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January 18, 2008

CITIZEN'S PETITION

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: **Citizen's Petition: FDA should issue a formal determination that when applied to foods and dietary supplements, California's Proposition 65 causes consumer confusion, "misbrands" safe and wholesome products, and frustrates FDA's ability to carry out its statutory mandates.**

Dear Commissioner von Eschenbach, M.D.:

Swanson Health Products, Inc. ("Swanson"), a manufacturer and retailer of foods and dietary supplements, hereby petitions the U.S. Food and Drug Administration ("FDA") pursuant to 21 C.F.R. §10.30, requesting the Commissioner of Food and Drugs to expeditiously take all appropriate steps to prevent California's Safe Drinking Water and Toxic Enforcement Act ("Proposition 65")[1] from being applied to foods and dietary supplements, on the ground that Proposition 65 on its face, and as applied, conflicts irreconcilably with the Federal Food Drug and Cosmetic Act of 1986 ("FFDCA") and FDA's implementing regulations.

[1] Proposition 65 is codified at California Heath & Safety Code §25249.5 et. seq. The warning provision, which is the subject of this petition, is section 25249.6 "Required Warning Before Exposure to Chemicals Known to Cause Cancer or Reproductive Toxicity. 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, except as provided in Section 25249.10."

Proposition 65 requires that ***all*** products that expose persons in California to ***any detectable amount*** of a chemical "known to the State" to cause cancer or reproductive harm must be accompanied by a warning. Foods and dietary supplements may, and often do, contain minute amounts of naturally occurring chemicals that may be toxic or carcinogenic in large doses, but are benign in the small amounts found in these foods and products.

Proposition 65 permits ***anyone*** to bring an action to enforce its requirements, and to recover attorneys fees and costs if the ***defendant*** – in an unwarranted reversal of the normal burden of proof – fails to meets ***its*** burden of showing at trial that a warning is ***not*** required. Proposition 65 thus creates an incentive for plaintiffs who are, in effect, professional "private enforcers," to bring actions against, and extort settlements from, small and mid-size defendants who cannot afford the exorbitant expenses of mounting a full-scale defense against these claims. The resulting settlements typically provide for the formulation of a "warning" that is based not on sound medicine or science, but rather on litigation necessity and practicality. Such warnings are frequently alarmist for no legitimate reason, and are antithetical to FDA's mission to ensure that warnings on foods and dietary supplements are accurate and reflect the best available knowledge drawn from reliable medical and scientific evidence.

Although this petition is filed by Swanson in the context of current Proposition 65 litigation, the issues presented apply equally to *all* foods and dietary supplements. FDA should use this opportunity, and the facts and evidence Swanson presents as exemplars, to provide guidance and assistance to the entire food and dietary supplement industry.

I.
INTRODUCTION

A. Background

For well over a decade, public prosecutors and private enforcers have sued the manufacturers, distributors, and retailers of hundreds of foods and dietary supplements for alleged violation of Proposition 65. To date, targeted products include but are not limited to: wine, calcium supplements, cheese, chocolate, fish oil, tuna and other seafood,

vinegar, French fries and other fried foods, and scores of dietary supplements. These suits tend to run through product categories for years – until the entire industry has been sued and has signed one or more "private agreements," or until enough "big companies" are sued that a collective defense may be formed to work through the courts to resolution.

In recent cases, when FDA has expressly recognized that Proposition 65 conflicts with the FDA regulatory scheme, California courts have deferred to FDA.[2] The State of California and private enforcers of Proposition 65 appear undeterred by the *Dowhal* and *Tri-Union* decisions and construe them narrowly to apply solely to the products at issue in those cases. Currently, public prosecutors and private enforcers continue to file Proposition 65 enforcement actions against food companies and dietary supplement manufacturers - and there is evidence that this trend is escalating, as more private enforcers and some district attorneys are taking steps to join the fray. Through these "enforcement actions," the private and public enforcers compel manufacturers, distributors, and retailers to place misleading and alarmist warning on their products, or to comply with arbitrary "standards" imposed inconsistently via "private agreements." Essentially, Proposition 65 is giving free reign to plaintiffs' attorneys to set the standards for what acceptable levels will be of listed chemicals in foods and dietary supplements – and to profit from it.[3]

Without FDA's involvement, food and dietary supplement manufacturers, especially small and medium sized companies such as Swanson, are simply not able to mount an effective defense to this paralyzing law, which literally requires warnings on

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[2] See *Dowhal v. Smithkline Beecham Consumer Healthcare, et. al.*, 32 Cal. 4th 910, (2004); *People ex rel. Lockyer v. Tri-Union Seafoods, LLC* 2006 WL 1544384 (Cal.Superior May 11, 2006).

[3] Proposition 65 provides that the private enforcers are entitled to 25% of all civil penalties they collect. Health & Safety Code 25249.7. *See* discussion below at III.B.3. California also has a "private attorney general" statute, Code of Civil Procedures §1021.5, which is applied in Proposition 65 enforcement actions to require that defendants pay plaintiffs' attorneys' fees and costs as a condition of settling the case. Cal. Code Regs Tit. 11 § 3200.

foods and supplements for *any detectable level* of a listed chemical. If a food or supplement manufacturer considers the state warning to constitute misbranding, and does not provide it, *anyone* may sue under Proposition 65 to compel the warning, and for profit. ***Simply put, Proposition 65 considers every food and dietary supplement "hazardous" and compels misbranding by labeling to this effect.***

Although defendants are given the *opportunity at trial* to prove that warnings are not required on a product-by-product, chemical-by-chemical basis, as a practical matter, this is unworkable, ruinously expensive, and illusory.[4] There are few California-adopted standards and fewer state-approved methods for quantifying exposures, and the burden of proof is on the defendant.[5] The determination that warnings are not required is made by a court, or usually by a private agreement - ***after the fact***. There is simply no way for a food or dietary supplement manufacturer to know with certainty whether the products it sells require a Proposition 65 warning or not – until the court makes a determination after a trial. This state of affairs compels food and dietary supplement manufacturers to either add the misleading Proposition 65 "warning" to labels as a prophylactic measure, or to wait to be sued and enter into a private agreement where quantifiable "standards" and test methods are set by a prosecutor or private plaintiff.[6] Clearly, the entire Proposition 65 regulatory scheme conflicts irreconcilably with the FFDCA, and compromises FDA's ability to fulfill its statutory mandates.

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[4] See Section III.B.2 below.

[5] See discussion in Section III.B.3.

[6] See discussion in Section III.B.4. Even where a Proposition 65 defendant enters into a private agreement, this will not prevent another Proposition 65 lawsuit for the *same chemical exposure* in the future – even when the Attorney General of the State of California sets the original standards in a court-approved settlement! *Brimer v Royal Doulton USA, Inc.*, San Francisco County Superior Court, CGC-07-459941 (case dismissed after settlement December 31, 2007). The defendants in *Royal Doulton USA* were the same defendants that had settled with California in *People v. Wedgwood USA, Inc. et.al*., San Francisco County Superior Court, No. 938430 (1993).

As explained below, there is simply no way for the two laws and their regulatory schemes to be harmonized. With every lawsuit and settlement, FDA's regulatory authority is further degraded. With every prosecution, more fundamentally untrue and misleading warnings are compelled to misbrand products and alarm consumers. With every settlement, more inconsistent and arbitrary standards are established. To avoid "death by a thousand cuts," FDA should act immediately to issue a determination that Proposition 65 on its face and as applied to foods and dietary supplements conflicts with the FFDCA, misbrands products, confuses consumers, and frustrates FDA's ability to carry out its statutory mandates.

B. Factual background concerning Proposition 65 litigation against Swanson

To enable FDA to evaluate Swanson's petition in the context of an actual Proposition 65 enforcement action, Swanson provides the following statement of facts.[7] Swanson's experience is typical, not the exception, and illustrates how Proposition 65 is applied to foods and dietary supplements by the State of California and so-called "private enforcers."

Swanson is a family-owned vitamin and health food manufacturer and retailer located in North Dakota. Since 1969, Swanson has formulated its own brand of products and is in compliance with FDA requirements. Swanson is a member of and complies with the Natural Products Association ("NPA") Good Manufacturing Process ("GMP") program,[8] and works only with other GMP-compliant companies and suppliers.[9]

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[7] Where noted, Swanson has attached pleadings, private agreements and other documents as exhibits. If FDA deems it necessary or desirable, Swanson is willing to provide sworn declarations and/or to testify before FDA under oath concerning the factual background section of this Petition.

[8] Only 10 to 15% of healthcare companies participate in the NPA GMP voluntary program. Recognizing and insisting upon the purity and healthfulness of its ingredients as well as the formulated products it sells, Swanson works only in conjunction with other GMP-compliant manufacturing partners.

[9] Swanson also complies with FDA's recently adopted GMP standards.

Swanson does not have a presence in California, but markets its products exclusively via telephone, on-line (www.swansonvitamins.com), and through mail order.

On May 29, 2007, As You Sow ("AYS"), a Proposition 65 private enforcer, issued a 60-day notice of intent to sue, alleging that Swanson's products contained lead and lead compounds and thus violated Proposition 65's warning requirement.[10] On August 14, 2007, AYS filed suit in San Francisco Superior Court.[11] Swanson has advised AYS that its products comply fully with FFDCA and the California Sherman Food and Drug Act ("Sherman Act").[12] *AYS does not contest Swanson's compliance with FFDCA or the Sherman Act*. In fact, AYS does not contest that some of the products named in the complaint meet the same standards that AYS itself established in some of its own private settlements with other dietary supplement manufacturers.[13] The thrust of AYS' position, which mirrors the Attorney General's position set forth in *Tri-Union* and other cases, is that compliance with FDA requirements, and even California's Sherman Act, is entirely irrelevant to the question of whether a Proposition 65 warning is required.[14]

Consumers receiving Proposition 65 warnings are both confused and angry. As a prophylactic measure, and to avoid imposition of ruinous civil penalties and liability for AYS' attorneys' fees and costs, Swanson has begun providing Proposition 65 warnings

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[10] A copy of the 60-day notice of intent to sue is attached as Exhibit 1.

[11] *AYS v. Swanson Healthcare Products, Inc.*, San Francisco County Superior Court, No 466169. A copy of the complaint is attached as Exhibit 2.

[12] Sherman Food and Drug Act, California Health and Safety Code §109875, et.seq.

[13] See *AYS v. Nature's Way*, San Francisco County Superior Court, No 422848, (2005). *Nature's Way* and several other AYS private agreements establish a 3.5ug naturally occurring level for lead. When this quantified level is added to Proposition 65's so-called "safe harbor" exposure level of .5ug, AYS allows Nature's Way and other companies to warn only for those products whose recommended daily dose exceeds 4 ug. See discussion below in section III.B.5.

[14] Proposition 65 provides that its remedies may be imposed in addition to remedies imposed by other laws. California Health and Safety Code §25249.13.

for products shipped to California consumers.[15] As FDA recognizes, virtually every food and dietary supplement contains detectable levels of one or more of the listed chemicals.[16] Swanson anticipated that because Californians are inundated with ubiquitous Proposition 65 warnings, they would understand that the "dose makes the poison" - and would also know that Proposition 65 requires that warnings be given when any detectable amount of a listed chemical is present – such that the provision of this "warning" does not mean that the products are impure, unsafe, or unhealthful. Swanson was mistaken.

Based upon the inquiries and order cancellations Swanson has received, even California consumers do not expect Proposition 65's alarmist statements to be associated with healthful foods and vitamin/mineral dietary supplements. Consumers are confused.[17]

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[15] Although there is no case law upholding it, the Office of the Attorney General has promulgated regulations that appear to allow a putative defendant like Swanson, to avoid having to pay a private plaintiffs attorneys' fees, which routinely exceed the amount of civil penalties, after the putative defendant agrees in writing to give the Proposition 65 warning. Cal. Code Regs. tit. 11 §3102 (c) It is our experience that the private plaintiffs' attorneys will refuse to offer any settlement terms to defendants who refuse to pay them. Thus, this provision is of little practical value.

[16] Under federal law, these chemicals are deemed "naturally occurring." For many reasons, articulated over the years, FDA does not have a "zero tolerance" policy – opting for a flexible scientifically based regime. A few months ago, FDA restated its views when responding to comments concerning contaminents in dietary supplements: "We do not have a 'zero tolerance' policy for such unavoidable contaminants but we have issued some regulations and guidance to address certain common contaminants. We also have issued a booklet entitled "Action Levels For Poisonous Or Deleterious Substances In Human Food And Animal Feed" (Ref. 30; available at http://www.cfsan.fda.gov). The booklet is a useful resource for manufacturers who seek information about common contaminants that may adulterate a dietary supplement product or lead to adulteration. (Another resource is the Foods Chemical Codex, which includes monographs on many substances, such as salts that are used as sources of minerals used in both dietary supplements and conventional food. These monographs include limits on common contaminants, such as lead or other heavy metals. In addition, the regulations in 21 CFR part 109 provide information about certain contaminants.) 72 Fed Reg 34751, 34840 (July 25, 2007).

[17] Swanson has been keeping track of the many calls that it has received from alarmed consumers about the Proposition 65 warnings. For the most part, consumers are confused by the statutory scheme that requires warnings at any detectable level and does not recognize an exemption for foods and dietary supplements that meet all FDA requirements. They simply do not believe Proposition 65 requirements, even when Swanson refers them to the OEHHA website for information about Proposition 65. Swanson

Footnote Continued on Next Page

Further, they are angry about receiving the "warning." Even long term customers, after being told that the products are the same and that the products meet or exceed all federal standards, do not accept the explanation. They simply do not understand the counterintuitive Proposition 65 regulatory scheme that forces a company like Swanson, who for four decades has been a leader in manufacturing and distributing much needed health foods and dietary supplements, to make such statements with respect to its safe, pure, and nutritious products.

II.
ACTION REQUESTED

FDA should issue a formal determination that, when applied to foods and dietary supplements, California's Proposition 65 causes consumer confusion, "misbrands" wholesome products, and frustrates FDA's ability to carry out its statutory mandates.[18] Recognizing that FDA may choose to act in a deliberative and public process on this important issue, Swanson suggests a two step process: First, issue a directive finding that Proposition 65 on its face conflicts with the FFDCA; and second, to initiate a full evaluation to ensure that all parties have an opportunity to be heard, before the directive becomes final.

By taking the first step and issuing the requested directive, Swanson and other food and dietary supplement manufacturers who have been ensnared in Proposition 65 enforcement actions, may under the primary jurisdiction doctrine request California

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has experienced product returns, and a great deal of hostility. Swanson has lost a number of customers as a result of its attempts to provide a Proposition 65 warning. A copy of the phone log (redacted to protect consumer identity) is attached as Exhibit 3.

[18] Over the years, FDA has received a number of requests to issue guidance concerning Proposition 65's application to FDA regulated products. We understand that these requests, however, have been product or chemical specific. This request differs in that it is submitted as a formal Citizen's Petition and asks FDA to evaluate Proposition 65 Act on its face and as applied to determine whether this unique California law conflicts irreconcilably with the FFCA. The logic and analysis contained in FDA's earlier guidance, issued with regard to nicotine patches and tuna, appears to apply broadly to the questions raised here.

courts to stay the proceedings against them until the conclusion of the formal proceeding. This "stay" should prevent further erosion of the FFDCA's requirements and of FDA's authority until the final decision on preemption has been rendered.

C. Recommended Steps to Implement Swanson's Request

The specific steps Swanson requests that FDA take are as follows:

1. Open a docket in response to this petition.

2. Issue a letter to the State of California, Environmental Protection Agency, Office of Environmental Health Hazard Assessment, ("OEHHA") that FDA's review of Proposition 65 and the manner in which the state has implemented it indicate that Proposition 65 warnings conflict irreconcilably with the FFDCA, with respect to foods and dietary supplements.

3. Call for public comments by placing a notice in the *Federal Register* and holding a public hearing.

4. After complete investigation, including allowing the State of California and the public a full opportunity to be heard, issue findings and conclusions, in the form of formal guidance or a directive[19] that:

    a. Proposition 65 conflicts irreconcilably with federal law, diminishes the ability of FDA to maintain public confidence in the nation's food supply, confuses and alarms consumers, conflicts with federal labeling laws, "misbrands" products, and sets arbitrary and capricious standards for naturally occurring substances in foods and dietary supplements.

    b. Private settlement agreements established under color of Proposition 65 are not in the public interest, in part, for the

[19] Of course, FDA may elect to issue regulations in addition to, or in lieu of, formal guidance.

reasons set forth in 4.a above, and conflict irreconcilably with the FFDCA and its implementing regulations to the extent that they:

i. Mandate Proposition 65 warnings that misbrand the product;

ii. Set standards that conflict with FDA's regulatory scheme (e.g. fail to recognize an allowance for naturally occurring contaminants) and purport to set standards that are not: 1) established by sound science, and 2) adopted by a federal or California agency with *specific jurisdiction and competence* to issue standards for foods and/or dietary supplements.

FDA should make clear that the burden of proving that a private agreement does not conflict with federal law shall fall on the proponent (plaintiff) of the private agreement.

D. Actions that Are Not Requested

This Petition asks FDA to take action *only* on Proposition 65. It does not go beyond that law, and specifically does not ask FDA to evaluate or take any action whatsoever to limit California's ability to regulate foods and dietary supplements under California's Sherman Food and Drug Act. Nor does this Petition seek to address the effect of private tort litigation under common law and other state consumer protection statutes. By taking action to prevent California from applying Proposition 65 to foods and dietary supplements, FDA would leave untouched these state-law mechanisms that traditionally are used to partner with FDA to ensure food safety and to protect consumers within California's borders.

III.
STATEMENT OF GROUNDS

A. FDA Comprehensively Regulates Foods and Dietary Supplements

FDA has been the primary guardian of the safety of the nation's food and drug supply since 1906.[20] With regard to foods and dietary supplements, the FFDCA grants FDA broad authority to establish food safety standards and good manufacturing practices, to regulate labels for food products, and to issue food advisories as warranted.[21] From its inception, the FFDCA has focused on labeling as a principal means of communicating accurate information about foods and dietary supplements.[22]

The 1990 Nutrition Labeling and Education Act ("NLEA")[23] preempts state labeling requirements for foods, but allows states to establish and enforce safety standards exceeding those of FDA. California's Sherman Food and Drug Act is one of several state statutes that establishes state authority over food safety.[24] Significantly, California's authority to regulate foods and dietary supplements under the Sherman Act is not at issue in this Petition. FDA has mandated national uniformity in product labels and safety standards, although states retain the power to enforce higher standards through

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[20] The Food and Drug Act of 1906 was the first nationwide consumer protection law that made it illegal to distribute misbranded or adulterated foods, drinks, and drugs across state lines. It was reissued in 1938, and has undergone a number of modifications and additions since, including the Fair Packaging and Labeling Act, the Nutrition Labeling and Education Act of 1990, and The Dietary Supplement Health and Education Act of 1994. The Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U. S. C. § 301 et seq.).

[21] 21 U.S.C. § 341; FFDCA § 401; The FFDCA provides FDA authority for food labeling. FFDCA § 403 also prohibits misbranding.

[22] S*ee* generally, Samia Rodriguez, *Food Labeling Requirements*, THE FUNDAMENTALS OF LAW AND REGULATION 238-256 (Robert E. Brady et al. ed. 1997).

[23] Pub. L. No. 101-535, 104 Stat. 2353 (1990); 21 U.S.C. § 343-1.

[24] Sherman Food, Drug and Cosmetic Act, Health and Safety Code §109875, et. seq.

state product liability suits and in California through standards adopted under the Sherman Food and Drug Act and under the state's public nuisance statute.[25]

Congress' purpose in adopting the NLEA was to strengthen FDA's authority to require nutrition labeling on foods, and to establish circumstances when claims may be made about a food's nutrient content. In large measure, the NLEA was a congressional response to the increased role of the states in regulating food labeling and advertising.[26] In recent decades, medical research has demonstrated a direct correlation between consumer dietary habits and the prevalence of disease.[27] With the dissemination of this information, including FDA's own outreach programs, consumers have become increasingly concerned about the accuracy of nutrition information.[28] Moreover, the food industry is no longer local, but truly international. Consequently, state regulations, especially those that depart markedly from FDA's regulatory format, increase the probability of conflicts with national regulations and international treaties.

Congress enacted the NLEA to address these concerns, requiring standard-format nutrition labeling for manufactured food products. The NLEA achieved national uniformity by preempting state nutritional labeling standards, including nutrition content and health claims,[29] and by authorizing states to cooperate in enforcing the standards with FDA.[30]

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[25] California Civil Code §3479, et. seq. and California Civil Code §731.

[26] H.R. Rep. No. 538, 101st Cong., 2d Sess. 7 (1990).

[27] *See* INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, (Donna V. Porter & Robert O. Earl, ed., 1992) at 4.

[28] See *id*.; See also see fn. 83 below and accompanying discussion of consumer attitudes toward labeling. Hodgson and Bruhn, *Consumer Attitudes Toward the Use of Geographical Product Descriptors As A Marketing Technique for Locally Grown or Manufactured Food.* JOURNAL OF FOOD QUALITY 16 (1993) 163-174.

[29] 21 U.S.C. §343-1(a)(4). *See* generally, 55 Fed. Reg. 5191 (Feb. 13, 1990); Hearings on S. 1425 Before the Senate Comm. on Labor and Human Resources, 101st Cong., 1st Sess. 164 (1989) (statement

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Recognizing "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention," Congress passed the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[31] DSHEA recognizes that dietary supplements are foods, and regulates them as such, creating a new category within framework of food. DSHEA includes the following provisions: 1) definitions of dietary supplements and dietary ingredients;[32] 2) safety provisions;[33] 3) statements of nutritional support;[34] 4) dietary supplement labeling requirements;[35] 5) new dietary ingredients regulations;[36] and 6) dietary supplement good manufacturing practices.[37]

Congress considered the accurate labeling of dietary supplements of sufficient importance to establish an independent Commission on Dietary Supplement Labels ("CDSL"), with seven members appointed by the President.[38] The Act charged CDSL to determine how best to provide *truthful, scientifically valid, and not misleading information to consumers* so that they may make informed and appropriate health care

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of Sen. Hatch). Craig Jordan, *Preemption and Uniform Enforcement of Food Marketing Regulations*, 49 FOOD & DRUG L. J. (1994).

[30] Although NLEA contains provisions that expressly preempt states from imposing food labeling requirements, this Petition asks FDA to focus on the *conflict* between Proposition 65 and FFDCA.

[31] Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in various sections of 21 U. S. C.) (quote at § 2.).

[32] Pub. L. No. 103-417, 108 Stat. 4325 (1994) at §3; (codified at 21 U. S. C. §§ 321(ff), 321(s)(6), 350(c)(1)(B)).

[33] *Id.* § 4 (codified at 21 U. S. C § 342(f)).

[34] *Id.* § 6 (codified at 21 U. S. C. § 343(r)(6)).

[35] *Id.* § 7 (codified at 21 U. S. C. §§ 343(s), 343(q)(5)(F), 343(r)(2)(F), 350(b)(2)); *see also id.* at § 10 (codified at 21 U. S. C. § 343(s)); and § 5 (codified at 21 U. S. C. § 343-2).

[36] *Id.* § 8 (codified at 21 U. S. C. § 350b).

[37] *Id.* § 9 (codified at 21 U. S. C. § 342(g)).

[38] *Id.* § 12.

choices.[39] CDSL issued its final report in 1997.[40] The report emphasized the need for clarity – finding that label statements should "not be false or misleading" and should provide scientifically valid information to the consumer so that consumers can make informed decisions.[41] To ensure that regulations and labels are based on science, DSHEA created an Office of Dietary Supplements, within the National Institutes of Health to direct and coordinate research on dietary supplements and serve as an advisor to FDA.[42]

B. Proposition 65 Overview

Proposition 65 is easily the most controversial environmental law in the country. Written by environmental activists and politically ambitious public prosecutors, it was adopted by ballot initiative in the November 1986 election, after a flamboyant campaign that played to the electorate's fear of chemicals. The Proposition 65 ballot argument set the tone for this law:

> Nearly every week sees a new toxic catastrophe. Children in [California] have already been exposed to chemicals that make them sterile or give them cancer.
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> * * *
>
> Our present toxic laws are not tough enough. Despite them, polluters contaminate our drinking water and expose us to extremely toxic chemicals without our knowing it. The

[39] Id. Letter from Malden C. Nesheim, Ph.D. Chairman, CDSL, to President Clinton, November 24, 1997, transmitting the CDSL Final Report.

[40] *Report from the Commission on Dietary Supplement Labels,*November 1997, available at http://web.health.gov/dietsupp/cover.htm.

[41] Id. at Chapter III.

[42] *Id.* § 13 (codified at 42 U. S. C. § 287c-11).

> health of innocent people is jeopardized. And the public must pay massive costs for clean-up.[43]

Uniquely, Proposition 65 applies to all products or processes containing or producing any amount of a listed chemical, regardless of the amount of the chemical that is present or produced; it places the burden on the defendant to prove the level in question is safe; and it is enforced through lawsuits filed in state courts by public prosecutors and private parties, rather than through an administrative process with right of judicial review.

In practice, Proposition 65's substantive requirements have been implemented on an ad hoc basis through settlement agreements negotiated defendant-by-defendant, rather than through the regulatory process. Each successive wave of industry settlements becomes the "floor" for the next round of negotiations, until uncodified apocrypha, rather than reasonable interpretations of the implementing regulations issued by the state, become the standards to which putative defendants must measure up. This makes it difficult to comply with Proposition 65, and many companies who thought they were in compliance with it have settled with private enforcers to avoid litigation, after receiving 60-day notices of intent to sue claiming novel theories of violations.

To assist FDA in understanding the application of this unique and deceptively complex law as it applies to foods and dietary supplements, we discuss the major provisions in more detail below.

1. Proposition 65 Warning Statute

Proposition 65's warning provision requires any person who exposes an individual in California to ***any detectable amount*** of a chemical "known to the state" to cause cancer or reproductive toxicity to give a clear and reasonable ***warning***. The statute reads:

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[43] A copy of the Proposition 65 Proponents' Ballot Argument (1986) is attached as Exhibit 4.

> **25249.6. Required Warning Before Exposure To Chemicals Known to Cause Cancer Or Reproductive Toxicity.** 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, except as provided in Section 25249.10.[44]

To avoid liability, the defendant at trial must both a) establish what the "safe" level of exposure should be, and b) prove that the actual level of exposure does not pose an unacceptable risk, on a product-by-product, chemical-by-chemical basis.[45] By this artifice***, the statute sets the warning threshold at the level of trace detection for all products and all listed chemicals, but preserves the illusion of higher levels by providing that a defendant may establish them as an affirmative defense at trial.***.

The "affirmative defense standards" set forth in Section 25249.10(c) are themselves inchoate:

> An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.[46]

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[44] California Health and Safety Code section 25249.6.

[45] California Health & Safety Code 25249.10(c). Section 25249.10 contains two other provisions. Section 25249.10(a) allows a one year grace period after a chemical is listed before the warning requirement is enforceable. Section 25249.10(b)

[46] *Id.*

2. Proposition 65 warnings

California has adopted "safe harbor" warning language. For a carcinogen, the warning is:

> WARNING: This product contains a chemical known to the State of California to cause cancer.[47]

For a reproductive toxin the warning is:

> WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.[48]

Although variants in this language are not unheard of, the signal word "WARNING" is always present, as is the phrase "known to cause" cancer or birth defects. As applied to foods, the warning always begins with the word "**WARNING**," often in larger type and bolded. In the case of dietary supplements, the current warnings demanded are:

> WARNING: The use of this product will expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.[49]

Settlements involving supermarkets and restaurants that have been sued for selling fresh and frozen fish and certain fried foods provide other examples of warnings. Aware that FDA had written to California expressing its disagreement with the State's enforcement of Proposition 65 with regard to certain seafood,[50] the Office of the Attorney

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[47] Cal. Code Regs. tit. 22, § 12601(b)(4)(A).

[48] *Id.* § 12601(b)(4)(B).

[49] For example, see *AYS v Nature's Way* ¶2; *Gillett v Nexgen* ¶2 . § 12601(b)(4)(B).

[50] Letter from FDA Commissoner Lester Crawford to California Attorney General Bill Lockyer, dated August 12, 2005, (Crawford Letter) is attached as Exhibit 5.

General attempted to incorporate some information about the health benefits of eating fish to balance the adverse effect of the Proposition 65 warning. Required to be posted where the fish is offered for sale, the warning is a 10"x 10" sign with the word **WARNING** in one inch high bold letters centered on top. The word "warning," however, clearly overpowers the other information.[51]

In the so-called "French fry" cases,[52] the Office of the Attorney General tried a slightly different approach in a settlement with Kentucky Fried Chicken.[53] Each restaurant may choose from several options. They may post large warning signs, or a smaller sign at each ordering station that gives a bare bones warning accompanied by a brochure that provides clarification, including a statement that "FDA does not advise

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[51] See Consent Judgment, *People v. Safeway, et. al.*, San Francisco County Superior Court, No. CGC-03-417139. The first case was brought by the Office of the Attorney General against a number of grocery stores for selling certain fish without a Proposition 65 warning. The warning agreed to as a condition of settling the case was an attempt to provide consumer information to balance the effect of the warning with accurate information about the health benefits of fish. These 10" x 10" signs are posted in supermarkets where packaged fish are sold. A copy of the warning is attached as Exhibit 6. This was not the only lawsuit. The Office of the Attorney General also sued California restaurants to compel Proposition 65 warnings for the seafood they sell. *See People v. Benihana*, et. al. , San Francisco Superior Court No. BC 293749 (2003). Further, scores food establishments have been targeted by several private enforcers, including Consumer Defense Group Action, Public Media Center, AYS, and the Working Group on CISC. See details on the Office of the Attorney General's web-page, Proposition 65 notice search: http://proposition65.doj.ca.gov.

[52] *People v. Frito-Lay, et al*, Los Angeles County Superior Court, BC 338956. In these coordinated cases, Attorney General Bill Lockyer sued over a dozen snack food manufacturers, restaurant chains, and 100 Does, for failing to provide Proposition 65 warnings for acrylamide, which occurs naturally when starchy foods are cooked. Significantly, this litigation was commenced even though the State of California has not issued a so-called safe harbor level for acrylamide, but was planning to do so. Concerned, FDA wrote to Joan Denton, Director, OEHHA, opposing Proposition 65 warnings for several reasons, including stating "premature labeling of many foods with warnings about dangerous levels of acrylamide would confuse and potentially mislead consumers, both because the labeling would be so broad as to be meaningless and because the risk of consumption of acrylamide in food is not yet clear." Letter from FDA to Joan Denton, OEHHA, dated June 13, 2003.

[53] Consent Judgment of Kentucky Fried Chicken, *People v. Frito-Lay*. A copy is attached as Exhibit 7.

people to stop eating baked or fried potatoes."[54] Significantly, none of the warning versions tell consumers that FDA opposed the provision of the warnings.[55]

At trial in *People v. Tri-Union*, the Attorney General argued that warnings of the ilk used in *Safeway* and *Kentucky Fried Chicken* did not conflict with the FFDCA, in part because the warnings were balanced and incorporated FDA guidance.[56] Of course, the trial court ruled otherwise.[57]

3. The Proposition 65 list of chemicals that require warnings

The Proposition 65 list contains approximately 800 chemicals, many of them "families of chemicals" (e.g. lead and lead compounds; soots, tars, and mineral oils), hormones (e.g. estrogen and testosterone), and even substances needed to preserve health (e.g. vitamin A, chromium and chromium compounds). Where chemical elements are listed along with their compounds, the listing does not speciate or differentiate between

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[54] *Id* at ¶¶2-3.

[55] In March 2007, FDA wrote a second letter opposing Proposition 65 warnings, restating its concern that "the warnings may have the following adverse effects, among others:

- Create unnecessary and unjustified public alarm about the safety of the food supply;
- Dilute overall messages about healthy eating, and
- Mislead consumers into thinking that acrylamide is only a hazard in store-bought food."

Letter from Terry C. Troxell, Phd., Director, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, to Joan Denton, Director, OEHHA, and Deputy Attorney General Ed Weil, dated March 21, 2006 ("Troxell 2006 Letter"). A copy of the Troxell 2006 letters are attached as Exhibit 8.

[56] *See* generally, *People ex rel. Lockyer v. Tri-Union Seafoods, LLC* 2007 WL 1786439 (Cal.App. 1 Dist.). A copy of the Attorney General's Opening Brief is attached as Exhibit 9.

[57] *See* generally, People *ex rel. Lockyer v. Tri-Union Seafoods, LLC* 2006 WL 1544384 (Cal.Superior May 11, 2006). A copy of the trial court's Findings of Fact and Conclusions of Law is attached as Exhibit 10.

substances that are beneficial to life, chemically inert in the body, or hazardous.[58] Moreover, chemicals are placed on the list based upon data from high-dose animal tests, which may or may not be relevant to humans. The list is therefore overinclusive, and because it does not focus on relevant harm to humans, deceptively inaccurate. [59]

Although Proposition 65 has been law for over twenty years, the Office of Environmental Health Hazard Assessment ("OEHHA"), the lead agency for administering Proposition 65, has adopted "safe harbor" exposure levels for fewer than one-third of the listed carcinogens, and only a handful of reproductive toxins. These safe harbor levels are of limited use, especially in the case of foods.[60]

First, like the chemical listing documents from which they are derived, these levels are based almost exclusively on animal tests, and do not take human physiology into account.[61]

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[58] In some cases, such as hexavalent chromium and methyl mercury, these variants of chromium and mercury respectively, are listed separately as well as in the more all inclusive elemental listing.

[59] FDA has considered and rejected a regulatory scheme that would establish a list of contaminents, similar to Proposition 65. Recently, when promulgating Good Manufacturing Practices for dietary supplements, FDA said: "It is impractical to provide an exhaustive list of relevant types of contamination, and a list that is longer, but not exhaustive, is more likely to be misunderstood as suggesting that the only types of contamination that are significant are the types of contamination in the list. For that reason, we have eliminated the reference to contamination to clarify that in any instance where it is appropriate quality control personnel must ensure that the disposition decision is based on a scientifically valid reason and also approve the reprocessing." 72 Fed Reg 34751, 34860 (July 25, 2007).

[60] California Code of Regulations tit 11 §12705 (carcinogens); California Code of Regulations tit 11 §12805 (reproductive effects).

[61] For example, exposure to high levels of chromium (particularly among chrome industry workers) is associated with cancer of the respiratory tract. Mice subjected to lifetime exposure to large doses of chromium develop tumors, while similarly exposed rats do not. Chromium is a carcinogen in some species at some doses, and has been judged a human carcinogen by the International Agency for Research on Cancer. Yet chromium is an essential element constantly present in the human bloodstream, necessary for the maintenance of normal blood glucose levels,

Footnote Continued on Next Page

Second, California does not take the "form" in which the listed chemical appears in food into consideration when either listing the chemical or establishing the safe harbor level. For example, lead in food is often found with calcium or other metals, and is either chemically inert or not 100% biologically available. However, California's "safe harbor" levels fail to take the critical factor of much reduced biological availability into consideration; instead, the state considers the amount of the listed chemical "crossing the lips" to be the "level of exposure" for ingested chemicals. Where OEHHA has not adopted a safe harbor level, the defendant at trial is required to do so, on a chemical-by-chemical, product-by-product basis.

Third, the safe harbor levels fail to take into consideration that plants naturally produce some of the listed chemicals. To illustrate, carcinogenic pesticides produced naturally by plants to defend themselves are found at levels greater than 10 parts per million in apples, celery, coffee, carrots, cauliflower, grapes, honey, potatoes, and many other common foods.[62]

Fourth, there is a lack of guidance on how the regulated community is to evaluate foods and dietary supplements under Proposition 65. This is not likely to be remedied soon, considering the lack of state approved analytical methods, and the lack of expertise within OEHHA on foods and nutrition. We do note, however, that California does have such expertise within the state's Department of Health Services' Food and Drug Branch, which is the lead agency for administering the Sherman Food and Drug Act.

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and is naturally present in common foods. Chromium deficiency can cause serious illnesses; supplemental chromium is administered as a medication to treat these diseases. Chromium is a carcinogen, but it is also a medicine and a normal component of the human diet and physiology. (Citations available.)

[62] Ames and Gold, "Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis; *Science*, Vol. 249, p. 970 (1990). See also, Ames, Magaw and Gold, "Ranking Possible Carcinogenic Hazards," *Science*, Vol. 236, pp. 272, 273 (1987).

Fifth, the levels are not binding. Although they are afforded presumptive effect, either side may challenge them at trial.

4. The Proposition 65 Enforcement Scheme

Failure to give a Proposition 65 warning before exposure is punishable by a civil penalty of up to $2,500 per violation, per day. As interpreted by the Office of the Attorney General, each item sold in California constitutes a separate violation.

The Act is enforced through civil lawsuits, which under this unique law places the burden of proof on defendants. Although primary jurisdiction is vested in the State Attorney General and designated city and county prosecutors, in fact and in practice, *anyone* may bring suit to enforce the Act, as long as the putative plaintiff first gives written notice to the alleged violator and designated public prosecutors, and the public prosecutors fail to commence a civil action within sixty days (the "60-day Notice").

In the view of many, Proposition 65 permits legalized extortion of the business community by private enforcers, who retain twenty-five percent of any civil penalty, as well as recoupment of their attorneys' fees and costs.[63] As a practical matter, a business that is unable to show that it has complied with Proposition 65 to the *satisfaction of the private enforcer* is left with two alternatives: to settle with the private enforcer on its terms, or to litigate the merits of the case. At trial, the plaintiff need only show that one of over 800 listed chemicals is present in ***any*** amount, and the defendant is left to prove at trial that the exposure at issue did not require a warning. This is an uphill battle at best.

The cost of such defense to a single defendant is prohibitive, a fact that bounty hunters and the Attorney General count on to compel settlements on terms they dictate. In the 21 years that Proposition 65 has been law, thousands of businesses have settled

[63] California Health & Safety Code 25191.7 provides that private enforcers in Proposition 65 actions keep 25% of all civil penalties imposed.

with plaintiffs involving tens of thousands of products. Because these are private agreements, they do not have the effect of preventing future lawsuits, but merely are a contract between the parties. Many defendants have been sued over and over again, even for the same products. Moreover, full compliance with a settlement between a company and the State of California will not even protect a business from future lawsuits by a non-signatory private enforcer! To illustrate, in *People v. Wedgwood USA, Inc., et al.*,[64] the Office of the Attorney General entered into a consent judgment with over a dozen large international manufacturers of decorated dinnerware, setting standards for allowable lead in the products and establishing tests to prove compliance. In the late 1990's, several private plaintiffs began suing smaller manufacturers in the industry and established *different and varying standards and tests* in numerous private agreements.[65] In 2006, one of these private plaintiffs, Russell Brimer, decided to sue some of the original *Wedgwood* defendants on the ground that he disagreed with the standards and tests that the Office of the Attorney General imposed in the *Wedgwood* settlement. When the Office of the Attorney General refused to defend its own settlement and the validity of the standards it contained, the defendants gave up, paid up and settled with Brimer, agreeing with the private enforcers new and different standards in yet another private agreement.

Recent events ensure that Proposition 65 defendants will continue to be forced to make a "business decision" and pay to settle, rather than litigate the merits of these cases (e.g. defendants will not undergo the time, excessive expense, uncertainty, and heavy burden to litigate to establish quantified exposure levels under 25249.10(c) that would exculpate their decisions not to provide warnings).

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[64] *People v. Wedgwood USA, Inc. et. al*., San Francisco County Superior Court, No. 938430 (1993).

[65] Three of the principal settlements are: *Lehman v. Arc International, et. al*.; San Francisco County Superior Court, No 418025 (2003); *Brimmer v. Boelter, et.al.*; San Francisco County Superior Court, No 418025; *DiPirro v Royal Doulton*, above. These and other private enforcement actions against decorated glass and ceramic products and tableware span most of a decade and are not over yet - these actions involve prosecutions of *several hundred companies*.

California Code of Civil Procedures §1021.5 provides that a successful party who achieves a significant public benefit shall be entitled to reimbursement of its reasonable attorneys' fees and costs of suit from the opposing party. Although the statute is neutral, applying to both successful defendants as well as plaintiffs, in practice it is a one way street in the direction of Proposition 65 plaintiffs. In 2003, the Office of the Attorney General promulgated regulations ostensibly to give guidance to the courts and parties on how settlements should be construed.[66] Section 3200 provides that, where a defendant provides a warning where it has not done so before, the provision of that warning is "deemed" to be "in the public interest." By this simple statement, the Attorney General has ensured that private enforcers can recoup their attorneys' fees and costs under California's private attorney general statute from foods and dietary supplement manufacturers.[67]

Compounding the inequity, the California Court of Appeal ruled in *DiPirro v Bondo Corporation* that a defendant who proved at trial that the level of consumer exposure to toluene from automotive touch up paint was not entitled to recoup its attorneys' fees and costs from the plaintiff, because the defense did not provide a "public benefit."[68] The denial was at the urging of the Office of the Attorney General who, after briefing was closed, submitted a brief arguing in part that Proposition 65 contained a civil penalty provision, and as a consequence, defendants should *never* be entitled to reimbursement of their fees and costs, because to avoid the imposition of the penalty they must litigate. Bondo sought review by the California Supreme Court, but the *writ of certiorari* was denied in a split decision.[69]

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[66] Cal. Code Regs tit. 11 § 3000, et. seq. See California Health and Safety Code 25249,7(d)-(f).

[67] Cal. Code Regs Tit. 11 § 3200.

[68] *DiPirro v Bondo Corporation* 153 Cal. App. 4th 150 (62 Cal. Rptr. 3d 722).

[69] *Id., cert denied,* Oct, 24, 2007.

5. Proposition 65 establishes arbitrary standards, via inconsistent enforcement, and allows private individuals to overstep FDA by dictating warning requirements and deciding when they are not necessary

Proposition 65 turns rational regulation on its head. Public prosecutors and private enforcers have set food safety standards on a company-by-company, product-by-product, chemical-by-chemical basis using private settlement agreements to establish the levels of "naturally occurring" listed substances that are permitted to be sold without the Proposition 65 warning. These levels are inconsistent. Without exception, Proposition 65 "acceptable" levels are negotiated in secret, and are arbitrary at best. These "standards" are not based upon science; none have even been reviewed by a state or federal agency with either the technical expertise or a mandate to set food safety standards. Because these standards are created by contract between different enforcers and defendants, the allowable levels of listed chemicals, even for the same food or dietary supplement, vary greatly from settlement to settlement.[70]

In the case of foods and dietary supplements, this is well documented, as we show using the dietary supplement enforcement actions over the past few years.[71] A number of settlements require the defendant to provide warnings regardless of the level of the listed chemical in the product, and do not recognize California's .5 ug per day "safe harbor" threshold.[72] *AYS v Herba Enterprises, Inc.*,[73] and *Gillett v Nexgen Pharma, Inc.*[74] are two examples. In marked contrast, other settlements, such as *AYS v. Nature's Way Products, Inc, AYS v. Threshold Enterprises, Ltd; AYS v. Nature's Sunshine Products, Inc.; and*

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[70] To illustrate, compare *AYS v Nature's Way* (Exhibit 11), *Gillett v. Nexgen* (Exhibit 12).

[71] A chart listing many of the dietary supplement settlements is attached as Exhibit 13. This chart shows the variation in settlement terms in a handful of sample settlements.

[72] California has issued two " safe harbor" levels for lead: .5 ug/day for reproductive effects (Cal.Code Regs. tit 22 §12805); and 15 ug/day for cancer (Cal.Code Regs. tit 22 §12705).

[73] *AYS v Herba Enterprises, Inc, et. al.* San Francisco Superior Court, No. 313637, (5/25/01).

[74] *Gillett v Nexgen Pharma, Inc,* San Francisco Superior Court, No. 465289, (9/19/07).

AYS v. Irwin Naturals allow the .5 ug and establish a 3.5 ug "naturally occurring" amount. These companies are thus allowed 4 ug/day exposure for lead. It appears that the ***companies that paid the most money got higher allowable exposure levels*** compared to smaller companies. Note: minority owned, Herba Enterprises and Kwok-Shing got no relief and must always warn. To further add to the mix, in Swanson's pending enforcement action, AYS has offered Swanson a different standard to settle – at 2 ug/day.[75]

There is another troubling provision in recent settlements that gives the plaintiff the right to determine when Proposition 65 warnings are not necessary. Consider the *Gillett v. Nexgen* settlement. Although Nexgen must provide warnings for all the products it sells, if Nexgen believes that warnings are not needed, Nexgen may conduct tests specified in the private agreement and submit them to Gillett for his concurrence. If Nexgen proceeds without Gillett's approval, Gillett may reopen the litigation and require Nexgen to litigate the merits of its decision.[76] Importantly, the underlying lawsuit involved only exposures to lead and lead compounds – yet the settlement establishes Gillett as the arbiter of when warnings are required for lead and three other chemicals – arsenic, mercury and cadmium – even though those chemical were not identified in the 60 day notice.

Private plaintiff AYS assumes even more extensive regulatory powers for itself. As a condition of settlement, AYS currently requires the companies it sues to submit testing and monitoring data for five years so that AYS can judge whether the company has complied with the settlement. For example, in some settlements AYS requires that 25% of all product lots be sent to it for evaluation for the first three years and 10%

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[75] *AYS v. Swanson*, above, Proposed Settlement at ¶ 2. The proposed settlement is attached as Exhibit 14.

[76] *Gillett v Nexgen* settlement at ¶2.

thereafter.[77] Like Gillett, AYS's monitoring requirements extend beyond lead and lead compounds to include arsenic, mercury and cadmium. AYS also routinely includes a provision that grants AYS discretion to allow defendants to remove warnings from certain products after submitting data to AYS for concurrence.[78] In still other agreements such as with *Nexgen*, no end date for the testing obligation is specified – leaving the settling company on the hook to the private enforcer indefinitely.

Under Proposition 65, private agreements must be submitted to the Office of the Attorney General and approved by the court before the enforcement action may be dismissed, but this review does nothing to ensure that settlements are consistent.[79] Even if the separation of powers doctrine did not prohibit it, courts simply do not have the ability or the time to ensure that the appropriate scientific and health considerations have been applied accurately, and that standards imposed through Proposition 65 private agreements are consistent.[80]

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[77] See *AYS v Nature's Way*, Consent Judgment at ¶2; See also, *AYS v. Swanson*, Proposed Settlement, ¶2 which has similar provisions, but different levels.

[78] Id. at ¶ 2.1. and ¶8.2.

[79] California Health & Safety Code 25249.7 (f), Cal. Code Regs. tit.11 §3003.

[80] The hearing on the *Gillett v Nexgen* settlement illustrates this point. Nexgen's settlement had been negotiated by Nexgen's in-house counsel, who had little experience with Proposition 65. After signing the agreement, but before the hearing to dismiss the case, Nexgen learned that plaintiff Gillett offered other defendants selling the same products higher lead levels before their warning obligations kicked in. At the hearing, Nexgen asked the court to construe the Nexgen settlement so that it complied with the allowable lead levels in other settlements. AYS argued that Nexgen had signed the agreement and should not be allowed to revise it. AYS also argued that the Office of the Attorney General had already reviewed the signed agreement, and that if the court made changes it would deny the Attorney General the opportunity to review again. Finally, AYS speculated that the Attorney General would likely disapprove the higher levels that had previously been entered by the court on other settlements. The court noted that a settlement agreement was in the nature of a contract, and that because Nexgen had signed it, the court would not reform it or construe its terms. A transcript of the hearing is attached as Exhibit 15.

C. FDA's Failure to Take Action Will Dilute and Diminish FDA's Regulatory Authority over Foods and Dietary Supplements and Continue to Erode Consumer Confidence in the Nation's Food Supply

1. Proposition 65 warnings confuse and alarm consumers, and impugn the wholesomeness of the nations' food supply

Proposition 65 requires a clear and reasonable "warning." As discussed above in section III.B.3, the wording may differ slightly from product to product, but the law mandates a "warning." More importantly, this warning always conveys to the consumer the message that eating the food or dietary supplement at issue will expose them to a carcinogen, a reproductive toxin, or both.

Clearly, the use of the signal word "**Warning**" coupled with the statement that the food or dietary supplement contains carcinogens and/or reproductive toxins, is alarmist and undercuts consumer confidence in the nation's food supply.[81] By the very terms of Proposition 65's warning statute, the application of a warning to healthful and nutritious foods and dietary supplements simply negates the entire foundation upon which Congress and FDA have based food regulation for over a century. Swanson's experience responding to upset and angry consumers to whom these warnings are directed bears witness to this unfortunate reality.[82]

The Proposition 65 warnings purport to be a factual statement – that the food contains one or more California-listed chemicals, but it is misleading to the point of being untruthful. Research on consumer response to nutritional labels shows that consumers expect labels to be truthful, although they also expect a certain amount of pro-product

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[81] FDA recognized this problem in its March 21, 2007 letter to Joan Denton and Ed Weil, discussed above at fn 55. Proposition 65 warnings "create unnecessary and unjustified public alarm about the safety of the food supply."

[82] See discussion accompanying fn. 17 above.

"puffing."[83] They do not, however, expect food and dietary supplement manufacturers to give a WARNING when a healthful and nutritious food complies fully with FDA requirements. This is an irreconcilable conflict and further compelling evidence of why the time is ripe for FDA to act on this Petition.

2. Proposition 65 warnings conflict with the FFDCA, and there is no way to harmonize Proposition 65 with federal law

Proposition 65 applies the warning indiscriminately, and without a thoughtful and scientific determination specific to the products at issue. Clearly, the warning's application to food fails to take into consideration that the "dose makes the poison." It omits facts about the possible harm caused by the food or dietary supplement in question, or the amount of food necessary to cause the harm. As explained above, the word "Warning" itself is misleading and untruthful. Thus, Proposition 65 warnings "misbrand" foods and dietary supplements, and therefore, violate Section 403 (a)(1) of the Act, which deems food and dietary supplements to be misbranded if "its labeling is false or misleading in any particular."

The Proposition 65 statute compels warnings at the level of detection, not the level of significant harm. Thus, Proposition 65 ***mandates overwarning***. As the California Supreme Court recognized in *Dowhal v Smithkline Beecham*, overwarning leads consumers to ignore all warnings.[84] This finding applies as much or more to foods as it

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[83] Although we are unaware of specific research on consumer perceptions of Proposition 65 warnings on foods, academic researchers, Aurora S. Hodgson and Christine M. Bruhn, have conducted focus group studies that illustrate the point that consumers may expect some overstatement, but that they expect the labels to be "truthful." See, Hodgson and Bruhn, *Consumer Attitudes Toward the Use of Geographical Product Descriptors As A Marketing Technique for Locally Grown or Manufactured Food.* JOURNAL OF FOOD QUALITY 16 (1993) 163-174.; Hodgson and Bruhn, *Geographical Names on Product Labels: Consumer Attitudes Toward Their Use*, FOOD TECHNOLOGY, February 1992.

[84] *Dowhal v. Smithkline Beecham*, above at fn 2.

does to the smoking cessation products at issue in Dowhal. This overwarning, if compelled, will over time lead consumers to ignore all warnings and health advisories, such as those FDA deems necessary to assist consumers in making personal health decisions.

Clearly, Proposition 65 warnings frustrate FDA's carefully considered federal approach to advising consumers of both the benefits and possible risks associated with foods and dietary supplements. FDA has recognized this. Discussing Proposition 65's application to canned tuna, FDA Commissioner Lester Crawford wrote to Bill Lockyer, California Attorney General, advising that the Agency believed that Proposition 65 is preempted under federal law:

> **The [FFDCA] provides broad authority for FDA to regulate the labels of food products. However, rather than requiring warnings for every single ingredient or product with possible deleterious effects, FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information, taking action in instances of adulterated and misbranded foods, and, only in exceptional circumstances, requiring manufacturers to place warnings on their products. As part of this deliberate regulatory approach, FDA has required warnings only when there is a clear evidence of a hazard, in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem.**[85]

[85] Commissoner Crawford Letter, above at fn. 50, (Exhibit 5) *See also*, Director Troxell Letter, above at fn.55, (Exhibit 8).

FDA's statement of policy articulated in this letter, applies to *all* foods and dietary supplements, and compels FDA to issue this guidance formally so that all food and dietary supplement manufacturers may benefit from it.

Because foods and dietary supplement manufacturers cannot comply with both FFDCA's stricture against misleading statements and misbranding, and Proposition 65's obligation to place warnings on all products having a detectable level of a listed chemical, an irreconcilable conflict exists. Under the Supremacy Clause of the Constitution of the United States, Proposition 65 warnings for foods and dietary supplements are therefore preempted.

3. Proposition 65 conflicts with the FFDCA's regulatory scheme and FDA's authority to implement it, because Proposition 65 allows prosecutors to establish arbitrary standards for foods and dietary supplements, and mandates warnings on a product-by-product, chemical-by-chemical basis

In practice, Proposition 65 also conflicts with the federal regulatory scheme and its goals, because it enables and even encourages standards to be established by private agreements. Moreover, many of these settlements establish individuals as the monitoring and regulatory authority for foods and dietary supplements used in California.[86] Thus, it is undeniable that, as applied Proposition 65 results in inconsistent warnings, and arbitrary decisions about when these warnings must be given to avoid litigation.

Even if FDA disregards the abhorrent inequity and unfairness of Proposition 65's enforcement process, it cannot turn a blind eye to the simple fact that standards are being set by plaintiffs through a private agreement mechanism, and that this has resulted and will continue to result in inconsistent: 1) warning requirements for the same foods or

[86] See discussion above at III.B.

ingredients; and 2) standards being set by lawyers in private negotiations – not by a regulatory agency with scientific expertise in food and nutrition. They are truly arbitrary.

Proposition 65 was adopted in part to allow *anyone* to challenge the lack of a warning for *any* exposure to a detectible amount of a listed chemical.[87] Thus, Proposition 65 cannot be applied or even modified to ensure consistent, scientifically-based warning requirements are applied to foods and dietary supplements.

One of the fundamental purposes of the FFDCA, and a primary goal for over a century, has been to establish a *consistent* regulatory scheme, with consistent standards that apply to the same foods and dietary supplements, regardless of the manufacturer of the product. Where, as here, a state law creates and enforces inconstant requirements for the same foods and dietary supplements, FDA must act to preserve its own mandates.

D. FDA Should Act Now

Recent events compel FDA to take action now. Within the past few months, FDA has promulgated important programs and policies, whose purposes and goals may be compromised by Proposition 65's continued application in the context of food and dietary supplements Second, the number of Proposition 65 lawsuits and their application to foods and dietary supplements continues to grow. Third, the time is right to act now – the evidence of irreconcilable conflict is compelling, and recent California court rulings support FDA's finding.

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[87]. California Health & Safety Code §25249.7(d). *See* generally, Proposition 65 Proponents Ballot Argument (1986) (Exhibit 4).

1. Proposition 65 warnings conflict with important new policies and programs – including the Food Protection Plan

In November 2007, FDA issued its Food Protection Plan ("the Plan") to address changes in food sources, production, and consumption that our nation faces in today's global economy. This comprehensive plan builds upon and improves the nation's food safety protection capability, outlining a strategy to protect the nation's food supply from both unintentional contamination and deliberate attack.[88] In addition to maintaining consumer confidence in the food supply, accurate and timely communication with consumers is central and a primary tool that FDA uses to implement the Food Protection Plan and achieve its important goals. The Plan is "driven by science and modern information technology," allocating resources "to identify potential hazards and counter them before they can do harm."

Proposition 65 frustrates the goal and interferes with this important program at many levels - from the questionable and over-inclusive listing of chemicals and "families of chemicals," to the application of the law through litigation, which results in ad hoc standards and quasi-regulatory requirements administered by private individuals and prosecutors.[89] Under these circumstances, the provision of a WARNING for healthful and nutritious foods and dietary supplements, even if the text of the warning was not misleading, cannot be harmonized with federal law and policy.

2. Proposition 65's application to food and dietary supplements is escalating

What began in the late 1990's as a few prosecutions of food and dietary supplement manufacturers is snowballing. With regard to acrylamide, not only is the

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[88] Department of Health and Human Services, FDA, *Food Protection Plan*: *An Integrated Strategy for Proctecting the Nation's Food Supply*, November 6, 2007. Available on line at: http://www.fda.gov/oc/initiatives/advance/food/plan.html.

[89] See discussion above III.B.

Office of the Attorney General suing to enforce warnings, but five other private plaintiffs have filed notices of intent to sue over the past three years.[90] There are now scores of products for which warnings are sought – snack foods, cereal, coffee substitutes, energy drinks, as well as potato chips and French fries. As to dietary supplements, at least one of the several private enforcers has advised Swanson that it plans an industry-wide enforcement action shortly, which it claims will result in the entire industry agreeing to follow the requirements that it is demanding of Swanson.[91] New actions are initiated frequently, and private enforcers, seeing the vast amount of money that is to be made, identify more food and dietary products that they can prosecute.[92]

3. The time is right – there is now substantial and sufficient evidence upon which FDA may determine that Proposition 65 irreconcilably conflicts with FFDCA

For all the reasons stated above and the supporting evidence submitted with this Petition, the time to issue formal and public industry guidance that Proposition 65 conflicts with the FFDCA is now. Recently, California courts have issued strong opinions supporting FDA's view that Proposition 65 warnings mislead consumers and overwarn.[93] Rather than issuing piecemeal guidance on a product-by-product, or chemical-by-chemical basis, FDA should act as soon as possible to make its views

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[90] The Office of the Attorney General maintains a web-site dedicated to Proposition 65. The site includes a feature that allows the public to search including recently filed 60-day notices by chemical, product, private enforcer and defendant. http://ag.ca.gov/prop65/. Another feature, entitled "Annual Summaries of Private Settlements," provides reports of private settlement agreements for each year since 2000. The data show total penalties, attorney fees and other funds collected, and a brief description of actions defendants were required to take to remedy alleged violations. The Office of the Attorney General makes copies of individual settlements on request.

[91] See discussion concerning AYS demands of Swanson above at III.B.

[93] See *Dowhal* above at fn 2, and *Tri-Union Seafood,*, above at fn. 2.

known. By taking this step, FDA will not only secure its ability to achieve its statutory mandates, but over time will conserve its limited resources, as the regulated community can refer to and use such public guidance without a need for individualized opinions from FDA.

IV.
ENVIRONMENTAL IMPACT

An environmental impact statement is not required for this petition.

FDA regulations governing the preparation of environmental impact statements, Title 21, Part 25 of the Code of Federal Regulations, provide that environmental impact information is required only if a petition requests approval of food, color additives, drugs, biological products, animal drugs, or certain medical devices, or for a food to be categorized as generally recognized as safe (GRAS). This petition does not fall within any of these categories, but rather deals with state-imposed statements concerning the safety and wholesomeness of foods and dietary supplements, that conflict with federal law, confuse and alarm consumers, and impugn FDA's statutory mandate.

V.
CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the Petition.

SEDGWICK, DETERT, MORAN & ARNOLD LLP

/S/	/S/
Carol Brophy Counsel for Swanson Health Products, Inc.	Stephanie Sheridan Counsel for Swanson Health Products, Inc.

cc: Michael O. Leavitt, Secretary of Health and Human Services
Honorable John Hoeven, Governor of North Dakota
Senator Bryon L. Dorgan, North Dakota