies to adopt *Gurrieri's* proposed cautionary labeling, the court reasoned, would frustrate Congress's purpose:

> A finding that specific local warnings pursuant to state law must apply to products containing less than 4% of methyl alcohol would create a system of possibly fifty or more different labeling requirements throughout the country, contrary to Congress's obvious intent in passing the FHSA to "provide nationally uniform requirements for adequate cautionary labeling."[123]

Therefore, the court found the FHSA preempted Gurrieri's "failure to warn" claim.[124]

Unlike the general duties not to manufacture adulterated or misbranded devices or to obey general electric codes as identified in *Medtronic*, the FHSA and Prop. 65 require particular cautionary labeling warnings for specific products. *Cipollone's* Cigarette Labeling Act preempts state law claims so long as cigarette advertising contains requisite warning language. All advertising, however, does not fall within the Cigarette Labeling Act's province. Only an advertisement (i.e., all package labels, billboard advertisement, magazine and newspaper advertisements or sporting event ads) that advertises cigarettes, a term the statute defines, and contain the requisite cautionary labeling fall within the discernible class.[125] Similarly, the FHSA preempted the *Gurrieri* plaintiff's claim because the FHSA required cautionary labeling for a discernible product (i.e., those containing methyl alcohol).[126]

The FHSA requires particular cautionary labeling for a discernible class of consumer products. These include toxicants, corrosives, irritants, strong sensitizers, flammables, and substances that generate pressure.[127] The FHSA excludes poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act and food, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, as well as stored fuels used in heating, cooking, or refrigeration. Furthermore, only those toxics, corrosives, irritants, strong sensitizers or flammables that "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children" are subject to FHSA's cautionary labeling requirements.[128] "Substantial personal injury or substantial illness," the FHSA's legislative history notes,

> should be read in the light of the purposes of the bill. On the one hand, it is not intended to impose the impracticable and self-defeating requirement of cautionary labeling against the wholly insignificant or negligible illness or injury, such as the very temporary indisposition that a child might suffer from eating a piece of the standard type of toilet soap. The committee recognized that virtually every substance used in or about the household is capable of causing some degree of illness or injury if accidentally or intentionally misused. . . . On the other hand, the term "substantial" is not intended to limit the requirement of cautionary labeling to situations in which the injury or illness to be guarded against would be severe or serious.[129]

122. *Gurrieri*, 728 A.2d at 841.
123. *Id.*
124. *See id.*
125. *See id.*
126. *See id.*
127. 960 U.S.C.C.A.N. 2833.
128. *Id.* at 2837.
129. *Id.*

Moreover, CPSC clearly recognizes that "substantial personal injury or substantial illness" includes both cancer and reproductive toxicity. In 1992, CPSC published "Guidelines for Determining Chronic Toxicity of Products Subject to the FHSA." CPSC notes in the Guidelines that

> the definition of "hazardous substance" requires both that the substance fall into one of the designated hazard categories, in this case that of "toxic," and that the substance "may cause substantial personal injury or illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." Any of the chronic hazards, including but not limited to cancer, neurotoxicity or developmental or reproductive toxicity addressed by this notice constitute "personal injury or illness."[130]

FHSA requires products bearing these characteristics to include specific statutory required warnings.[131] Furthermore, courts recognize the FHSA affords the CPSC additional authority to "establish by regulation reasonable variation or additional labeling requirements."[132]

Prop. 65 applies narrower warnings to a narrower product class. Prop. 65 requires a manufacturer to add to its federally mandated cautionary labeling if a product contains a chemical California believes causes cancer or reproductive toxicity. Like the cigarette advertising subject to the Cigarette Labeling Act's preemption, the products containing the chemicals California determines might cause cancer or reproductive toxicity constitute a discernible class that requires Prop. 65's warnings. As with the FHSA, a product falls in the category required to contain a warning simply by containing an identified chemical. Products with such a chemical must warn that the product contains "a chemical known to [California] to cause cancer or reproductive toxicity."[133]

The FHSA preempts Prop. 65's cautionary labeling for consumer products, not food served in food facilities, fresh fruits, nuts and vegetables, or alcoholic beverages. The products covered by the FHSA, i.e., those consumer products containing toxicants, corrosives, irritants, strong sensitizers, flammables or that generate pressure and pose a risk of substantial injury or illness, include chemicals California finds may cause cancer or reproductive toxicity.[134] Furthermore, the FHSA's cautionary labeling requirements include warnings for cancer and reproductive toxicity. Therefore, as the FHSA applies to a discernible class which includes Prop. 65's chemicals and the FHSA requires cautionary labeling that includes reproductive toxicity and cancer, the FHSA preempts Prop. 65.

Claims that require specific warnings for a discernible product class, whether arising from the Gurrieri plaintiff's common law warning or from Prop. 65's statutory warning, resemble those in *Cipollone*, not those in *Medtronic*. Indeed, the *Cipollone* court preempted "failure to warn" claims only for those "advertisements" that advertised cigarettes and contained statutorily required warnings. Likewise, the *Gurrieri* court held the FHSA preempted claims for a hazardous substance, i.e., methyl alcohol, containing the requisite cautionary labeling. By contrast, the *Medtronic* defendant failed to identify either a particular medical device sub-category or particular warnings that might preempt state "general duty" claims. At most, the *Medtronic* defendant identified a general class, i.e., all medical devices, to which a general warning, i.e., to inform users and purchasers of all potential dangers, applied. This differs from the FHSA, which requires specific cautionary labeling (i.e., those found in 15 U.S.C. § 1261

130. 57 Fed. Reg. 46,626 (1992). *See also* Busch v. Graphic Color Corp., 662 N.E.2d 397, 341 (Ill. 1996), (cancer); 56 Fed. Reg. 15,672 (1991) (reproductive toxicity).

131. *See* 15 U.S.C. § 1261.

132. Gurrieri v. William Zinsser & Co., 728 A.2d 832, 836 (N.J. Super. Ct. App. Div. 1999).

133. CAL. HEALTH & SAFETY CODE § 25249.5.

134. *See, e.g.*, Corrosion Proof Fittings v. Environmental Prot. Agency, 947 F.2d 1201 (5th Cir. 1991) (asbestos); A&B Wiper Supply, Inc. v. Consumer Prod. Safety Comm'n, 514 F. Supp. 1145 (E.D. Pa. 1981) (TRIS phosphate).

and the corresponding regulations) for a discernible product class (i.e., those consumer products containing toxicants, corrosives, irritants, strong sensitizers, flammables or that generate pressure and pose a threat of substantial personal injury or illness); and from Prop. 65, which requires specific cautionary labeling (i.e., that a consumer product contains chemicals known to California to cause cancer or reproductive toxicity) to a specific product class (i.e., those consumer products containing chemicals California determined may cause cancer or reproductive toxicity).

In short, if a court identifies federal warnings or cautionary labeling and a discernible class to which the cautionary labeling or warnings apply, if intended, the federal requirements preempt state warnings for a similarly discernible state class. Prop. 65 establishes a substantive requirement, i.e., cautionary labeling not identical to the FHSA's cautionary labeling requirements, for a particular device, i.e., products containing specific chemicals. The predicate for a bounty hunter's Prop. 65 claim rests not upon a general duty to warn about cancer, but upon a defendant's failure to warn that a product contains a specific chemical known to California to cause reproductive toxicity. In C*ipollone* and G*urrieri*, the courts found particular discernible product classes to which Congress mandated warnings, while the M*edtronic* court located neither a discernible class nor particular warnings. A comparison between Prop. 65's duty to warn about cancer and a general duty to warn about cancer illustrates this point.

Some jurisdictions recognize a manufacturer's general duty to warn includes cancer warnings.[135] This general duty requires a manufacturer to warn its product causes cancer

> at least insofar as it subjects manufacturers to strict liability for injuries caused by their products sold in an unreasonably dangerous condition. Comment k to Sec. 402A provides that some products inherently unsafe can be prevented from being unreasonably dangerous by furnishing the user with an adequate warning of the hazards of the product. . . . Because one of the purposes of the warning is to allow the user to make his own decision whether to expose himself to the risks of harm, . . . a manufacturer fulfills its duty to warn in this context only if it warns of all dangers associated with its products of which it has actual or constructive knowledge.[136]

The FHSA does not preempt claims that a manufacturer failed to satisfy this general duty because there is no specific warning or a discernible class to apply the warning. Like the M*edtronic* case, this duty requires a manufacturer to warn of all dangers including, but not limited to, cancer or reproductive toxicity, associated with all products including, but not limited to, consumer products within the FHSA. The general duty imposes no specific warning for a discernible product class. Therefore, the FHSA does not preempt a statutory or common law duty that requires manufacturers to provide all warnings necessary to render a product safe. The FHSA preempts those claims that require a manufacturer to add, detract or alter its FHSA cautionary labeling requirements. The FHSA does not preempt state law requirements that impose a duty upon a manufacturer to warn consumers in a manner other than "cautionary labeling," i.e., television, radio, or reporting to a state agency, that a particular product contains a chemical known to California to cause cancer or reproductive toxicity. Prop. 65, however, requires a FHSA-compliant manufacturer to include in its cautionary labeling a warning that a consumer product contains a chemical that causes cancer or reproductive toxicity. As M*edtronic* recognized, requiring a manufacturer to include such a warning in its cautionary labeling "threatens to interfere with a specific federal interest," *e.g.*, uniform cautionary labeling.

135. S*ee*, *e.g.*, Jackson v. Johns-Manville Sales Corp., 750 F.2d 1314, 1320 (5th Cir. 1985).

136. I*d*.

A recent California Supreme Court decision, *Carrillo v.* ACF I*ndustries*,[137] also recognizes that a federal statute preempts a state claim that seeks to alter or amend duties imposed by federal statute, but not a general duty to obey the law. In C*arrillo*, plaintiff Jose Carrillo ("Carrillo") sued defendant ACF Industries, Inc. ("ACF") for failing to equip a railroad car with safety devices necessary to secure a worker atop the car against falls.[138] The California Supreme Court recognized that the Safety Appliance Act ("SAA"), 42 U.S.C. § 20301 et seq., preempts state common law defective design claims premised upon the failure of a safety device:

> "[T]he United States has exercised its exclusive powers over interstate commerce so far as to take possession of the field [of rail safety appliance], [and thus] the States can no more supplement its requirements than they can annul them." [Citation omitted.] . . . "So far as the safety equipment of [rail] vehicles is concerned, these Acts operate to exclude state regulation whether consistent, complementary, additional, or otherwise." [Citation omitted.] As Justice Holmes succinctly explained, "The subject matter in this instance is particularly one that calls for uniform law. . . ." [Citation omitted.].[139]

However, the California Supreme Court also recognized the SAA does not preempt a general duty to design safe cars and locomotives.[140] Nevertheless, the court found, Carrillo's claim intended to increase ACF's obligations beyond those the SAA required.[141] Assuming the California Supreme Court permitted Carrillo to increase ACF's obligations, "Congress's goal of a uniform federal railroad regulation would be undermined."[142] The SAA's preemption clause, however, barred such a result.

Likewise, the FHSA bars a common law or statutory cautionary labeling claim that adds, detracts or clarifies cautionary labeling risks of injury or illness subject to FHSA warnings. Prop. 65 imposes upon businesses a duty to warn consumers through cautionary labeling that particular products contain certain chemicals California believes cause cancer or reproductive toxicity. A cautionary label warning that "California believes a chemical causes cancer or reproductive toxicity" is an additional warning imposed by state law. Each state might require a similar cautionary label warning for different chemicals it determines cause cancer. G*urrieri* recognized this "would create a system of possibly fifty or more different labeling requirements throughout the country, contrary to Congress's obvious intent in passing the FHSA to 'provide nationally uniform requirements for adequate cautionary labeling.'"[143] Requiring manufacturers to include additional or clarifying language in their cautionary labeling falls squarely in the FHSA's preemption provision.

The California courts recognize the FHSA preempts "cautionary labeling" content. They define "cautionary labeling" to avoid the FHSA's preemptive effect. The courts' definition, however, exceeds the "cautionary labeling" definition Congress provided. A CPSC promulgated "cautionary labeling" definition reflects the manner in which Congress defines the term and remedies the California courts' erroneous definition.

B. CPSC Should Define "Cautionary Labeling" to Reflect Congress's Intent to Preempt "Cautionary Labeling" Requirements.

In addition to holding the FHSA does not preempt Prop. 65 because both statutes apply general duties to non-discernible products, the California courts find that "[a] retail outlet can comply with Proposition 65 by posting a sign in

137. 980 P.2d 386 (Cal. 1999).

138. I*d*. at 388.

139. I*d*. at 389.

140. S*ee, e.g.*, Atlantic Line v. Georgia, 234 U.S. 280 (1914) (permitting plaintiff to maintain claim for railroad's failure to affix a state mandated light).

141. C*arrillo*, 980 P.2d at 390.

142. I*d*. at 393 (citing Law v. General Motors Corp., 114 F.3d 908, 910-11 (9th Cir. 1997)).

143. Gurrieri v. William Zinsser & Co., 728 A.2d 832, 841 (N.J. Super. Ct. App. Div. 1999).

a visible place specifying the products that are known to the state to cause cancer or that are reproductively toxic." "Point-of-sale" warnings, the court concluded, did not constitute "cautionary labeling."[144]

In *Chemical Specialties Manufacturers Association v. Allenby*, the court acknowledged FHSA section 17(b) preempts "all state mandated precautionary labeling that is not identical to that required by the Act."[145] The court endeavored to define "cautionary" or "precautionary" labeling. However, rather than adopting CPSC's "precautionary labeling" definition, the court grafted the definition of "label" and the "directions for use" requirement into a "labeling" definition:

> Under the FHSA, however, "all accompanying literature where there are directions for use, written or otherwise" is defined as cautionary labeling, 15 U.S.C. Sec. 1261(n)(2) (1988). Accompanying literature is defined as follows:
> Any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for . . . use in the household or by children.[146]

In circular fashion, the court concluded "point-of-sale" warnings contain no directions for use. Therefore, the FHSA does not preempt Prop. 65.[147]

The court in *Cotter Chemical Specialties*' tautological reasoning:

> The act defines label as a "display of written, printed, or graphic matter upon the immediate container of any substance . . . and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).) Congress chose to restrict the definition of a label to include accompanying literature only when that material contains "directions for use." (15 U.S.C. § 1261(n).) These words indicate the warning must tell the user how to use the product. . . . [I]f Congress wanted preemption under the FHSA to apply to all accompanying literature with "implied" directions for use, as Cotter argues, Congress could have specified that.[148]

Therefore, the court concluded the FHSA does not preempt Prop. 65.

Both courts graft the "directions for use" requirement into "cautionary labeling" in order to avoid preemption. However, Congress did not restrict either "label" or "labeling" to "accompanying literature" containing "directions for use." Both the FHSA's legislative history and Congress's use of "labeling" in other statutes demonstrate the FHSA includes "point-of-sale" warnings and preempts Prop. 65. A CPSC-promulgated "cautionary labeling" definition would restore Congress's preemptive intent and would correct the courts' errant rulings.

1. The FHSA's legislative history does not support the California courts' conclusion that either "label" or "labeling" include a "directions for use" restriction.

The Ninth Circuit Court of Appeals' and the California Court of Appeal's "cautionary labeling" definitions rest on the definition of "label" in FHSA section 2(n). Accompanying literature, according to the courts, is not a "label" unless it contains "directions for use."[149] Congress, however, separately defined "label" and "labeling." Neither definition requires "directions for use."

144. Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941, 944 (9th Cir. 1992).

145. *Id.* at 949.

146. *Id.* (citing 16 C.F.R. § 1500.3(c)(9) (1991)).

147. *Id.*

148. People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 378 (1997).

149. *See Chemical Specialties*, 958 F.2d 941, 949 (9th Cir. 1992); *Cotter*, 62 Cal. Rptr. 2d at 378.

In the 1938 Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., Congress both defined "label" and provided certain requirements. First, Congress stated that, "[t]he term "label" means a display of written, printed, or graphic matter upon the immediate container of any article."[150]

Second, Congress encumbered "label" with specific requirements:

> a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.[151]

Congress recognized "label" did not include items accompanying the article and defined "labeling" to mean, "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[152]

Therefore, placards, pamphlets, booklets, books, signs, or other written, printed, or graphic matter or visual devices used in connection with the display, sale, demonstration, or merchandising of an article, but not upon the immediate container, are "labeling," not a "label."

Likewise, in the 1960 FHSA, Congress both defined "label" and provided certain requirements. First, Congress defined "label" with reference to the FDCA, "'Label' is defined, as in the Federal Food, Drug, and Cosmetic Act, as a display of written, printed, or graphic matter upon the immediate container of any substance."[153]

Second, it is instructive that the FHSA's "label" *requirements* differ from the FDCA's requirements. Under the FHSA,

> [a] requirement issued pursuant to this legislation requiring certain information to appear on the label will not be considered to be complied with unless such information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise.[154]

Grafting the FHSA's "directions for use" requirement into the "label" definition appears inconsistent with Congress's original intent that FHSA and FDCA define "label" similarly. The FDCA's "label" definition lacks such a requirement, and Congress, by separately defining "labeling," exhibited no intent to graft the requirement into the definition. Instead, the phrase "where there are directions for use, written or otherwise" should be interpreted as a location, i.e., the warnings should appear on accompanying literature in the same location as directions for use. This interpretation reconciles both Congressional purposes. First, it maintains Congress's intent that both the FHSA and the FDCA similarly define "label." Second, it furthers the national labeling uniformity Congress mandated through the FHSA. Requiring companies to place their warnings in juxtaposition to directions for use directs individuals seeking such information to a single location on accompanying literature. The CPSC recognized this intent in promulgating its regulations.

One such CPSC regulation, promulgated at 16 C.F.R. § 1500.125, provides that

> [w]hen any accompanying literature includes or bears any directions for use (by printed word, picture, design, or

150. 21 U.S.C. § 321(k).

151. *Id.*

152. 21 U.S.C. § 321(m).

153. 1960 U.S.C.C.A.N. 2833, 2839.

154. *Id.*

> combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act.[155]

CPSC recognized this regulation "simply requires that literature that accompanies a hazardous substance, *and that contains instructions for use*, must bear the cautionary material required under section 2(p) of the Federal Hazardous Substances Act."[156] However, this regulation also implicitly recognizes that if a placard, pamphlet, booklet, book, sign or other written, printed, or graphic matter or visual device used in connection with the substance's merchandising does not contain a direction for use, the statute imposes no such requirement.[157] The CPSC's definition identifies what constitutes "accompanying literature"—i.e., any placard, pamphlet, booklet, book, sign, or other written, printed or graphic matter or visual device—and reaffirms Congress's intent that CPSC warnings appear on accompanying literature in juxtaposition to the directions for use. CPSC's subsequent regulations and comments confirm this understanding.

In 1984, CPSC promulgated 16 C.F.R. § 1500.121, which establishes the "type size and placement requirements for cautionary material in accompanying literature."[158] In response to this regulation, commenters argued 16 C.F.R. § 1500.125 "adequately addresses the subject of labeling in accompanying literature and that the proposed requirements should be stricken."[159] CPSC, however, noted these commenters misconstrued 16 C.F.R. § 1500.125's purpose. The regulation does require accompanying literature with "directions for use" to include FHSA warnings. However, the regulation indicates where to locate these warnings:

> [I]f there were not requirements for placement of the cautionary material, the cautionary material easily could be obscured by its placement in the text. F*or example, if the instructions for use appeared on the second page of a ten-page booklet and the cautionary material appeared on page ten, the benefit contemplated by the statute clearly would not be achieved*.[160]

National uniform labeling, including one location for directions for use and FHSA warnings, constitutes Congress's intended benefit.

CPSC's regulations reflect Congress's intent that any placard, pamphlet, booklet, book, sign, or other written, printed or graphic matter or visual device (i.e., accompanying literature) that contains directions for use have FHSA warnings placed adjacent to the directions for use. As 16 C.F.R. § 1500.125 recognizes, not all accompanying literature will contain such directions for use and need not comply with the "label" requirement to avoid "misbranded hazardous substances" status. Grafting the "directions for use" element into "accompanying literature," the California courts improperly limited the FHSA's application.

Furthermore, "labeling" and "label" are not interchangeable terms. "Label," under both the FHSA and the FDCA, means written, printed or graphic displays upon the article, while "labeling" includes written, printed or graphic displays either upon any article, its container or wrappers, or accompanying the article.[161] The 1976 Amendment employs "labeling," not "label." The 1976 Amendment, in pertinent part, provides that

> if a hazardous substance or its packaging is subject to a *cautionary labeling* requirement under section 2(p) or 3(b)

155. 16 C.F.R. § 1500.125 (2000).

156. 49 Fed. Reg. 50,374 (1984) (emphasis added).

157. CPSC defines "accompanying literature" to include "any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children." 16 C.F.R. § 1500.3(9).

158. I*d*.

159. 49 Fed. Reg. 50,374 (1984).

160. I*d*. (emphasis added).

161. Congress amended 15 U.S.C. § 1261(n) in 1966 to define "label" for unpackaged articles or articles not packaged in an immediate container intended for delivery to the ultimate consumer. The core definition, however, remains the same. 1966 U.S.C.C.A.N. 1521-1522.

> . . . designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a *cautionary* labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury. . . .[162]

Congress's amendment identifies each "cautionary labeling" requirement, *e.g.*, those found in sections 2(p) and 3(b). These sections require that "cautionary labeling" requirements mirror "label" requirements. This is consistent with Congress's intent to "provide nationally uniform requirements for adequate cautionary *labeling*."[163] Employing "labeling" rather than "label" demonstrates Congress's intent to extend 2(p) and 3(b) requirements beyond "label" to include written, printed or graphic matter accompanying such article.[164] Furthermore, it evidences no intent to limit "cautionary labeling" to accompanying materials with "directions for use." Congress, however, failed to define "cautionary labeling."[165] Agencies authorized to enact regulations necessary for a statute's efficient enforcement give meaning to words Congress employs.[166]

The FDA, the FHSA's previous regulatory body, recognized the "labeling" and "label" dichotomy in promulgating its "precautionary labeling" definition:

> Precautionary labeling includes such information as warnings, registration or identification numbers, disclosure of hazards, antidote information, ingredient statements, and other similar *labeling* requirements.[167]

CPSC adopted FDA's precautionary labeling definition verbatim.[168] Courts presume agencies promulgate regulations with knowledge of existing laws.[169]

California courts recognize "point of sale" warnings are warnings accompanying an article under the FHSA.[170] California courts have grafted a "directions for use" requirement into the FHSA "label" definition and refuse to recognize that the FHSA preempts Prop. 65.[171] The FHSA "label" definition, however, neither applies to written, printed, or graphic material *accompanying* an article nor encases a "directions for use" requirement within the definition. "Labeling," which Congress uses, includes accompanying items and also contains no "directions for use" requirement. In short, the California courts' "cautionary labeling" definition finds no support in the FHSA's legislative history.

2. A "directions for use" requirement restricts "labeling" beyond Congress's intent.

Additionally, Congress defines "labeling" in various other statutes,[172] including other CPSC regulated statutes.[173] Significantly, no identified federal "labeling" definition contains a "directions for use" element. Generally, courts "give effect to this plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning."[174] California courts, however, interject a "directions for use" element into "cautionary

162. Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976) (emphasis added).

163. 1960 U.S.C.C.A.N. 2833 (emphasis added).

164. 21 U.S.C. § 321(m).

165. *See* People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 373 (1997); *see also* Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 860 (1984) ("The definition in Sec. 302(j) [major stationary source] tells us what the word 'major' means[,] . . . but it sheds virtually no light on the meaning of the term 'stationary source.'").

166. *See, e.g.*, Schweiker v. Gray Panthers, 453 U.S. 34 (1981); *Chevron*, 467 U.S. 837.

167. 21 C.F.R. § 191.4 (c) (emphasis added).

168. 16 C.F.R. § 1500.7(c).

169. 5 U.S.C. § 557(c).

170. *Cotter*, 62 Cal. Rptr. 2d at 376.

171. *Id.*

172. *See, e.g.*, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136(p)(2); Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 321(m); Poultry and Poultry Products Inspection Act (PPPIA), 21 U.S.C. § 453(s); Meat Inspection Act, 21 U.S.C. § 601(p).

173. Congress transferred to CPSC the authority to regulated the FHSA, the PPPIA, and the FDCA. See 15 U.S.C. § 2079.

174. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521-22 (1992) (citing Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 97 (1983)).

labeling" that limits "labeling" beyond Congress's intent.

Congress requires other industries to adhere to "labeling" requirements. Congress defines "labeling" in at least five other statutes.[175] Generally, these statutes' "labeling" definitions include two elements, neither of which is a "directions for use" element. First, "labeling" includes "label." This includes all written, printed or graphic matter on or attached to the article. Second, "labeling" includes "written, printed, or graphic matter accompanying the article."

California courts erroneously narrowed "labeling" by defining it through "label." Including "labeling" within "label" rather than including "label" as a "labeling" subset provided the California courts with a platform to graft the "label" "directions for use" requirement into a "labeling" definition. The California courts' definition, however, contradicts Congress's "labeling" definition. Congress includes "label" as a "labeling" subset. By making "label" a "labeling" subset, Congress demonstrates an intent to expand "labeling" beyond "label" to include items "accompanying" the article, whether or not they contain directions for use. A CPSC promulgated "cautionary labeling" definition would restore the appropriate "labeling"-"label" relationship and correctly overturn the California courts' erroneous interpretation.

The relationship between "label" and "labeling" in the context of the FDCA was explained by the United States Supreme Court in *Kordel v. United States*.[176] In *Kordel*, the Court held that written, printed, or graphic information which is used in connection with the sale of a product (such as literature or point of sale signs), and which "supplements or explains" the product or its label, should be considered to be "accompanying" the product and, therefore, is "labeling."[177] Furthermore, "[n]o physical attachment of one to the other is necessary. It is the textual relationship that is significant."[178]

C. A CPSC-promulgated "Cautionary Labeling" Definition Would Restore Congress'Congress's Intent.

Congress conveyed sufficient authority to the CPSC to promulgate a "cautionary labeling" regulation. Congress intended to "vest omnibus product safety authority in a single Federal agency"[179] that, among other things, "develop[s] uniform safety standards for consumer products and . . . minimize[s] conflicting State and local regulations."[180] Congress empowered CPSC "to issue regulations, direct the course of all litigation, and make legislative and budgetary recommendations, without the approval or clearance by outside agencies."[181] Indeed, Congress expressly authorized CPSC "to promulgate regulations for the efficient enforcement of this chapter."[182]

Furthermore, Congress transferred authority to CPSC to implement the FHSA.[183] Pursuant to this authority, CPSC defined "precautionary labeling" to include "such information as warnings, registration or identification numbers, disclosure of hazards, antidote information, ingredient statements, and other similar labeling requirements."[184]

In 1976, Congress codified the FHSA's preemptive authority.[185] The FHSA's preemption clause bars any

> State or political subdivision of a State [from] establish[ing] or continu[ing] in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling

175. S*ee supra* note 173.

176. 335 U.S. 345 (1948).

177. Id. at 350.

178. I*d*.

179. United States v. Anaconda Co., 445 F. Supp. 486, 492 (D.C. Cir. 1977) (citing H.R. Rep. No. 92-1153 (1972)).

180. 15 U.S.C. § 2051(b)(3); 16 C.F.R. § 1000.1(a)(3).

181. S. Rep. No. 92-835, at 7 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4573, 4579.

182. 15 U.S.C. § 1269(a).

183. S. Rep. No. 94-251, at 11 (1976), *reprinted in* 1976 U.S.C.C.A.N. 993, 1003.

184. 16 C.F.R. § 1500.7; 38 Fed. Reg. 27,012, 27,016 (1973).

185. Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976).

> requirement is identical to the labeling requirement under section 2(p) or 3(b).[186]

CPSC revoked its preemptive regulation but never altered its "precautionary labeling" definition.[187]

Congress's 1976 codification recognized CPSC's right to define cautionary labeling.[188] Promulgating a regulation that defines "cautionary labeling" to include "point-of- sale" warnings that a product can cause cancer or birth defects falls squarely within CPSC's earlier precautionary labeling definition and both its current and previously recognized preemptive authority. Indeed, as repeatedly recognized by the U.S. Supreme Court, a validly promulgated federal regulation "has no less preemptive effect [on state laws] than federal statutes."[189] Furthermore, defining "cautionary labeling" to include "point-of-sale" warnings minimizes Prop. 65's burden and sets a binding, statutorily supported precedent for other states.

Prop. 65 and its progeny undermine CPSC's duty to develop uniform national safety standards for consumer products and minimize state and local regulations. Congress authorized CPSC to maintain uniform national safety standards to minimize "increased costs to consumers and burden on manufacturers that could result when States are allowed to maintain different standards over and above the uniform Federal standard."[190] Furthermore, uniform national safety standards "facilitate the education of the public in the cautionary use of these products . . . [and] enable physicians to administer antidotes immediately rather than waste precious time in determining the active ingredients of the product."[191] Prop. 65 increases manufacturer and distributor costs and destroys national uniformity.

Prop. 65 primarily obligates producers, packagers, manufacturers and distributors (collectively referred to as manufacturers) to affix special labeling to each consumer product potentially sold in California if the consumer product contains chemicals that California believes causes cancer or birth defects.[192] Failure to affix Prop. 65 labels renders FHSA-compliant manufacturers susceptible to public and private enforcement suits.[193] Manufacturers seeking to avoid such enforcement suits face either the burden of policing their consumer product's distribution to avoid California or the additional costs to affix Prop. 65 labels to all consumer products. Small businesses lack the resources necessary to individualize or monitor their product flow into California. However, defining cautionary labeling to include "point-of-sale" warnings, including Prop. 65 warnings, eliminates small businesses' concerns. Furthermore, including Prop. 65 warnings within "cautionary labeling" does not eliminate a state's ability to promulgate innovative labeling requirements.

Congress recognized that a state's unique circumstances may require innovative labeling programs. Congress exempted a state's cautionary labeling program if, upon its application, the state established that (1) compliance with the program does not cause the product to violate CPSC's requirement; and that (2) the state program provides a significantly higher degree of protection than CPSC's rule affords and does not unduly burden the product's manufacture or distribution in interstate commerce.[194] Requiring California to submit Prop 65's labeling program to CPSC scrutiny maintains CPSC's preeminence in consumer product labeling, notifies other states considering similar programs that CPSC reserves the right to scrutinize their consumer product labeling programs and guarantees minimal increased costs to consumers and a lesser burden on manufacturers.

186. *Id.*

187. 47 Fed. Reg. 57,489 (1982).

188. Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976).

189. See, *e.g.*, Fidelity Savings & Loan Ass'n v. Del la Cuesta, 458 U.S. 141, 153-54 (1982) (quoting United States v. Shimer, 367 U.S. 374, 383 (1961)).

190. 15 U.S.C. § 2051(b)(3); 16 C.F.R. § 1000.1(a)(3).

191. 37 Fed. Reg. 18,628 (1972).

192. *See* CAL. HEALTH & SAFETY CODE §§ 25249.6, 25249.11(f) (West 2000).

193. *See* CAL. HEALTH & SAFETY CODE § 25249.7 (West 2000).

194. *See* 90 Pub. L. No. 94-284, §17, Stat. 510, 11 (1976).

D. Courts Would Sustain a CPSC-promulgated "Cautionary Labeling" Definition.

Finally, courts should sustain a CPSC-promulgated "cautionary labeling" definition.

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not addressed the precise question at issue, the court does not simply impose its own construction on the statute as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.[195]

Applying this analysis, courts give agency regulations deferential treatment:

> The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress. [Citations omitted.] If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.[196]

Although opponents of CPSC's "cautionary labeling" definition might argue for the application of this standard, two courts struck down a CPSC Advisory Opinion that "point-of-sale" signs constitute "directions for use."[197] Advisory opinions, however, differ from formal regulations in two respects. First, courts afford advisory opinions less deference. Second, unlike the Advisory Opinion, defining "cautionary labeling" is consistent with Congress's purpose.

1. Advisory opinions are entitled to little deference.

Generally, "courts do not accord *Chevron* deference to non-binding advisory opinions of an administrative agency."[198] According *Chevron* deference to advisory opinions effectively

> endow[s] them with force of law where Congress did not intend them to have such force. By this process, the agency would bind the public without itself being bound by interpretations in these formats. And since these formats are exempt from A[dministrative] P[rocedures] A[ct] public participation requirements, an especially odious frustration is visited upon the affected private parties: they are bound by a proposition they had no opportunity to help shape and will have no meaning-

195. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984).

196. *Id.* at 843-44.

197. *See, e.g.*, People *ex rel.* Lungren v. Cotter & Co., 62 Cal. Rptr. 2d 368, 382 (1997) ("[W]e find the CPSC's interpretation is 'plainly erroneous' and entitled to no deference.").

198. Mid-America Care Found. v. National Labor Relations Bd., 148 F.3d 638, 642 (6th Cir. 1998). *See also* Crandon v. United States, 494 U.S. 152 (1990) (Scalia, J., concurring); Kilgore v. Outback Steakhouse, 160 F.3d 294 (6th Cir. 1998); Management Recruiters Int'l v. Bloor, 129 F.3d 851 (6th Cir. 1997); Southern Ute Indian Tribe v. Amoco Prod. Co., 119 F.3d 816 (10th Cir. 1997). *But see* Elizabeth Blackwell Health Ctr. for Women v. Knoll, 61 F.3d 170 (3d Cir. 1995).

> ful opportunity to challenge when it is applied to them.[199]

Southern Ute Indian Tribe effectively explains why courts do not afford advisory opinions *Chevron* deference. In *Southern Ute Indian Tribe*, the Southern Ute Indian Tribe ("Tribe") sued various defendants, including the Department of Interior ("Department"), to determine who owned coal bed methane ("CBM") contained in coal the Tribe acquired "as successor in interest to a statutory reservation of coal to the United States."[200] In finding the Tribe owned the CBM, the court rejected the Department's argument that the court owed *Chevron* deference to a 1981 advisory opinion from the Department's Solicitor General.[201]

> To satisfy *Chevron*, the delegation of authority to form binding policy must include not only discretion to formulate interpretations but also discretion to utilize the particular format selected. "Chevron should be held to apply to the meanings agencies give statutes in all legislative rules and in most adjudications. [But] it should not be held to apply to agency pronouncements in less formal formats. . . ." [Citations omitted.] . . . As we have unequivocally held, "it is elementary administrative law that in order for [agency actions] to have binding force there are only two methods that an agency may use in formulating policy. It may be established binding policy either through rule-making procedures or through adjudications that create binding precedents." [Citations omitted.][202]

Procedural protections required of formal rulemakings or adjudications but not of advisory opinions explain why courts do not afford *Chevron* deference to advisory opinions.

> There are three main differences between a legislative rule and a general statement of policy. First, except in specified circumstances, an agency cannot promulgate a legislative rule without first following notice and comment procedures; by contrast, APA Sec. 553(b) specifically exempts general statements of policy from notice and comment procedures. Second, a valid legislative rule has the same binding effect as a statute; a general statement of policy has no binding effect on members of the public or on courts. A general statement of policy also is not judicially enforceable against an agency . . . . Third, [while] many legislative rules are subject to potential judicial review before they are applied in a particular case[,] most general statements of policy are not subject to judicial review in the abstract.[203]

The Solicitor General's advisory opinion, the court recognized, issued without notice or comment at the Solicitor's whim, might similarly be overruled, modified or otherwise altered at the Solicitor's whim.[204] Accordingly, "[i]f this opinion were accorded *Chevron* deference, it would have a retroactive impact on private rights conveyed by the government some seventy years earlier."[205] Therefore, the court accorded the advisory opinion no deference.

Similarly, the California courts owed the CPSC Advisory Opinion no *Chevron* deference. First, the timing is questionable. CPSC's Office of General Counsel issued its Advisory Opinion on March 6, 1991, at the Chemical Specialties Manufacturers Association's ("CSMA") request. The opinion concluded Prop. 65's warnings constituted "directions for use." In December 1991, CSMA argued Prop. 65 warnings constitute "directions for use."[206] The Advisory

199. *Southern Ute Indian Tribe*, 119 F.3d at 833.

200. *Id*. at 819.

201. *See id*. at 829.

202. *Id*. at 832.

203. *Id*. (citing 1 KENNETH C. DAVIS & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE, § 6.2, at 228 (3d ed. 1994).

204. *See id*. at 833.

205. *Id*. at 830.

206. Chemical Specialties Mfrs. Ass'n, v. Allenby, 958 F.2d 941 (9th Cir. 1992).

Opinion appears calculated to advance CSMA's position rather than to suggest a binding interpretation. Second, the Office of General Counsel issued the opinion without notice or comment or any other APA-required public participation.[207] As *Southern Ute Indian Tribe* noted, "APA Sec. 553(b) specifically exempts general statements of policy from notice and comment procedures."[208] Therefore, "[a]s a simple policy statement . . . the [General Counsel's] opinion fail[ed] to provide the procedural protections required for Chevron deference to attach."[209] As a result, the California courts properly accorded it no deference.[210]

2. Defining "cautionary labeling" is consistent with Congress's purpose.

By contrast, courts regularly afford *Chevron* deference to agency regulations promulgated through either APA rulemakings or adjudications.[211] To determine whether a regulation receives *Chevron* deference, the court initially determines whether Congress addressed the precise question at issue. "When Congress has not addressed 'the precise question at issue,' an agency requesting *Chevron* deference to its statutory interpretation must show that it has been delegated authority to address the question."[212] Second, the court must determine whether the agency construction is "arbitrary, capricious, or manifestly contrary to the statute."[213] *Chevron* demonstrates the quintessential analysis.

In *Chevron*, the Clean Air Act Amendments of 1977 ("Act") required States not attaining the national air quality standards the EPA established to create a permit program regulating "new or modified major stationary sources."[214] EPA defined the term "stationary source" to permit existing plants containing several pollution-emitting devices to install or modify equipment without meeting a state's permit requirements so long as the installation or modification did not increase pollution emissions.[215] The Court of Appeals found EPA's regulation inconsistent with the Act's purpose, but the United States Supreme Court reversed.[216] First, the Court found Congress failed to address the precise question at issue. The Court found the Act defines "major stationary source," but fails to reference "stationary source."[217] Second, the Court found Congress delegated to the EPA the authority to "publish a list of categories of sources of pollution and to establish new source performance standards ("NSPS")."[218] Finally, the Court analyzed EPA's regulation to determine its consistency with the Act's purpose.

> The section has two main purposes:
> (1) to allow reasonable economic growth to continue in an area while making reasonable further progress to assure attainment of the standards by a fixed date; and
> (2) to allow States greater flexibility for the former purpose that EPA's present interpretative regulations afford.[219]

207. Although information obtained through a Freedom of Information Act ("FOIA") request discloses various individuals, including the Attorney General of California, and Prop.65 proponents and opponents, offered the General Counsel's office information, some individuals offered information before the General Counsel's office issued its Advisory Opinion while others participated after the opinion's issuance. The APA would be necessary in this instance to establish participation timetables.

208. *Southern Ute Indian Tribe*, 119 F.3d at 833.

209. *Id.*

210. Additionally, "cautionary labeling" definition opponents might argue that the CPSC is without authority to promulgate a "cautionary labeling" definition because the California courts not only rejected the Advisory Opinion's form, but also rejected its reasoning. Rejecting the Advisory Opinion's reasoning, however, does not bar CPSC from defining "cautionary labeling." As previously noted, "labeling" as used in the Food, Drug and Cosmetic Act contains no "directions for use" component. Therefore, a FHSA "cautionary labeling" definition consistent with the Food, Drug and Cosmetic Act "labeling" definition should not have a "directions for use" component.

211. See, *e.g.*, Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); *Southern Ute Indian Tribe*, 119 F.3d 816.

212. *Southern Ute Indian Tribe.*, 119 F.3d at 816.

213. *Chevron*, 467 U.S. at 844.

214. *Id.* at 840.

215. *See id.*

216. *See id.* at 842.

217. *See id.*

218. *Id.* at 846.

219. *Id.* at 851-52. When Congress passed the Act, EPA maintained two "stationary source" definitions. One definition permitted some industries to avoid permit compliance so long as their total emissions did not increase pollution emissions, and a second definition required a permit when modifying or installing new equipment. *See id.*

The Act's accompanying Senate Committee Report found industrial expansion permissible if a state "demonstrate[s] that these facilities can be accommodated within its overall plan to provide for attainment of air quality standards."[220] Furthermore, the Court found EPA previously permitted some states to install or modify facilities without meeting permit requirements.[221] Finally, the Court found EPA's regulation comported with the Act's purpose.

> [H]istory plainly identifies the policy concerns that motivated the enactment; the plantwide definition is fully consistent with one of those concerns—the allowance of reasonable economic growth—and, whether or not we believe it most effectively implements the other, we must recognize that the EPA has advanced a reasonable explanation for its conclusion that the regulations serve the environmental objectives as well.[222]

Therefore, the Court sustained EPA's regulation.

Similarly, a court would sustain a CPSC "cautionary labeling" regulation. First, Congress failed to define "cautionary labeling" as used in the FHSA.[223] Although opponents might argue the California courts found that Congress defined "cautionary labeling,"[224] the courts derive this definition from "label." Defining "label," however, does not address the precise question at issue.[225] Indeed, Congress defines "label" with reference to the Federal Food, Drug, and Cosmetic Act, which separately defines "label" and "labeling."[226]

Second, Congress expressly authorized CPSC to "promulgate regulations for the efficient enforcement of [the FHSA], except as otherwise provided in this section."[227] When Congress failed to define "precautionary labeling," CPSC defined it to include "warnings."[228] Congress has not altered or amended its delegation since 1973.[229] Promulgating a current regulation that defines "cautionary labeling" to include "warnings" falls squarely within Congress's unchanged delegation to CPSC.

Finally, defining "cautionary labeling" is consistent with Congress's intent. Congress enacted the FHSA

> to provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use.
>
> . . . .
>
> The labeling requirements will advise the user of these hazardous substances in the use of the product and make available immediate information for physicians who are called upon to treat cases of accidental injury. It should also provide a pattern which States may follow in enacting similar legislation.[230]

Promulgating a cautionary labeling regulation that includes "warnings," including Prop. 65's "point of sale warnings," furthers the FHSA's uniform national labeling requirements. First, it provides a national definition utilized by both state and federal agencies. This eliminates the potential for differing and/or conflicting definitions promulgated by either courts or

220. *Id*. at 852.

221. *See id*. at 857.

222. *Id*. at 863.

223. 15 U.S.C. § 1261 (2000).

224. *See* Chemical Specialties Manufacturers Ass'n v. Allenby, 958 F.2d 941, 949 (9th Cir. 1992).

225. *See Chevron*, 467 U.S. at 860 ("Congress's 'major stationary sources' definition 'tells us what the word "major" means . . . but it sheds virtually no light on the meaning of the term "stationary source."'").

226. 21 U.S.C. § 321.

227. 15 U.S.C. § 1269. "Past experience shows that unless the agency has the power to issue regulations, . . . its effectiveness will be substantially impaired." 1972 U.S.C.C.A.N. 4573, 4579.

228. 16 C.F.R. § 1500.7(c); 38 Fed. Reg. 27,012, 27,016 (1973).

229. Congress codified CPSC's preemption regulation in 1976. *See* Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976). Significantly, nothing suggests Congress altered or eliminated the "precautionary labeling" definition.

230. 1960 U.S.C.C.A.N. 2833.

agencies. Second, including "warnings" within "cautionary labeling" establishes a label prototype that states might emulate in their statutes. Including Prop. 65 warnings within "cautionary labeling" does not eliminate a state's ability to promulgate innovative labeling requirements as Congress created an exemption procedure.[231] Significantly, CPSC employed a similar procedure when it included "warnings" within "precautionary labeling."[232]

Courts would sustain a CPSC-promulgated "cautionary labeling" definition. First, Congress did not define the term and delegated to CPSC all authority necessary to implement the FHSA. Furthermore, a CPSC-promulgated "cautionary labeling" definition is consistent with Congress's desire to create uniform national labeling. Therefore, a "cautionary labeling" definition, promulgated in accordance with the APA, is due C*hevron* deference.

E. CPSC Can Harmonize Congress's Intent With California's Safety Concerns.

Prop. 65 proponents will argue that defining "cautionary labeling" to include "point-of-sale" warnings will eliminate Prop. 65 and similar state initiatives designed to provide residents with necessary warning. OSHA, however, conditionally approved Prop. 65 for California enforcement without eliminating its intent.[233] Likewise, the FHSA permits CPSC to approve Prop. 65 notwithstanding the FHSA's preemptive effect.

The FHSA provides the following:

> (3)(A) Upon application of a State or political subdivision of a State, the Commission may, by regulation promulgated in accordance with subparagraph (B), exempt from paragraph (1), under such conditions as may be prescribed in such regulation, any requirement of such State or political subdivision designed to protect against a risk of illness or injury associated with a hazardous substance if -
>
> (i) compliance with the requirement would not cause the hazardous substance (or its packaging) to be in violation of the applicable requirement described in paragraph (1), and
>
> (ii) the State or political subdivision requirement (I) provides a significantly higher degree of protection from such risk of illness or injury that the requirement described in paragraph (1), and (II) does not unduly burden interstate commerce.
>
> In determining the burden, if any, of a State or political subdivision requirement on interstate commerce the Commission shall consider and make appropriate (as defined by the Commission in its discretion) finding on the technological and economic feasibility of complying with such requirement, the geographic distribution of the substance to which the requirement would apply, the probability of other States or political subdivisions applying for an exemption under this paragraph for a similar requirement, and the need for a national, uniform requirement under this Act [this chapter] for such substance or its packaging.[234]

This provision permits CPSC to approve Prop. 65 with certain conditions. Permitting out-of-state Prop. 65 defendants to raise FHSA compliance as an affirmative defense and enabling the California Attorney General to disapprove frivolous lawsuits are two necessary conditions to CPSC approval.

Congress passed the FHSA to ensure national uniform labeling. Congress recognized national uniform labeling educates the public that certain products must be used with caution and permits doctors to administer necessary antidotes without wasted time. Permitting states to enact their own cautionary

231. S*ee* Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976).

232. 16 C.F.R. § 1500.7(e); 38 Fed. Reg. 27,012, 27,016 (1973).

233. 62 Fed. Reg. 31,159 (1997).

234. Pub. L. No. 94-284, § 17(a), 90 Stat. 510 (1976).

labeling regimes inhibits Congress's intent. Allowing out-of-state Prop. 65 defendants to raise FHSA compliance as an affirmative defense protects Congress's intent and still allows Prop. 65's enforcement.

Currently, a Prop. 65 bounty hunter need only prove that a defendant's product contains a chemical known to the State of California to cause cancer or reproductive toxicity and lacks the necessary warnings. Compliance with FHSA's national labeling standard is no defense. Allowing out-of-state Prop. 65 defendants to raise FHSA compliance as an affirmative defense, however, supports Congress's intent for a national uniform labeling system and does not prohibit bounty hunters from enforcing Prop. 65. Indeed, in addition to the two current requirements, the Prop. 65 bounty hunter need only prove a Prop. 65 defendant's failure to comply with FHSA. Furthermore, it recognizes Congress's right to regulate interstate commerce[235] without infringing upon California's right to regulate intrastate commerce.

Second, CPSC should require, as a condition of Prop. 65's approval under the FHSA, a provision that provides the California Attorney General the authority to disapprove frivolous lawsuits. Currently, California requires bounty hunters to file 60-day intent-to-sue notices with the Attorney General's office. The Attorney General, however, lacks the authority to bar those suits its deems frivolous. As a result, all suits, whether frivolous or not, proceed. Bounty hunters, however, are essentially "assistant" attorneys general. As Deputy Attorney General Ed Weil notes, "If they weren't around you'd have to complain more about me."[236] As "assistant" attorneys general, Prop. 65 should enable the state to disapprove those claims deemed frivolous. Approving Prop. 65 with such requirements empowers the Attorney General to eliminate frivolous lawsuits.

IV. Conclusion

Congress enacted the FHSA to provide uniform national labeling for consumer products. Congress wanted to ensure consumers obtained necessary information to alleviate injuries. By regulating the labels, Congress eliminated duplicative or unnecessary warnings. Furthermore, by limiting the required information, Congress increased the possibility that individuals would discern the material and use it in an emergency.

Prop. 65 upsets Congress's intent. It imposes a duty upon manufacturers doing business in California to warn in their cautionary labeling that California believes certain chemicals in the product cause cancer or reproductive toxicity. These additional warnings duplicate the dangers against which FHSA warnings guard and potentially increase the cautionary labeling warning's content. Assuming each state requires a similar warning, the potential exists that the cautionary labeling's content will be so great that people will ignore the warnings, fail to read them, or attempt to read the cautionary labeling but not find the necessary information in an emergency because the content is too great.

Congress passed the FHSA to preempt Prop. 65-type statutes. The FHSA warns consumers of possible injuries and dangers a product presents. Furthermore, assuming California demonstrates a unique situation requiring a unique warning, the FHSA enables California to petition the CPSC and obtain the necessary approval. CPSC, however, and not California, should determine the cautionary labeling's content. By exercising its FSHA-recognized authority and promulgating a "cautionary labeling" definition, CPSC can harmonize Congress'Congress's intent to create national uniform labeling with California's need to protect its citizens. In effect, this returns Prop. 65 back to the federal labeling barn.

235. U.S. CONST. art. I, § 8.

236. PROP. 65 NEWS, May 1997.