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September 18, 2008

CITIZEN'S PETITION

Supplemental Submission – Composite Reply to Oppositions Submitted

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: **SWANSON'S CITIZEN'S PETITION: DOCKET FDA-2008-P-0049-0001**
Swanson's Response to the Oppositions filed by the California Office
of Health Hazard Assessment, the Office of the Attorney General, and
As You Sow

Dear Commissioner von Eschenbach, M.D.:

Swanson Health Products, Inc. ("Swanson"), submits this Response to the oppositions to Swanson's Citizen Petition filed by the California Office of Health Hazard Assessment ("OEHHA"), the Office of the Attorney General ("AG"), and plaintiff As You Sow ("AYS") to Swanson's Citizen Petition (Docket FDA-2008-P-0049-0001).

Although intended to dissuade the U.S. Food and Drug Administration ("FDA") from acting favorably on Swanson's Petition, these three submissions ironically provide significant evidence – no less from the State itself – that actually supports and underscores the important factual and legal issues Swanson has raised. The Attorney General's opposition for example argues that the "end justifies the means" by focusing on the purported "benefits" achieved under Proposition 65. As explained below, however, these alleged benefits come at an increasingly intolerable price – the imposition by the State of California of a law that infringes on food and supplement manufacturers' constitutional rights to Free Expression and Due Process. Furthermore, both the Attorney General and AYS misapply the law of preemption, among other

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things applying case law dealing with express preemption to this conflicts preemption situation.¹ Finally, the Oppositions filed by AYS and the Attorney General stoop to personal attacks against Swanson, based on irrelevant hyperbole and substantial factual inaccuracies, which further illustrate the dangers inherent in allowing private plaintiffs, with limited understanding of the federal regulatory scheme for foods and no medical or scientific knowledge, the right to prosecute and to set standards through what amounts to contracts of adhesion, with the apparent blessing and support of the Attorney General. This only serves to emphasize why the FDA's intervention now is so important.

I.
**THE OPPOSITIONS ACTUALLY SUPPORT SWANSON'S OBJECTION TO
PROPOSITION 65'S APPLICATION TO FOODS**

A. Swanson Has Clearly Characterized Proposition 65 As It Applies to Foods -- And For all Practical Purposes it Does in Fact Apply at the Level of Detection Despite Protests to the Contrary

The Attorney General and OEHHA claim that Swanson has mischaracterized Proposition 65 in its Citizen Petition, but examination of these Oppositions proves otherwise. It is undisputed that Proposition 65 requires warnings for exposures to listed chemicals, and that it contains "exemptions" where the *defendant can prove the statute does not apply* to an exposure from a product or service under the affirmative defense standard set fourth in California Health & Safety Code (HSC) §25249.10 (c). Superficially, the Oppositions take issue with Swanson's statement that warnings are "required" at the level of detection, claiming that warnings are not "required" unless the exposure at issue exceeds the affirmative defense standard. This is a word game.

Simply put, Proposition 65 is triggered – *meaning private and public prosecutors can sue* - if the plaintiff has a *reasonable belief* that an exposure to a detectible level of a listed chemical has occurred. (HSC §25249.7(d).)

¹ Rather than including a rebuttal of some of the specific legal issues the Oppositions raise, Swanson is attaching a copy of its Motion for Summary Judgment, along with the supporting Declarations of Dr. Louis W. Sullivan and Dr. James Embree, filed July 25, 2008 in AYS v Swanson, San Francisco Superior Court No. CGC-07-466-169, as Exhibits 1-3 to this Composite Reply.

And, if the only way to protect oneself from being sued is to provide prophylactic warnings at the level of detection, then the statute *requires* warnings at the level of detection. The fact that some businesses choose not to provide warnings, and hope they will not be sued does not prove that Proposition 65 *requires* warnings at an undefined higher "affirmative defense level." It *is* evidence however, of the impossibility of complying with both Proposition 65 and FDA's strictures against misbranding.

At trial, the burden to prove innocence (e.g. that the statute does not apply to a specific product) shifts to the defendant. Clearly, *if a company can be sued based upon anyone's belief of an exposure at the level of detection, then the statute, for all practical purposes, applies at the level of detection.* As discussed below, it is this unbridled right to sue coupled with a complete lack of clear and certain standards, which violates federal and state rights to due process.

It is well-recognized that there are detectible levels of listed chemicals in all foods – and thus, the food and agricultural industries are "sitting ducks" for Proposition 65 enforcers. Even OEHHA and the California court's recognize this. (*Nicole-Wagner v. Duekmejian* (1991) 230 Cal.App.3d 652, 660 (finding virtually all foods contain some amount of naturally occurring listed chemicals); FSR 27 C.C.R. § 25501 pp. 3-4 (finding that California's so-called "naturally occurring" exemption from the Proposition 65 warning requirement for foods is necessary because nearly all foods contain levels of listed chemicals).)

1. The Naturally Occurring "Exception" Is Completely Impractical to Apply

California's "naturally occurring" exemption under Proposition 65 is ineffective for two principal reasons. First, it does not prevent a plaintiff from suing, but may again only be raised by the defendant as an affirmative defense at trial. (27 C.C.R. § 25501(a).)

Second, the naturally occurring exemption, like all Proposition 65 regulations, lacks clarity and is virtually impossible to apply, which essentially makes it worthless as a defense for defendants like Swanson. Despite the fact the "naturally occurring" defense is so often touted an option for defendants to employ in Proposition 65 actions regarding herbal supplements, it is telling that it has only been successfully asserted once in the entire history of enforcement against this industry.

In *As You Sow v. Brion Herbs Corp.*, the parties entered into a Consent Judgment prohibiting defendant from selling herbal products containing any lead, unless such products contained a warning or defendants could establish that the lead content was "naturally occurring" pursuant to the requirements of 22 CCR §12501. In lieu of going to trial to prove that no warnings were required under the statute, the *defendant paid nearly \$300,000 in penalties to settle the action.* Subsequently, the defendant proceeded to binding arbitration in order to establish that the lead content at issue in its products was indeed "naturally occurring."

The defendant was forced to incur enormous expense to establish that the lead content was not the result of "human activity," as required by statute. To satisfy this heavy burden, the defendant presented scientific and expert testimony addressing virtually every aspect of the growing, cultivating and manufacturing processes. This included evidence that the herbs were grown only in desert and mountainous regions of China, away from all human activity, paved roads, smelters, factories, power plants or other urban exposures. The defense experts addressed the effect of airborne heavy metals in the atmosphere in China, the depositing of these chemicals in soil through rain and wind, the more substantial effect of this on mountainous regions, and the elevated levels of such chemicals in China due to their use of leaded gasoline until 1999. Finally, defendant submitted evidence relating to its manufacturing and drying processes to ensure that "good manufacturing practice" was being used and that such practices reduced the actual lead concentration to the "lowest levels currently feasible."

After reviewing all the evidence submitted, the arbitrator found that lead content in the products was, in fact, "naturally occurring" and that the defendants employed "good manufacturing practices," so that no warning was required. As a result of AYS's simple allegation that the herbs were the source of lead exposure, the manufacturer was forced to incur hundreds of thousands of dollars in expenses on top of already steep settlement payments, to prove that its products were, in fact, in compliance with the statute all along. With this single illustration in mind, it is no wonder other defendants have not employed the "naturally occurring" dispute.²

2. Inconsistent Terms in Privately Negotiated Consent Judgments Mislead Consumers

The Attorney General also argues that the inconsistency of terms contained in prior Consent Judgments, particularly the varying levels of negotiated "naturally occurring" levels of lead, is irrelevant. He attributes these discrepancies to the ever-increasing feasibility of manufacturers to reduce lead in their products. Despite these varying standards for warning requirements, the Attorney General states that if "consumers are informed accurately that a product intended for their health contains a chemical such as lead, that is not naturally occurring, they may reasonably decide not to purchase the product and look for alternative products that are not contaminated."

² That is further true because most defendants in these cases, unlike Brion Herbs, source raw materials from multiple avenues, making it even more impossible for them to ever be able to clear the difficult, and cost-prohibitive hurdle of proving up a "naturally occurring" defense.

The fallacy of this argument is illustrated by the fact that these varying standards of acceptable "naturally occurring" lead levels have been negotiated by private enforcers of Proposition 65 with individual defendants during the course of settlement discussions. Often, defendants have settled with private enforcers for hundreds of thousands of dollars to ensure that favorable, negotiated "naturally occurring" levels were written into their Consent Judgments, thus releasing them from any obligation to provide warnings for products whose lead levels far exceed the statutory safe harbor exposure limits. **Therefore, a consumer has absolutely no way of knowing whether an herbal product without a Proposition 65 warning actually contains no lead, or whether the particular manufacturer of the product simply paid for the privilege of entering into a favorable Consent Judgment, which eliminated that manufacturer's duty to warn. In short, this enforcement scheme renders the presence or absence of a Proposition 65 warning, virtually meaningless to the consumer who wishes to compare certain products to determine whether the consumer is actually being exposed to lead.**

B. OEHHA Has Abdicated Its Role to Establish Clear, Certain and Workable Standards – and In Doing So Has Recognized that Proposition 65 Is Structured to Delegate Food Safety Standards and Policy to Plaintiffs' Lawyers and the Courts

Although California's Governor has appointed OEHHA as the lead agency to implement Proposition 65, OEHHA has abdicated its responsibility to establish standards and the analytical methods for applying them. Even the limited "safe harbor" numbers are of little practical value, because the Agency has failed to adopt necessary tests and analytical methods. OEHHA even *repealed* the one regulation that had given a modicum of guidance, 22 C.C.R. §12901 (Methods of Detection). OEHHA's official reason for the repeal is telling, finding that it was "too confusing" and that "it fostered litigation." (Repeal of 22 C.C.R. § 12901.) Rather than exercise its quasi-legislative power to provide *useful* guidance, OEHHA told industry to *use the California Rules of Evidence to decide which tests are appropriate*: "Given that existing law provides well-established structure for the conduct of and admissibility of scientific test results, there is no need for [OEHHA to provide a regulation]." (FSR Repeal of §12901.) Although it recognizes how intractable the selection of test methodology can be, OEHHA has affirmed that Proposition 65 delegates the task of establishing standards to lawyers and the courts.

In its place, OEHHA issued 27 C.C.R. §25900, a regulation that includes no standards and no guidance, but instead provides that a company that conducts "appropriate" tests at least annually, and where *every test* (presumably for *every* listed chemical) shows a non-detect, then such tests may be used as a defense that Proposition 65 does not apply (presumably at trial). ***The fact that OEHHA adopted this regulation proves that Proposition does in fact, apply at the level of detection and that warnings are required at this level.*** If - as the Opposition attempts to assert - the Act does not apply until the notably undefined "affirmative defense level" or even the few "safe harbor" levels are exceeded, OEHHA should have said so and adopted regulations

that fairly require every putative plaintiff to have evidence of an actual exposure above a *clearly defined* "affirmative defense level" before being able to prosecute.

In adopting §25900, OEHHA further recognized that Proposition 65 is structured to delegate standard setting to plaintiffs' lawyers and the courts:

"The Act expressly places the burden of proving that an exposure does not require a warning on the business causing the alleged exposure, not with the lead agency," and Proposition 65 does not require "the lead agency to establish testing methodologies for chemicals listed under the Act."

(FSR 27 C.C.R. § 25900; Responses to Comments App. I pg. 2.)

OEHHA's wholesale abdication of any responsibility to issue useful guidance has had the inevitable effect of leaving a regulatory vacuum that further allows private plaintiffs to use Proposition 65 to dictate food law and policy. Although every state may enforce violations of federal law under their own names, California's Attorney General uses Proposition 65 as his preferred enforcement tool instead – giving him the power and authority to set standards unsupervised by state or federal policy makers. As Dr. Louis W. Sullivan cogently observed:

In at least one high-profile instance, California chose to prosecute what was a clear cut example of food adulteration and misbranding under Proposition 65 as a "failure to warn" action, rather than to proceed under either California's Sherman Act or the FFDCA. In *People v. Alpro Alimento Proteinicos, S.A. de C.V., et al.*, for example, the Office of the Attorney General prosecuted certain manufacturers and distributors of Mexican-style candies under Proposition 65 for allegedly failing to provide warnings under that statute.³ This case could, and should, have been prosecuted by the State as both a violation of the FFDCA and Sherman Act adulteration provisions – not as a failure to warn case. It is notable that the evidence on which the Office of the Attorney General proceeded stemmed from FDA's 1995 notices to Mexican candy makers concerning its findings that lead in packing as well as

³ *People v. Alpro Alimento Proteinicos, S.A. de C.V., et al.*, Los Angeles County Superior Court, No. BC318207 (2004).

excessive lead in various ingredients rendered these products adulterated and subjected them to seizure.⁴

It is particularly troubling that standards for allowable lead in these products was established through settlement agreements, negotiated in private by lawyers – not scientists, qualified policy makers, or health professionals. *Establishing allowable tolerances for contaminants by this method is not defensible from a public policy perspective*, even if it may be warranted under California law. The fact that the standard negotiated may have been based upon federal guidelines, and that the California legislature required the Department of Health Services to formally adopt a regulation to set a tolerance (after the fact) is not exculpating. Rather, the State's after-the-fact adoption of standards illustrates that California had the legal authority to do so *before* using Proposition 65 to prosecute. There is no reason, except perhaps ease, expediency and the elimination of the need to bear the burden of proof, that California could not have prosecuted under the Sherman Act and/or the FFDCa.

(Declaration of Dr. Louis W. Sullivan, Secretary of Health and Human Services, in Support of Swanson's Motion for Summary Judgment, *AYS v. Swanson*, San Francisco Co. Superior Court CGC-07-466-169.)

⁴ *Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers*, Fred R. Shank, Ph.D., Director, Center for Food Safety and Applied Nutrition, FDA (June 13, 1995); *Letter to Manufacturers, Importers, and Distributors of Imported Candy*, Janice F. Oliver, Deputy Director, Center for Food Safety and Applied Nutrition, FDA (March 25, 2004); *Supporting Document for Recommended Maximum Level for Lead in Candy Likely to be Consumed Frequently by Small Children [Docket No. 2005D-0481]*, Center for Food Safety and Applied Nutrition, FDA (November 2006).

C. The Oppositions Fail to Provide An Accurate Description of the State's Ineffectual Attempts to Prevent Arbitrary Enforcement and Abuse Under Proposition 65

1. The Certificate of Merit "Requirement" Does Nothing to Stop Truly Meritless Proposition 65 Suits

The Attorney General contends that Proposition 65's Certificate of Merit requirement acts to limit meritless suits and provide uniformity. A close examination of this statutory provision, its implementing regulations, the failed attempts by the Attorney General to prevent meritless lawsuits, and case law demonstrate how inaccurate a picture the state has painted. In fact, OEHHA has admitted that "It is true that once the *threshold level of evidence is established*, the burden of proof is shifted to the defendant to show no warning is required."⁵ Although not one of the oppositions state what this "threshold level of evidence" is – hoping to fool FDA into thinking that the plaintiff should have evidence of an exposure exceeding the affirmative defense standard – the Final Statement of Reasons ("FSR") to 11 C.C.R. § 3200 clarifies that the only evidence needed is enough to prevent the court from finding the plaintiff guilty of violating California Rule of Civil Procedure 128.7.⁶ This is an exceedingly low legal standard, requiring only a *reasonable belief* that after discovery the plaintiff may find a detectable exposure. Moreover, courts are understandably reluctant to sanction plaintiffs in any case, out of concern for chilling the plaintiff's constitutional right to bring causes before the court, *and* because in every other law except Proposition 65, it is the plaintiff that has the burden of proof. Finally, the validity of the Certificate of Merit can only be reviewed by a court to determine whether it is frivolous at the *conclusion* of a Proposition 65 action. H.S.C. § 25249.7(h)(2). Thus, if an action has been resolved by way of settlement or judgment, court review of the certificate avails no one of any benefit.

As a practical matter, the Attorney General is unable to prevent the filing of meritless Proposition 65 lawsuits – but his Opposition fails to mention this. To illustrate, consider the Attorney General's recent letter concerning lead in lipstick written to plaintiff's counsel. Taking the extraordinary step of providing the scientific basis for its conclusions, the Attorney General urged putative plaintiffs **not** to proceed against the defendants on the grounds that a Proposition 65 enforcement action over lead in lipstick was not warranted on the facts, and not in

⁵ Letter from Dr. Joan Denton, Director, OEHHA, to FDA Commissioner Von Eschenbach, dated May 16, 2008, App I. pg. 4.

⁶ CCP 128.7 is California's version of Federal Rule 11.

the public interest.⁷ (Letter from Edward Weil, Supervising Deputy Attorney General to David Lavine, Esq., March 3, 2008 (“We hope this objective review of the merits of the issue will discourage your client and any other private plaintiff’s from pursuing these matters.”).) Nevertheless, as of this date, at least four cases have been filed against multiple parties.⁸

Even California courts have recognized how “absurdly easy” it is for a plaintiff to file a Proposition 65 case, regardless of the Certificate of Merit “requirement”:

Next, call up a local chemistry professor who will tell you that, at least *in sufficient quantities*, substances in those common objects will cause cancer, and are in fact on the list. It doesn’t make any difference that there may be no “significant” exposure -- remember the burden will be on the defendant to prove that. This phone call to your friendly professor will allow you to file the certificate of merit.

(*Consumer Defense Group v. Rental Housing Members*, (2006) 137 Cal.App.4th 1185, 1215-16 (Proposition 65 litigation is “absurdly easy [for plaintiff] given the burden shifting provisions of section 25249.10”).)

In practice, the Certificate of Merit is simply another sham provision to make it appear that there is some constraint on Proposition 65 enforcement, when there is none in actuality -- and cannot be any given the configuration of the underlying statute and its implementing regulations.

⁷ At the beginning of litigation against the automotive touch-up paint industry in 2002, the Attorney General wrote a similar, but less technically explicit, letter to counsel for Michael DiPirro, but to no avail. (Letter from Edward Weil, Deputy Attorney General to Hudson Bair, Esq., Jan 22, 2002.) After five years of litigation, Bondo prevailed. (*DiPirro v Bondo*, (2007) 153 Cal. App. 4th 150.)

⁸ Cases filed in Alameda County Superior Court are: *Leeman v. Ivy Enterprises et. al.*, No. 08385458, (filed May 2, 2008); *Leeman v. Zalan Products*, No 08382738 (filed April 19, 2008); *Leeman v. New Milani Group*, No. 08372758 (filed Feb. 22. 2008); *Leeman v. Shims Bargins, et. al.*, No. 08378509 (filed March 25, 2008).

2. Safe Use Determinations Are Impractical and an Unreasonable Tool

OEHHA's Opposition suggests it is *possible* for a business to obtain a so-called Safe Use Determination ("SUD") and that OEHHA intends to make regulatory changes so SUD's will be given more weight in an enforcement action.

This is a desperate argument that can have no practical effect on Proposition 65's application to foods for three reasons. First, *in over 20 years*, OEHHA has *issued only about seven* SUD's. It is not uncommon for OEHHA to take *years* to evaluate the applications. For example, it took nearly *seven years* for OEHHA to develop a "hand to mouth transfer factor" methodology to quantify the lead exposures from handling fishing tackle. Second, the fact that OEHHA is taking some steps to strengthen the SUD program is an admission that there is no mechanism in place now that to protect food manufacturers. Third, it is telling that *OEHHA* would issue SUDs for exposures from foods, rather than California's Department of Health Services, which is the state agency that has expertise in food safety and health issues and administers California's Sherman Food, Drugs and Cosmetics Act.

OEHHA also advises that it is *working* on a regulation to develop "clear and reasonable" warnings for foods, which it claims may avoid conflicts with federal law. This too, is an admission that the current regulations are ineffective and lack clarity; it is not a guarantee that the conflicts between the state and federal law can and will be avoided. Finally, OEHHA also claims that it is working on a regulation that will address Proposition 65's application to vitamins and nutraceuticals. This should be cause for alarm, rather than reassuring. That California eschews the Department of Health Services, the State's appointed agency for regulation of health risks from food, and allows OEHHA to develop regulations and policy for foods defies logic. The regulated community has advised OEHHA of its view that the agency has limited understanding of the scientific and federal regulatory issues involving foods and should not undertake the project.⁹ Taken with the points established above, OEHHA's Opposition only further illustrates why FDA's immediate action on Swanson's Petition is both necessary and timely.

⁹ See OEHHA website public comments.

II.
**PROPOSITION 65'S MEAGER ENDS DO NOT JUSTIFY ITS VIOLATION OF
DEFENDANT'S FIRST AMENDMENT AND DUE PROCESS RIGHTS**

The Oppositions' claim that Proposition 65 has resulted in significant public benefit, providing a list of such settlements and actions. As a threshold matter, Swanson notes that in the few cases touted pertaining to the enforcement against foods, such as the so-called Mexican Candy Case, that matter could and should have been brought as an enforcement action under the federal Food, Drug and Cosmetic Act and/or Sherman Act adulteration provisions. (See reference to Dr. Louis Sullivan's Declaration on that issue at pp. 6-7.) The fact that the State was able to use this abusive statute in lieu of other state and federal laws that do not abuse the constitutional rights of defendants, is shameful and not a reason for congratulations.

Assuming *arguendo*, that some of the Proposition 65 enforcement actions could not have been brought under color of any other state or federal laws, which is extremely unlikely, and that the "private agreements" negotiated had some meaningful benefit – the fact remains that *Proposition 65's ends do not justify the means.*

Proposition 65's violations of Due Process are inherent in its structure. As explained more fully in Swanson's Motion for Summary Judgment, Proposition 65 fails to provide clear and unambiguous standards for industry to use to determine in advance how to comply with it. Rather, the statute establishes a complicated and prohibitively expensive "process" that the defendant must present to a court for a determination, on a chemical by chemical, product by product basis, to decide whether the affirmative defense standard is met. Because a business cannot know with reasonable certainty whether it would meet the affirmative defense standard until after the court makes its decision at trial, the defendant lacks notice. This clearly violates due process rights, which renders Proposition 65 void-for-vagueness.

Proposition 65 also violates procedural due process grounds, because the statute allows plaintiffs unfettered access to the courts. A hallmark of a vague statute is one that fails to establish clear criteria for prosecutors and the courts to apply the law, which fosters arbitrary enforcement and inconsistent settlements. Swanson's Citizen Petition placed a number of AYS' private agreements, all dealing with the issue of lead levels in dietary supplements, before FDA, which illustrate the inconsistent and alarmingly unfair application of the law. (See Chart of Representative Dietary Supplement Proposition 65 cases, attached hereto as Exh. 4.)

Finally, Proposition 65 also violates the regulated community's rights to substantive due process. Its structure *intentionally* creates a regulatory vice. Defendants are either compelled, via a Proposition 65 warning to make a statement about their products that - when applied to FDA-compliant and nutritious foods – which amount to compelled self-libel, or risk grossly abusive prosecution with the attendant possibility of ruinous civil penalties. Caught in this vice, the overwhelming majority of defendants, hundreds each year, execute consent judgments, on

the plaintiffs' terms.¹⁰ As a boon to defendants, or as an inducement to settle, these private agreements often establish *quantified exposure levels* and even specify the test methods to be used – something that defendants cannot even get from OEHHA. Thus, by paying a large tribute to the private plaintiff and likewise reward its attorneys, the defendant may finally get a standard – albeit negotiated by lawyers and the dictates of litigation necessity – for a modicum of protection for a decision not to warn. Thus, Proposition 65 tramples defendants' rights while allowing every plaintiff the power of the pre-Magna Carta sovereign.

A bedrock principal inherent in the Rule of Law, is that a defendant is considered innocent until *proven* guilty by its accuser. (*Coffin v. United States* (1895) 156 U.S. 432, 454 (tracing the evolution of the “innocent until proven guilty” doctrine from ancient times, and illustrating its incorporation into the American judicial system).) Proposition 65 subverts this principal by artifice – an artifice without precedent and wholly unjustified. It is the defendant, not the prosecutor, who must prove it is “innocent.” It must do so by both deriving *and* quantifying the standard, and then prove by a preponderance of the evidence that exposures from its products fall below the standard. (*Baxter Healthcare Corp. v. Denton*, (2004) 120 Cal.App.4th 333, 345-347 (defendant has “the burden of proving by a preponderance of the evidence that a chemical in its products poses no significant risk...”).) The defendant must carry the burden of proof even though the regulations are obtuse, at times contradictory, and at other times non-existent. California courts have expressly recognized that there is no way short of a full-blown trial for a defendant to dispose of a Proposition 65 case. (*Rental Housing* at 1215-16.) Even a cursory read of three recent opinions¹¹ confirms how complex, burdensome and ruinously expensive a defense is – making it impractical in application and unconscionable as a matter of law.

¹⁰ Hundreds of Proposition 65 lawsuits are filed each year, often naming several parties at once. The Office of the Attorney General is required by SB 1269 (1999) and SB 471 (2001) to maintain a record of each of the Proposition 65 cases settled by consent judgment. The number of cases settled, often involving multiple parties and consolidated actions for the past five years are:

2003 – 137 settlements;
2004 – 101 settlements;
2005 – 148 settlements;
2006 – 199 settlements;
2007 – 156 settlements.

¹¹ *People v Tri-Union Sea-Foods*, San Francisco Superior Court, Nos. CGC-01-402975, CGC-04-432394 (Findings of Fact and Conclusion of Law, May 11, 2006); *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333; *DiPirro v Bondo* (2007) 153 Cal. App. 4th 150.

No matter what the alleged benefits are of Proposition 65, the cost to a civilized society is too high. As the United States Supreme Court has held, "laws which actually affect the exercise of these vital rights cannot be sustained merely because they were enacted for the purpose of dealing with some evil within the State's legislative competence, or even because the laws do in fact provide a helpful means of dealing with such an evil." *United Mine Workers of America v. Illinois State Bar Assn.*, (1967) 389 U.S. 217, 222.

FDA should, of all who hold our basic rights dear, disregard this "end justifies the means" argument.

III.
**PERSONAL ATTACKS ON SWANSON IN THE OPPOSITIONS ARE
UNWARRANTED, AND ONLY SERVE TO FURTHER ILLUSTRATE THE
DANGERS OF PROPOSITION 65'S ENFORCEMENT SCHEME**

One of the more disturbing similarities between the oppositions submitted by AYS and the AG's office is that both entities stoop to personal attacks against Swanson, which only further illustrates the "David and Goliath" type of battle any small company like Swanson faces in attempting to challenge the overwhelming inequities and due process violations inherent within Proposition 65.

Not only do such companies like Swanson face uphill battles at every turn with respect to reversed burdens of proof and the absence of any real protection supposedly provided by illusory "defenses" like the naturally occurring defense, they also face attacks of the variety leveled by AYS, only to be joined by the Office of the Attorney General. On this latter note, it is very telling that while AYS attaches to their opposition three pages of purported "test results" of Swanson's products, only the first page involves any products that are currently at issue in the litigation. And it is further noteworthy that none of those products at issue in this case are outside of the range that has passed muster with both AYS and the AG's office for other defendants (who have paid high settlements) without providing any Proposition 65 warning. (See, Chart, Exhibit 4.) Nevertheless, the AG's office in its opposition, freely lists six of AYS's test results, only one of which is part of the current litigation. The AG even questions "if these levels are correct," so Swanson is not clear as to whether AYS has shared its test results with the AG's office, but let there be no doubt that none of these test results have been shared with Swanson, and the figures with the high readings are completely out of step with Swanson's own internal testing, which seriously calls into question the accuracy of AYS' "results."

Additionally, AYS levels attacks at Swanson as to several non-Proposition 65 issues, for example with respect to its red yeast rice product which is absolutely misleading given that Swanson is one of the few companies currently selling a compliant red yeast rice product.

**IV.
CONCLUSION**

As demonstrated by Swanson in its Citizen's Petition, and confirmed in this composite reply to the three oppositions that have been submitted regarding its Petition, as well as the attached documents, application of Proposition 65 to foods and dietary supplements, such as those at issue in the suit against Swanson by AYS, not only tramples upon Swanson's due process rights, it abdicates FDA's authority to regulate this important area. The abuses and inequities inherent in application of Proposition 65 in this area continue to mount: One need not look further than the fact that high-paying settling defendants were able to negotiate a "truce" in which they could continue to sell their dietary supplement products with higher levels of lead than is present in Swanson's current products, yet without any Proposition 65 warning to California consumers. Just what benefit does that provide to anyone (other than of course the obvious: the enforcers and their attorneys that profit from use of the statute)?

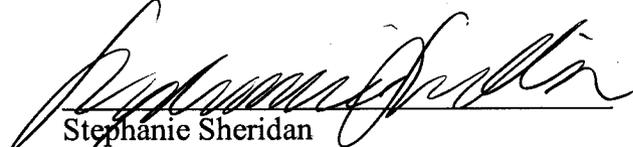
Allowing things to continue along the established status quo, only ensures that there will be further abuses and lack of consistent standards applied to companies who are otherwise following all state and federal regulations, including FDA good manufacturing practices. This is exactly the situation in which FDA should take a stand to prevent further abuses, halt additional public confusion and set fair standards so that everyone knows what is required to be in compliance.

Respectfully submitted,

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CRB|SAS|rdg

Enclosure(s):

- (1) Defendant Swanson Health Products Inc.'s MPA in Support of Motion for Summary Judgment;
- (2) Declaration of Louis W. Sullivan, M.D. in Support of Defendant's Motion for Summary Judgment;
- (3) Declaration of Dr. James Embree in Support of Defendant's Motion for Summary Judgment;
- (4) Consent Judgment in Dietary Supplement Proposition 65 Cases.

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

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Deputy Clerk

8 SUPERIOR COURT OF THE STATE OF CALIFORNIA
9 CITY AND COUNTY OF SAN FRANCISCO

11 AS YOU SOW,
12 Plaintiff,
13 v.
14 SWANSON HEALTH PRODUCTS, INC.,
15 Defendant.

CASE NO. CGC-07-466-169
**DEFENDANT SWANSON HEALTH
PRODUCTS INC.'S MEMORANDUM OF
POINTS AND AUTHORITIES IN SUPPORT
OF MOTION FOR SUMMARY JUDGMENT**

Hearing : October 8, 2008
Time : 9:30 a.m.
Dept. : 301
Judge : Hon. Peter Busch
Action Filed : August 14, 2007
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1 I. INTRODUCTION AND SUMMARY OF ARGUMENT

2 In this Proposition 65 case, plaintiff is demanding hundreds of thousands of dollars based on a
3 claim that defendant is violating the statute for selling its dietary supplements, which contain de
4 minimus amounts of “naturally occurring” lead, without first giving a Proposition 65 cancer and birth
5 defect warning. Aside from the fact that the amount of lead present in defendant’s products is no more
6 than is found in normal servings of milk and other nutritious foods, this case tees up serious
7 constitutional issues. This motion asks the Court to take a long hard look at the structure of
8 Proposition 65 and the violence that it does to federal food law and policy, as well as to Swanson’s
9 constitutionally protected rights of free speech and due process. To reach these issues, Swanson
10 challenges the constitutionality of Proposition 65 on four separate and distinct legal bases.

11 **Preemption.** For one hundred years, the federal Food, Drug and Cosmetic Act (FFDCA) has
12 regulated food on the twin premises that labeling must be truthful, and food containing significant
13 levels of contamination is considered adulterated and therefore banned. Integral to this regulatory
14 scheme is **FDA’s long-standing policy that warnings for food should not be imposed and FDA has**
15 **advised California that Proposition 65 warnings conflict with federal policy and misbrand foods.**
16 Under precedent from the Supreme Courts of both the United States and California, Plaintiff’s suit is
17 preempted as contrary to FDA policy, and is also preempted because Swanson cannot comply with
18 state and federal law at the same time: Swanson cannot put Proposition 65 warnings on its products
19 saying that they cause cancer and birth defects without violating 21 U.S.C. § 343(a), which prohibits
20 the making of false or misleading statements on food labeling.

21 **Free Speech.** To avoid being prosecuted, Proposition 65 compels Swanson to make false
22 speech in violation of the First Amendment and the California Constitution art.1 ¶2.

23 **Void-For-Vagueness.** Proposition 65 is unconstitutionally Void-for-Vagueness on two
24 separate bases. First, the statute fails to provide adequate notice concerning what Proposition 65
25 requires, when Proposition 65 requires it, and how to comply. Second, the statute permits arbitrary
26 and discriminatory enforcement and fails to provide sufficiently definite guidelines to prevent
27 inconsistent judgments.

28 **Substantive Due Process.** Proposition 65 violates Swanson’s right to Substantive Due

1 Process, because its structure and application creates a regulatory vice by infringing on three of
2 Swanson's fundamental rights: freedom of expression, the Rule of Law (the presumption of innocence
3 and that the accuser bears the burden of proving guilt), and Eighth Amendment protections against
4 excessive fines and penalties. The central feature of this regulatory vice is that Proposition 65 allows
5 any plaintiff to sue, but requires Swanson to prove its innocence by establishing both appropriate
6 quantified standards and that its products meet them— thus violating a paradigm of justice recognized
7 since the Magna Carta that a defendant must be *proven guilty*.

8 At the end of the day, this motion is not about Swanson or AYS. The questions posed here go
9 beyond one company and one private plaintiff. Although we anticipate that AYS's response, likely joined by
10 the Office of the Attorney General, will be an attempt to vilify Swanson, its experts, FDA policy makers,
11 and to extol perceived accomplishments under Proposition 65 – it is of no moment. As the United States
12 Supreme Court has said, “laws which actually affect the exercise of these vital rights cannot be sustained
13 merely because they were enacted for the purpose of dealing with some evil within the State’s legislative
14 competence, or even because the laws do in fact provide a helpful means of dealing with such an evil.”
15 (*United Mine Workers of America v. Illinois State Bar Assn.*, (1967) 389 U.S. 217, 222.)

16 II. STATEMENT OF FACTS

17 Swanson is a family-owned vitamin and health food manufacturer and retailer located in North
18 Dakota. Since 1969, Swanson has formulated its own brand of products and is in compliance with
19 FDA requirements. Swanson complies with FDA's recently adopted Current Good Manufacturing
20 Practices (“CGMP”) and works only with other GMP-compliant companies and suppliers. (See
21 Declaration of Lee Swanson (“Swanson Decl.”) at ¶ 2.) Swanson does not have a presence in
22 California, but markets its products exclusively via telephone, on-line (www.swansonvitamins.com),
23 and through mail order. (*Id.* at ¶ 3.)

24 As You Sow (“AYS”) is an active Proposition 65 “private enforcer.” Since 1999, AYS has
25 prosecuted scores of companies for alleged violations of Proposition 65's warning requirement with
26 regard to dietary supplements. Not one of these cases proceeded to trial – all have settled on terms
27

1 dictated by AYS.¹ Significantly, the injunctive terms are inconsistent, setting standards for lead in
2 dietary supplements by consent judgment that the parties agree will not require a Proposition 65
3 warning. In addition to establishing conflicting standards for the same food products, the settlements
4 give AYS the sole right to determine when Proposition 65 warnings are not necessary.

5 Since November 12, 2007, Swanson has been providing prophylactic Proposition 65 safe
6 harbor warnings for products shipped into California. (*Id.* at ¶ 13-14.) Nevertheless, in a relentless
7 effort to force a settlement, AYS has served two additional Proposition 65 notices on Swanson, despite
8 acknowledgement of receiving Proposition 65 warnings. (*Id.*)

9 III. ARGUMENT

10 A. SUMMARY JUDGMENT STANDARD

11 Summary judgment “shall be granted” where “all the papers submitted show that there is no
12 triable issue as to any material fact and that the moving party is entitled to a judgment as a matter of
13 law.” (Cal. Civ. Proc. Code § 437c(c); *Skrbina v. Fleming Cos., Inc.* (1996) 45 Cal.App.4th 1353,
14 1365 (“Summary judgment is properly granted to a defendant if it shows . . . that there is an affirmative
15 defense which bars recovery, and the plaintiff fails to set forth specific facts showing a triable issue of
16 material fact as to that . . . defense.”))

17 B. STATUTORY AND REGULATORY BACKGROUND PERTAINING TO DIETARY SUPPLEMENTS

18 1. The Federal Regulatory Scheme

19 FDA has been the primary guardian of the safety of the nation’s food and drug supply since
20 1906. The Food and Drug Act of 1906 (“FFDCA”) was the first nationwide consumer protection law
21 that made it illegal to distribute misbranded or adulterated foods, drinks, and drugs across state lines.
22 (The Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as
23 amended at 21 U.S.C. §301 *et seq.*.) The FFDCA grants FDA broad authority to establish food safety
24 standards and good manufacturing practices, to regulate labels for food products, and to issue food
25 advisories as warranted. (21 U.S.C. §341; Declaration of Secretary Louis W. Sullivan, MD in Support
26 of Motion for Summary Judgment ¶¶ 14-15 (hereinafter “Sullivan Decl.”).) Because the food industry
27

28 ¹ A chart listing many of the dietary supplement settlements that shows the variation in settlement terms is attached as Exhibit 3A to the Sheridan Declaration.

1 is no longer local, state regulations, especially those that depart markedly from FDA's regulatory
2 format, increase the probability of conflicts with national regulations. (*Id.*, ¶29.)

3 From its inception, the FFDCA has focused on labeling as a principal means of communicating
4 accurate information about foods and dietary supplements (collectively "food"). (Sullivan Decl. ¶¶16-
5 17.) Over the last two decades, Congress has continually strengthened FDA's authority to require
6 uniform nutrition labeling on foods, and to establish circumstances when claims may be made about a
7 food's nutrient content by adopting the Nutrition Labeling and Education Act of 1990 ("NLEA")²
8 (Pub. L. No. 101-535, 104 Stat. 2353 (1990); 21 U.S.C. §343-1.)

9 Recognizing "the importance of nutrition and the benefits of dietary supplements to health
10 promotion and disease prevention," Congress adopted the **Dietary Supplement Health and**
11 **Education Act of 1994**. ("DSHEA") (Pub. L. No. 103-417, 108 Stat. 4325 (1994)). (*See*, Sullivan
12 Decl. ¶6-47 (Overview the FFDCA and FDA regulatory scheme for food).) Importantly, DSHEA
13 recognizes that dietary supplements are foods, and regulates them as such. (Sullivan Decl. ¶35.)
14 Congress considered the *accurate* labeling of dietary supplements of such importance that it took
15 specific measures to ensure them, including establishing an independent Commission on Dietary
16 Supplement Labels ("CDSL") to determine how best to provide *truthful, scientifically valid, and not*
17 *misleading information to consumers* so that they may make informed and appropriate health care
18 choices. (Sullivan Decl ¶35-37.) To ensure that FDA regulations and labels are based on science,
19 DSHEA also created an Office of Dietary Supplements within the National Institutes of Health, to
20 direct and coordinate research on dietary supplements and serve as an advisor to FDA. (42 U. S. C.
21 §287c-11, Sullivan Decl. ¶37.)

22 2. Proposition 65's Regulatory Scheme

23 Proposition 65 is easily the most controversial environmental law in the country. Written by
24 environmental activists and politically ambitious public prosecutors, it was adopted by ballot initiative
25 in the November 1986 election, after a flamboyant campaign that played to the electorate's fear of
26 chemicals. Not only did Prop 65 appear on the ballot under the title "California's Safe Drinking Water
27

28 ² Congress' purpose in adopting the NLEA was to strengthen FDA's authority to require uniform nutrition labeling on food, and to establish circumstances when claims may be made about a food's nutrient content. (Sullivan Decl. ¶28.)

1 and Toxic Enforcement Act,” the Proposition 65 ballot argument set the tone for this law.³

2 Uniquely, Proposition 65 applies to all products containing *any amount of a listed chemical*,
3 *while it places the burden on the defendant to prove the level in question is safe as an affirmative*
4 *defense at trial*. (H.S.C. §§ 12249.6, 25249.10(c).) It is enforced through lawsuits by public
5 prosecutors and private parties. (H.S.C. §12249.7(d)-(h).) In practice, Proposition 65’s substantive
6 requirements have been implemented on an *ad hoc* basis through settlement agreements negotiated
7 defendant-by-defendant, usually through plaintiffs’ attorneys with a financial stake in the outcome
8 rather than through the regulatory process.

9 Proposition 65’s warning provision is triggered if an individual in California is exposed to *any*
10 *detectable amount* of a chemical “known to the state” to cause cancer or reproductive toxicity, and
11 allows a lawsuit if a “clear and reasonable *warning*” was not given. (H.S.C. §25249.6.)⁴
12 Proposition 65’s implementing regulations reiterate that Proposition 65 warnings are triggered at any
13 detectable level of exposure of a listed chemical. (27 C.C.R. § 25900 (no “knowing and intentional
14 violation” of Proposition 65 occurs if a defendant conducts “appropriate” tests that show “no
15 detectable levels” of listed chemicals).)

16 **a. Required Warning Language**

17 The warning language required by Proposition 65 for a carcinogen:

18 WARNING: This product contains a chemical known to the State of California to
19 cause cancer.

20 (27 C.C.R. §25601(b)(4)(A).) For a reproductive toxin:

21 WARNING: This product contains a chemical known to the State of California to
22 cause birth defects or other reproductive harm.

23 (*Id.* §25601(b)(4)(B).) Although variants are allowed, in practice the effect is to make the warning
24 more alarmist, not less. The “core and mandatory” signal word “WARNING” is *always* present, as is

25 ³ A copy of the Ballot Argument in Favor of Proposition 65 and Rebuttal to Argument in Favor of Proposition 65
26 (1986) is attached to the Request for Judicial Notice (“RJN”) as Exhibit 5x.

27 ⁴ 25249.6. Required Warning Before Exposure To Chemicals Known to Cause Cancer Or Reproductive
28 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.

1 the phrase “known to cause” cancer or birth defects. (27 C.C.R. §25601(a).) Taking care that
2 alternative warning text may never weaken the warning, the Office of the Attorney General has
3 adopted regulations that emphasize that a warning that uses “the adverb ‘may’” to condition the
4 exposure is “not clear and reasonable.” (11 C.C.R. §3202(b).)

5 **b. The Proposition 65 List of Chemicals That Require Warnings**

6 The Proposition 65 list contains approximately 800 chemicals, which even include substances
7 needed to preserve health (e.g., Vitamin A). Chemicals may be placed on the list based upon data
8 from high-dose animal tests, which may or may not be relevant to humans. (*AFL-CIO v. Deukmejian*
9 (1989) 212 Cal.App.3d 425, 438, fn. 7.)

10 Although Proposition 65 has been law for over twenty one years, the Office of Environmental
11 Health Hazard Assessment (“OEHHA”), the lead agency for administering Proposition 65, has adopted
12 “safe harbor” exposure levels for fewer than one-third of the listed carcinogens, and only a handful of
13 reproductive toxins. (27 C.C.R. §§25705 (carcinogens), 25805 (reproductive effects).) In the case of
14 foods, these safe harbor levels are of limited use because they do not take into account “naturally
15 occurring” chemicals, which are separately determined. (27 C.C.R. §25501.)

16 Where OEHHA has not adopted a safe harbor level, the defendant is required to do so at trial,
17 on a chemical-by-chemical, product-by-product basis. (*See, People v Tri-Union Sea-Foods, LLC*,⁵
18 San Francisco Superior Court, Nos. CGC-01-402975, CGC-04-432394 (Findings of Fact and
19 Conclusion of Law, pg. 8, May 11, 2006 (RJN Ex 5W) (hereinafter “*Tri-Union*”) at 13-26.) The lack
20 of relevant guidance on how the regulated community is to evaluate foods and dietary supplements
21 under Proposition 65 unfortunately plays into the hands of opportunistic private enforcers in extorting
22 settlements.

23 **C. PROPOSITION 65 ENFORCEMENT**

24 Proposition 65 is enforced through civil lawsuits, which places the burden of proof on
25 defendants. *Anyone* may bring suit to enforce it, as long as they first give written notice to the alleged
26

27 ⁵ *Tri-Union Seafood* is a trial court decision authored by Judge Dondero, finding preemption of Proposition 65 as
28 applied to tuna. It is presently on appeal and as such, it is not cited as precedent for this case. Because it is only the
second case to go to the Court of Appeal after a trial on the merits, however, and the only one involving food, the issues
raised and the procedures the court followed provides useful insight.

1 violator and designated public prosecutors, and the public prosecutors do not commence an action
2 within 60 days (the “60-day Notice”). Failure to give a Proposition 65 warning before exposure is
3 punishable by a civil penalty of up to \$2,500 per violation, per day. As interpreted by the Office of the
4 Attorney General, each item sold in California constitutes a separate violation. AYS has asserted that
5 the penalty calculation in this case may be based on the number of “servings” in each container. Thus,
6 for a single bottle of dietary supplements with a 30 day supply of nutrients, the potential fine to
7 Swanson could be \$75,000.00. Not only are the potential penalties ruinous to a company without any
8 evidence of damage or injury to anyone, the cost of such defense is prohibitive, a fact that plaintiffs
9 count on to compel settlements on the terms they dictate.

10 **D. PLAINTIFF’S CLAIMS ARE BARRED IN THEIR ENTIRETY BY CONFLICTS PREEMPTION**

11 The doctrine of federal preemption is grounded in the Supremacy Clause of the United States
12 Constitution, which provides a “[s]tate law that conflicts with a federal statute is ‘without effect.’”
13 (U.S. Const., art. VI; *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910,
14 923.) Proposition 65 warnings for foods are preempted under the Supremacy Clause.

15 Federal preemption arises in three distinct circumstances: express, field, and conflicts
16 preemption. (*Id.*, citing *Capital Cities Cable, Inc. v. Crisp* (1984) 467 U.S. 691, 698-99.) Only
17 conflicts preemption is relevant in this case, and it occurs “**when compliance with both state and**
18 **federal law is impossible, or when the state law stands as an obstacle to the accomplishment and**
19 **execution of the full purposes and objectives of Congress.**” (*Id.* at 699.) Proposition 65
20 irreconcilably conflicts with federal law on both prongs of “conflicts preemption” analysis.

21 **1. Proposition 65 is Preempted by FFDCAs Because it Stands as an Impediment to**
22 **the Accomplishment and Execution of the Purposes and Objectives of**
23 **Congress**

24 Imposition of Proposition 65 warnings directly conflicts with FFDCAs’ regulatory program for
25 foods on the ground that it impedes Congressional goals and objectives.

26 **a. FDA Has Determined Authoritatively That Warnings on Food Are Not**
27 **Appropriate – Which Establishes Preemption in this Case**

28 Congress granted FDA authority to require warnings on food and dietary supplements in the
FFDCAs. This authority is grounded in the misbranding provisions of the FFDCAs set forth in

1 §§403(a)(1) and 201(n), and FDA is empowered to promulgate labeling rules to achieve the policy and
2 purposes of the FFDCA. (*American Frozen Food Inst. v. Matthews* (D.D.C. 1976) 413 F.Supp. 548,
3 *aff'd*, 555 F.2d 1059 (D.C. Cir. 1977).)

4 In its exercise of this authority, FDA consistently has taken the position that warnings should
5 be used on FDA-regulated products judiciously, and only in cases that represent a significant risk.
6 (Sullivan Decl. ¶53-61.) FDA has made clear that the FFDCA “authorizes warnings and affirmative
7 disclosures only with respect to serious hazards.” (42 Fed. Reg. 22018 (April 29, 1977).)

8 **FDA has repeatedly expressed its strong concern about warnings on foods:**

9 A requirement for warnings on all foods that may contain an inherent carcinogenic
10 ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods
11 in a supermarket. Such warnings would be so numerous they would confuse the
12 public, would not promote informed consumer decision-making, and would not
13 advance the public health.

14 (44 Fed. Reg. 59509, 59513 (Oct. 16, 1979).) **FDA specifically rejected a suggestion that warnings
15 should be required on foods containing low levels of carcinogenic substances:**

16 The Commissioner advises that tolerances and action levels will be established at
17 levels intended to ensure that food marketed is not hazardous to health. The suggested
18 **warnings would therefore be unnecessary and inappropriate. If any food is found
19 to be hazardous to health, FDA will not permit it to be distributed in interstate
20 commerce.**

21 (42 Fed. Reg. 52814 (Sept. 30, 1977) (RJN Ex 5D).) FDA has noted that “too many warning labels on
22 foods could result in loss of consumer credibility and effectiveness.” (63 Fed. Reg. 37030, 37035 (July
23 8, 1998) (RJN Ex 5E).)

24 Since 1961, FDA has conducted the so-called Total Diet Study (“TDS”), which is an ongoing
25 program that determines levels of various contaminants and nutrients in foods. **This long term data
26 support FDA’s position that low level contaminants do not pose a concern.** (*See*,
27 www.cfsan.fda.gov/~comm/tds-toc.html (RJN Ex 5K); Sullivan Decl ¶¶ 50-53; Embree Decl.¶¶28-30.)
28 One of the chemicals FDA continuously monitors in food is lead. The TDS study indicates that
29 something as innocuous and obviously healthy as milk may exceed Proposition 65’s allowable level by
30 a factor of over five. (*See*, www.cfsan/fda.gov/~comm/tds-toc.html; Embree Decl. ¶29.)

31 In over 100 years, FDA has issued very few food label warnings: for certain protein products,
32 unpasteurized juice, and ephedra in dietary supplements. (21 C.F.R. §101.17(d); 21 C.F.R.

1 §101.17(g); Sullivan Decl. ¶¶62-65, 71.) Ephedra was later banned, evidencing the fact that where a
2 food or supplement poses a true health risk, FDA takes action to protect the public. (*Id.* ¶71.) It is of
3 great significance that the positions FDA has consistently expressed are *exactly* the same reasons that
4 FDA provided in explicit communications directed to the State of California explaining that
5 Proposition 65 warnings misbrand food and conflict with federal law. (Sullivan Decl. ¶¶86-90.)
6 Clearly, FDA has maintained a well-reasoned, consistent policy concerning warnings on foods, and the
7 position it has taken opposing application of Proposition 65 to foods comports with that policy.

8 **b. FDA's Has Determined That Proposition 65 Warnings on Foods**
9 **Interfere With and Frustrate Federal Goals**

10 Since its inception, FDA has had grave concerns about the application of Proposition 65 to
11 foods, and has repeatedly voiced these objections to California. As early as 1987, the following FDA
12 statement was issued to the California Scientific Advisory Panel:

13 **It is my strong belief that FDA regulated products that are lawfully sold in**
14 **accordance with federal law do not pose a significant risk to human health. It is**
15 **my further view that warnings on products that do not pose such a risk are**
unnecessary, are likely to be confusing and may be very costly to industry and
consumers.

16 (Statement of FDA Commissioner Frank E. Young to the California Scientific Advisory Panel
17 (Dec. 11, 1987); Sullivan Decl. ¶91.)

18 More recently, FDA has recognized that Proposition 65 warnings frustrate FDA's carefully
19 considered federal approach to advising consumers of both the benefits and possible risks associated
20 with foods and dietary supplements. Discussing Proposition 65's application to canned tuna, FDA
21 considered Proposition 65 preempted under federal law in the food context:

22 The [FFDCA] provides broad authority for FDA to regulate the labels of food products.
23 However, rather than requiring warnings for every single ingredient or product with
24 possible deleterious effects, FDA has deliberately implemented a more nuanced
25 approach, relying primarily on disclosure of ingredient information and nutrition
26 information, taking action in instances of adulterated and misbranded foods, and, only
27 in exceptional circumstances, requiring manufacturers to place warnings on their
28 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.

28 (Letter from FDA Commissioner Lester Crawford to California Attorney General Bill Lockyer,

1 emphasis added, dated August 12, 2005 (RJN Ex 5M).) In March 2006, FDA wrote another letter
2 opposing Proposition 65 warnings on foods, restating its concern that the warnings may have the
3 following adverse effects, among others: (1) create unnecessary and unjustified public alarm about the
4 safety of the food supply; (2) dilute overall messages about healthy eating.; and (3) mislead consumers.
5 (Letter from Terry C. Troxell, Ph.D., Director, Office of Plant and Dairy Foods, Center for Food Safety
6 and Applied Nutrition, to Joan Denton, Director, OEHHA, and Deputy Attorney General Ed Weil,
7 dated March 21, 2006 (RJN Ex 5N).) FDA’s statement of policy articulated in these letters, applies to
8 *all* foods and dietary supplements. (Sullivan Decl. ¶95.) As a practical matter, the text of
9 Proposition 65 warnings applied to foods is alarming, unbalanced, and misleading. (*Id.* ¶103.) And as
10 such, Proposition 65 warnings conflict with FDA’s long standing, carefully considered and nuanced
11 approach to food labeling. (*Id.* ¶¶91-95.)

12 **c. FDA’s decision that warnings are inappropriate does not leave a**
13 **vacuum in which a state may mandate warnings**

14 It is well known that a Congressional determination not to regulate a subject may provide
15 grounds for “negative” preemption. (*Arkansas Elec. Co-op. v. Arkansas Pub. Serv. Comm’n.* (1983)
16 461 U.S. at 384; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989) 489 U.S. at 151.) The same
17 holds true for a federal agency’s decision not to regulate. The Supreme Court has held *repeatedly* that
18 where federal officials have affirmatively refused to exercise their full authority, this decision not to
19 regulate takes on the character of a ruling that no regulation is appropriate pursuant to the policy of the
20 statute. In these circumstances, “states are not permitted to use their police power to enact such a
21 regulation.” (*Ray v. Atlantic Richfield*, 435 U.S. 151, 178 (1978); *See also, Napier v. Atlantic Coast*
22 *Line R. Co.*, 272 U.S. 605 (1926); *United States v. Locke* (2000) 529 U.S. 89, 110 (reaffirming *Ray*);
23 *Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 64 (stating that negative preemption by a federal
24 administrative agency is a “viable preemption theor[y]” but rejecting its application in that case based
25 upon the facts).)

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1 **2. Proposition 65 Is Preempted As Applied to Foods and Dietary Supplements,**
2 **Because It Is Impossible to Simultaneously Comply with FDA's Mandates and**
3 **Proposition 65's Warning Requirements**

4 Provision of a Proposition 65 warning directly and unavoidably conflicts with the FFDCA,
5 because providing the warning renders the product misbranded under 21 U.S.C. § 403(a)(1), while at
6 the same time the failure to include a Proposition 65 warning creates liability under California law.

7 **a. Proposition 65 Warnings Render Defendant's Products "Misbranded"**
8 **Under Federal Law**

9 21 U.S.C. § 403(a)(1) provides that a food shall be deemed to be "misbranded" if its labeling is
10 "false or misleading in any particular." FDA's regulations provide that the labeling of a food shall be
11 deemed to be misleading if it fails to reveal facts that are material.⁶ (21 C.F.R. §1.21(a).) FDA
12 regulations also expressly prohibit misleading statements on signs, brochures, packing slips and
13 product labels associated with a food. (Sullivan Decl. ¶ 30.)

14 **b. Proposition 65 Mandates WARNINGS, Which Are ALWAYS**
15 **Misleading When Applied to Foods That Are Safe and Healthful Under**
16 **Federal Law**

17 As a threshold matter, Proposition 65 mandates *warnings* – not disclosure, not information, but
18 *warnings*. (H.S.C. §25249.6.) The American Heritage Dictionary defines "warning" as "1) An
19 intimation, threat, or sign of impending danger or evil, 2) Advice to beware, 3) Counsel to desist from
20 a specified undesirable course of action, 4) A cautionary or deterrent example, 5) Something, such as a
21 signal, that warns." (THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, Fourth
22 Edition. Houghton Mifflin Company, 2004.)

23 The standard Proposition 65 warning: "WARNING: This product contains chemicals known
24 to the State of California to cause cancer, birth defects or other reproductive harm" – is untrue and
25 misleading because it seriously overstates the risks and omits altogether the health benefits. (Sullivan
26 Decl. ¶5(f), ¶ 97, ¶¶81-89 (noting FDA's long opposition to Proposition 65 as applied to foods).)

27 ⁶ AYS has erroneously implied that DSHEA allows warnings without triggering the misbranding prohibition. AYS is
28 wrong. DSHEA did not alter FFDCA §201(n), which provides that labeling will be considered misleading if it fails to
29 reveal a material fact. (21 U.S.C. §321(n).) Proposition 65 warnings, which alarm and overstate risks, clearly omit
30 material facts, constitute misbranding and frustrate federal policy and goals. Seen in light of DSHEA as a whole, 21
31 U.S.C. §343(s) is not a license to add inaccurate and misleading statements in the form of Proposition 65 warnings
32 to supplement labels, and misbrand products with impunity. (Sullivan Decl. ¶46.)

1 In *Tri-Union Seafood*, the California Attorney General sought to impose Proposition 65
2 warnings for tuna fish. However, Judge Dondero found that Proposition 65 warnings constituted
3 misbranding under FDA regulations and its long term policy to avoid warnings on food products.
4 (*Tri-Union* at p. 73. “**Any Proposition 65-compliant warning . . . conflicts with Federal law and**
5 **policy and is preempted by the Supremacy Clause of the United States Constitution.**”)

6 Further, FDA’s scheme of food regulation protects the public health because it prohibits the
7 marketing of unsafe food – which cannot be “cured” by adding a warning to labeling. (Sullivan Decl.
8 ¶98.) In this context – where the FFDCa policy prohibits warnings, and instead provides unhealthy
9 foods cannot be sold – the signal word WARNING and accompanying Proposition 65 warning
10 statements unavoidably and untruthfully assert that lawfully marketed foods are unsafe. At best, the
11 warning is misleading and renders the food misbranded. Since misbranding applies where a food label
12 is misleading *in any particular*, when applied to foods that FDA has determined are healthful and safe,
13 Proposition 65 misbrands the food. **Thus, Proposition 65 warnings always misbrand foods and this**
14 **irreconcilable conflict cannot be resolved.**

15 c. **Proposition 65 Mandates Warnings at Levels That Do Not Pose**
16 **Hazards – Making the Warnings Untrue and Misleading**

17 Five hundred years ago, Paracelsus, the father of modern toxicology, articulated what has
18 become a maxim: “the dose makes the poison.” Proposition 65, contrary to this often-cited wisdom,
19 triggers warnings at the level of detection, mandating “warnings” even when exposure levels are
20 clearly safe. Proposition 65 advocates claim that the Proposition 65 warning is “technically true,”
21 because the warning indicates that the product *contains* or *exposes* the user to a chemical known to the
22 state to cause cancer and reproductive toxicity. This argument is specious: the California Supreme
23 Court has considered and disregarded it. Finding that Proposition 65 was preempted, the California
24 Supreme Court in *Dowhal* observed “even though it is probably true that the nicotine in defendants’
25 products can cause reproductive harm,” the FFDCa prohibits even truthful statements, if they are
26 ‘misleading’ or if they are not stated in ‘such manner and form as are necessary for the protection of
27 users.’ (*Dowhal* at 12.) Three of the cases the *Dowhal* court cites as authority that even true
28 statements may violate FFDCa’s misbranding statute involve FDA’s regulation of food. (*See, United*

1 *States v. Ninety-Five Barrels of Vinegar* (1924) 265 U.S. 438, 444 (vinegar); *United States v. An*
2 *Article of Food, Etc.* (E.D.N.Y. 1974) 377 F.Supp.746 (finding the label of Manischewitz's Diet-Thin
3 matzos misleading because they contained the same number of calories as Manischewitz's plain
4 matzos, for "[e]ven a technically accurate description of a food or drug's content may violate 21
5 U.S.C. §343 if the description is misleading in other respects."); *United States v. An Article of Food*
6 (8th Cir. 1973) 482 F.2d 581 (holding that even though label was technically accurate, it was
7 misleading because some of the ingredients are not needed in human nutrition or are included in such
8 insignificant amounts as to be valueless.) It is significant for this case that the *Dowhal* court found
9 preemption by applying the strong and clear misbranding prohibition for food.

10 **E. PLAINTIFF'S CLAIMS ARE BARRED AS A MATTER OF LAW BECAUSE PROPOSITION 65**
11 **VIOLATES SWANSON'S FEDERAL AND STATE RIGHTS TO FREEDOM OF EXPRESSION**

12 Just as the First Amendment may prevent the government from prohibiting speech, it may
13 likewise bar the government from compelling speech. (*See, Riley v. Nat'l Fed'n of the Blind, Inc.*
14 (1988) 487 U.S. 781, 784, 786-87 (affirming unconstitutionality of North Carolina statute requiring
15 fundraiser to disclose certain facts in fundraising appeals); *Pac. Gas & Elec. Co. v. Pub. Util'y*
16 *Comm'n* (1986) 475 U.S. 1, 20-21 (order requiring privately owned utility company to allow third
17 party's speech in its billing envelopes was unconstitutional), *United States, et al. v. United Foods, Inc.*,
18 (2001) 533 U.S. 405 (government assessment to fund generic advertisements declared an
19 unconstitutional violation of commercial speech).) Businesses, as well as individuals, have
20 unrestricted first amendment rights. (*Consolidated Edison Co. v. Public Service Comm'n* (1980) 447
21 U.S. 530 (voiding a ban on utility's inclusion in monthly bills of inserts discussing controversial issues
22 of public policy).)

23 **1. Proposition 65 Violates Swanson's Unqualified Right to Free Speech**

24 Here, AYS's Proposition 65 action is barred as a matter of law, because it seeks to compel
25 overbroad and misleading speech in the form of Proposition 65 warnings in violation of the First
26 Amendment and the California Constitution. The law compels Swanson, and other food
27 manufacturers, to give warning statements about safe and nutritious food, which actually *chills a*
28 *commercial transaction*. Thus, Proposition 65 cannot be defined as commercial speech. (*Ohralik v.*

1 *Ohio State Bar Ass'n* (1978) 436 U.S. 447, 455-56; *Central Hudson Gas & Electric Corp. v. Public*
2 *service Comm'n* (1980) 447 U.S. 557, 561.") Proposition 65 is a content-based regulation of speech,
3 which requires manufacturers to make statements about their products. (H.S.C. §25249.6.) The Court
4 must therefore apply strict scrutiny in determining whether it impinges on constitutionally protected
5 speech. (See, *United States v. Carolene Products Company* (1938) 304 U.S. 144, fn. 4.)

6 To pass strict scrutiny, Proposition 65 must satisfy three prongs: 1) a compelling governmental
7 interest; 2) the law must be narrowly tailored to achieve that goal; and 3) the state must use the least
8 restrictive means to achieve its goal. (*Sable Communications v. FCC* (1989) 492 U.S. 115, 126.) The
9 Supreme Court has never delineated how to determine whether the state's interest is *compelling*, but
10 the case law refers to a necessary or crucial interest, such as matters of national security or preserving
11 the lives of multiple individuals. (See, *Korematsu v. United States* (1944) 323 U.S. 214.)
12 Proposition 65 was intended to further the State's interest in providing information to Californians
13 about exposures to listed chemicals, and is well-characterized as a "right to know" law. The provision
14 of a *one-size fits all* warning about unavoidable contaminants in foods, however, simply does not rise
15 to the level of a *compelling* governmental interest.⁷

16 Second, Proposition 65 is not narrowly tailored to achieve the State's interest, because it is
17 grossly over-inclusive. It is well-recognized that nearly all foods contain detectable levels of
18 contaminants. (*Nicole-Wagner v Duekmejian* (1991) 230 Cal.App.3d 652, 660 (virtually all foods
19 contain some amount of naturally occurring listed chemicals).) **And, there can be no rational basis**
20 **for mandating materially false and misleading warnings to consumers concerning food.** Third,
21 Proposition 65 also fails to achieve its ends by the *least restrictive* means. The law employs harsh and
22 draconian means. By allowing anyone to challenge a company's decision not to warn on the slimest
23 evidence of a detectible exposure, and then placing the burden of proving innocence at trial on the
24 defendant, the law infringes not only on free speech rights, but on due process rights as well.

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27 ⁷ Under Proposition 65, the court may issue an injunction requiring a warning and impose financial penalties, but may
28 not prohibit the sale of the product at issue *regardless* of the levels of contaminant. (See, H.S.C. §25249.5 et. seq.) In
contrast, the FFDCA and the Sherman Act *actually prohibit* the sale of adulterated foods.

1 **2. Proposition 65 Is Also Unconstitutionally Overbroad on Its Face and as**
2 **Applied to Swanson, Because It Chills First Amendment Rights**

3 In the First Amendment context, the overbreadth doctrine invalidates overbroad statutes, even
4 where some of their applications are valid. (*United States v. Salerno* (1987) 481 U.S. 739, 745.) This
5 is a separate and independent basis for a judicial finding that Proposition 65 is unconstitutional. (*Id.*)
6 Even though the statute may apply in some contexts, it is overbroad if it operates unconstitutionally for
7 a substantial category of the speakers. (*Village of Schaumburg v. Citizens for a Better Environment*
8 (1980) 444 U.S. 620, 634.) Proposition 65 infringes Swanson’s First Amendment rights by forcing
9 Swanson to give *untrue warnings* with its products at the level of detection to avoid suit, as well as
10 being overbroad because it inhibits the First Amendment rights of other parties. (*Id.* at 495.)

11 **F. PROPOSITION 65 VIOLATES SWANSON’S CONSTITUTIONAL RIGHT TO DUE PROCESS**

12 The concept of due process is one of the bedrock principals of justice in western jurisprudence
13 and predates written constitutions. The constitutional guarantee of due process of law, found in the
14 Fifth and Fourteenth Amendments to the U.S. Constitution, prohibits government from arbitrarily or
15 unfairly depriving individuals of their basic constitutional rights to life, liberty, and property. (U.S.
16 Const. amend. V; amend. XIV.) As a limitation on state’s legislative power, the Supreme Court has
17 held that the federal Due Process Clause has both “procedural” and “substantive” components that
18 restrict the ways in which the state may apply the law, as well as what laws may attempt to do.

19 The California Constitution also recognizes and incorporates the right to both substantive and
20 procedural due process. (Cal. Const., art. I, § 1, 7.) The due process protections afforded by the state
21 are independent of and at least as protective of liberty as their federal counterpart. (Cal. Const., art. I,
22 §24; *See, In Re Marriage Cases* (2008) 43 Cal.4th 757, 780 (2008), (finding a right to same-sex
23 marriage solely under the due process clauses art. I, § 1, 7 of the California Constitution).)

24 Proposition 65 violates Swanson’s rights to due process under both the federal and state
25 constitutions on both procedural and substantive grounds.

26 **1. Proposition 65 Violates Procedural Due Process Because it is Void-For-Vagueness**

27 The constitutional doctrine of Void-for-Vagueness acts to strike down laws like Proposition 65
28 that deprive defendants of procedural due process. The Void-for Vagueness doctrine acts to assure

1 that defendants have complete notice of the prohibitions of laws, and also to limit the ability of
2 prosecutors, both public and private enforcers, from using the law to harass and intimidate and, as
3 here, to establish private standards of conduct through coerced settlements on terms that greatly exceed
4 their right to injunctive relief under Proposition 65.

5 The United States Supreme Court summarized the principles of the Void-for-Vagueness
6 doctrine in *Grayned v. City of Rockford* (1972) 408 U.S. 104:

7 It is a basic principle of due process that an enactment is void-for-vagueness if its prohibitions
8 are not clearly defined. Vague laws offend several important values. First, because we assume
9 that man is free to steer between lawful and unlawful conduct, *we insist that laws give the*
10 *person of ordinary intelligence a reasonable opportunity to know what is prohibited*, so that
11 he may act accordingly. Vague laws may trap the innocent by not providing fair warning.
12 Second, if arbitrary and discriminatory enforcement is to be prevented, *laws must provide*
13 *explicit standards for those who apply them*. A vague law impermissibly delegates basic
14 policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis,
15 with the attendant dangers of arbitrary and discriminatory application. . . .

12 (*Id.*, at 108 (emphasis added).) Thus, a law is void-for-vagueness if a defendant cannot tell how to
13 comply with it until he finds himself in an enforcement action; or, if the law delegates basic policy
14 matters to prosecutors and judges. Proposition 65 is a poster child for both abuses. “To satisfy the
15 constitutional command [of certainty], a statute must meet two basic requirements: 1) the statute must
16 be sufficiently definite to provide adequate notice of the conduct proscribed; and 2) the statute must
17 provide sufficiently definite guidelines . . . to prevent arbitrary and discriminatory enforcement.”

18 (*Tobe v. City of Santa Ana, supra*, 9 Cal.4th 1069, 1106-1107 (citations omitted).)

19 **a. Proposition 65 Fails to Give Sufficient Notice of the Conduct Proscribed**

20 In the seminal case of *Connally v. General Construction Company*, the Supreme Court set the
21 standard by which the court could judge whether a statute provides adequate notice of conduct: [A]
22 statute which either forbids or requires the doing of an act in terms so vague that **men of common**
23 **intelligence must necessarily guess at its meaning and differ as to its application violates the first**
24 **essential of due process of law.** (*Connally v. General Construction* (1926) 269 U.S. 385, 391
25 (emphasis added).)

26 In the present context of Proposition 65’s application to foods, it simply is not possible for a
27 person of common intelligence to determine what Proposition 65 requires, and when it requires it, for
28 two principal reasons: 1) the Act defines a *process* for determining when liability may be imposed, and

1 then 2) places the burden of proof is on the defendant. Rather than establishing firm and clear guidance
2 for industry to follow, the implementing regulations give only broad-brush parameters, which are
3 capable of many interpretations. Every uncertainty works against the defendant, because the defendant
4 has the burden of proving his innocence. To illustrate, consider the uncertainty of two of the critical
5 components the defendant must contend with: 1) proving the naturally occurring allowance for food;
6 2) with a total lack of guidance concerning testing and analysis methods.

7 (i) **The Conundrum of the Naturally Occurring “Exception”**

8 For foods, the “naturally-occurring” allowance is crucial: “Human consumption of a food shall
9 not constitute an “exposure” for purposes of [Proposition 65] to a listed chemical in the food to the
10 extent that the person responsible for the exposure can show that the chemical is naturally occurring in
11 the food.” (27 C.C.R. §25501(a).) This exception purportedly allows the presence of listed chemicals
12 in food with the clear intention that companies should not be held responsible for providing warnings
13 for chemicals that are naturally present in their product. (*Nicole-Wagner* at 660; Embree Decl. ¶18.)

14 While the concept is clear, the regulation fails to provide the specificity required for a company
15 to implement it. Section 25501(a)(2) is illustrative of this issue: The “naturally occurring” level of a
16 chemical in a food may be established by determining the natural background level of the chemical in
17 the area in which the food is raised, or grown, or obtained, based on reliable local or regional data. For
18 most food manufacturers, there is no practical way to obtain or generate this data – individual
19 components may come from numerous, sources. (Embree Decl. ¶¶17-27.) Even if data could be
20 developed, the there is no definition of “reliable local or regional data” leaving data gathered with
21 good intentions open to attack. It is well-documented that background contaminants vary from year-
22 to-year, from lot-to-lot, and even from sample-to-sample. (Sullivan Decl ¶ 50.) The regulations give
23 no guidance about how to deal with this variability.

24 Furthermore, “a chemical is naturally occurring only to the extent that the chemical did not
25 result from any known human activity.⁸” (27 C.C.R. §25501(3).) Even if it were possible to identify

26
27 ⁸ The *Tri-Union* tuna trial illustrates the complexity of this determination. *Tri-Union* presented extensive evidence from
28 scientists and oceanographers that the methylmercury in tuna was naturally occurring, originating from deep ocean vents.
The Attorney General countered with its own battery of scientists, that virtually all of the mercury was caused by man,
because of the presence of mercury in industrial pollution, car exhaust, and stormwater runoff from urban areas.

1 and evaluate every ingredient source, there remains the problem of determining what amount is
2 “anthropomorphic” and what amount is “geologic.”

3 Significantly, while 27 C.C.R. §25501(4) was intended to allow industry to use compliance
4 with federal good manufacturing practices to show that contaminants in foods have been reduced to
5 the “lowest level currently feasible” and thus, comply with Proposition 65, both the Office of the
6 Attorney General and AYS adopt a more radical interpretation – that the “lowest level currently
7 feasible” requires using *the* most pure source of supply. (Final Statement of Reasons (“FSR”), 27
8 C.C.R. 25501 pp. 10-11 (RJN Ex 5G); Embree Decl ¶¶21-24 (discussing the Attorney Generals’
9 creation of a “lowest possible source” requirement.)

10 (ii) **Test Procedures and Methods Demonstrate the Impossible Feat**
11 **of a Defendant’s Compliance**

12 OEHHA is well aware that the selection of appropriate tests and analytical methods is
13 overwhelmingly complex, as it admitted in 2005 when it repealed 22 C.C.R. §12901 (Methods of
14 Detection), finding that it was too confusing and that it fostered litigation. The new regulation is even
15 more general and vague than its predecessor – basically saying that it is up to the defendant to identify
16 the most appropriate analytical method for the “medium” in question, and listing a panoply of
17 regulatory agencies as *possible* sources of tests. Industry overwhelmingly objected to the new
18 regulation, and asked over and over again for clear standards and methods – to no avail. (Notice of
19 Proposed Rulemaking, 22 C.C.R. §12901 (Repealed), p. 1 (RJN Ex 5J).)

20 The Agency’s response to industry’s comments during rulemaking are telling. First, OEHHA
21 made its view clear that *Proposition 65 does not require “the lead agency to establish testing*
22 *methodologies for chemicals listed under the Act.”* (FSR, 22 C.C.R. § 12901 (Repealed) Responses to
23 Comments App I pg. 2 (RJN Ex 5J).) Second, OEHHA recognized the impossibility of issuing
24 specific guidance, stating “*[i]t is not feasible for OEHHA to develop a regulation that would*
25 *establish a specific method of detection and analysis that is appropriate for every listed chemical, in*
26 *every medium and every exposure, discharge or release scenario.* (*Id.*) Third, OEHHA *refused* to
27 provide clarity, giving a hollow justification that “the Act expressly places the burden of proving that
28 an exposure does not require a warning on the business causing the alleged exposure, not with the lead

1 agency.” (*Id.*) These comments are particularly unresponsive and callous since they were made
2 during rulemaking intended to address how a business may determine whether Proposition 65 applies
3 in the first place. Although it recognized how intractable the selection of test methodology can be,
4 OEHHA affirmed that Proposition 65 delegates the task of establishing standards to the courts.

5 The inexorable fact is that businesses can only know whether correct decisions have been
6 made about what tests to use, what methods to follow, and a host of other critical decisions after a
7 court rules. Because the defendant bears the burden of proof, the correctness of each decision is
8 critical – but the regulations are unclear and guidance is often non-existent. The Supreme Court,
9 however, has made clear that “the dividing line between what is lawful and unlawful cannot be left to
10 conjecture.” (*Connally*, 269 U.S. at 393.) “The citizen cannot be held to answer charges based upon
11 penal statutes whose mandates are so uncertain that they will reasonably admit of different
12 constructions” by the fact finder. (*Id.*) Proposition 65 embodies this classic definition of Void-for-
13 Vagueness – a defendant cannot tell whether it has violated the law until the court rules after the fact.
14 Clearly Proposition 65 denies due process, particularly in this context as applied to foods.

15 **b. Proposition 65 Promotes Arbitrary Enforcement**

16 The Supreme Court has recognized that the prevention of arbitrary and discriminatory law
17 enforcement is the most important function of the Void-for-Vagueness doctrine. (*Grayned*, 408 U.S.
18 at 108-09, *see also*, *Tobe v. City of Santa Ana*, 9 Cal.4th 1069, 1106-1107.) Because Proposition 65
19 established generalized processes rather than determinative standards, it allows private plaintiffs to
20 both define the law and apply their interpretations, while forcing the defendant to bear the burden of
21 proof. The lack of definite and clear standards makes it impossible for the defendant to know what is
22 required and to take action to avoid suit, while simultaneously giving carte blanche to plaintiffs to sue
23 them. This not only poses a danger of arbitrary and discriminatory enforcement, it ensures it.

24 **(i) Public and private enforcers have sole discretion to file lawsuits**

25 Proposition 65 is structured to enable plaintiffs to file a lawsuit on the slimmest of evidence
26 that an “exposure” is occurring at the level of detection. (H.S.C. §25249.6.) As illustrated by
27 OEHHA’s prompt repeal of the Methods of Detection regulation (22 C.C.R. §12901) on the ground it
28 “fostered litigation” after a defendant had the temerity to make use of it to challenge the method of

1 analysis the plaintiff used to prove a “detectable” discharge, Proposition 65 is focused on making it as
2 easy as possible for a plaintiff to sue, but as difficult a possible for a defendant to comply and defend
3 against claims. (*See* Notice of Proposed Rulemaking, 22 C.C.R. §12901 (Repealed) (RJN Ex 5J).)

4 No other penal law in any civilized nation, criminalizes unavoidable conduct – detectable
5 levels of listed chemicals that are unavoidably present in virtually all foods – and uses the court as the
6 forum *for the defendant* to both quantify the appropriate standard and apply it. Lacking unambiguous
7 quantified standards for making these determinations, the trier of fact is inappropriately left to do so –
8 a role the constitution assigns to the legislature or quasi-legislative function of administrative agencies.

9 (ii) **Proposition 65 is structured to delegate regulatory decisions to**
10 **the court – leading to inconsistent results**

11 Another hallmark of a fatally vague statute is that it leads to inconsistent results. (*Tobe v. City*
12 *of Santa Ana, supra* 9 Cal.4th at 1106-1107 (statute must provide sufficiently definite guidelines . . . to
13 prevent arbitrary and discriminatory enforcement).) As noted above, Proposition 65 does not contain
14 quantified standards or clear guidelines for deriving them. Moreover, OEHHA has determined these
15 are not necessary because the Act requires the defendant to prove them at trial. (FSR, 27 C.C.R.
16 §25900, Appendix I, pg. 2. (RJN Ex 5H).) Thus, Proposition 65 *intentionally* delegates to courts the
17 function of determining the standard as well as applying it. This approach not only calls upon the
18 judiciary to fill the void left by the statute and OEHHA’s abdication on a defendant-by-defendant,
19 product-by-product, chemical-by-chemical basis, but will certainly lead to inconsistent results. This
20 propensity for inconsistency likewise illustrates that Proposition 65 is Void-for-Vagueness.

21 **2. Proposition 65 Violates Swanson’s Right to Substantive Due Process Under the**
22 **Federal and State Constitutions**

23 The doctrine of Substantive Due Process both incorporates basic *procedural* rights, and
24 protects basic *substantive* rights. The Substantive Due Process clause guarantees that life, freedom
25 and property cannot be taken without appropriate governmental justification, *regardless* of the
26 procedures used to do the taking. (*Washington v. Glucksberg* (1997) 521 U.S. 702, 719-20.) In
27 addition to violating the procedural due process clause – because it is Void-for-Vagueness –
28 Proposition 65 violates Swanson’s right to Substantive Due Process because its structure and

1 application impair three fundamental rights: freedom of expression, the Rule of Law (the presumption
2 of innocence and that the accuser bears the burden of proving guilt), and Eighth Amendment
3 protections against excessive fines and penalties.

4 **a. As a Statutory Scheme, Proposition 65 Imposes a Regulatory Vice That**
5 **Traps Defendants and Violates Their Substantive Due Process Rights**

6 Proposition 65's Substantive Due Process violation is inherent in its structure, which creates a
7 regulatory vice. Defendants are either compelled to make a statement about their products, which
8 when applied to FDA-compliant and nutritious foods amounts to compelled self-libel, or risk grossly
9 abusive prosecution with the attendant possibility of ruinous civil penalties and litigation expenses.
10 Caught in this vice, the overwhelming majority of defendants execute consent judgments on the
11 plaintiffs' terms. These private agreements often establish *quantified exposure levels* and even specify
12 the test methods to be used – something that defendants cannot even get from OEHHHA. Thus, by
13 paying a large tribute to the private plaintiff and its attorneys, the defendant may finally get a
14 standard – albeit negotiated by lawyers to the dictates of litigation necessity – and a modicum of
15 protection for a decision not to warn. Thus, Proposition 65 tramples defendants' rights while allowing
16 every plaintiff the power of the pre-Magna Carta sovereign.

17 A more detailed look shows how Proposition 65's reversal of the burden of proof, plus the
18 "warning" demand and the possibility of ruinous penalties, creates this intolerable situation. First, it
19 infringes upon free expression by imposing a draconian and fundamentally untrue warning on all
20 foods, which applies to "exposures" above the level of detection. Although regulations define
21 "exposure" to exclude all "naturally-occurring" chemicals, defendants are unable to avail themselves
22 of its protection, because it may only be invoked as an affirmative defense at trial. (27 C.C.R.
23 §25501(a), H.S.C. §25249.10(c).) Thus, the very act that triggers the application of the law – a
24 Proposition 65 *exposure* – is left to the defendant to *disprove* at trial.

25 Second, Proposition 65's enforcement scheme offends the long standing principals inherent in the
26 Rule of Law: 1) a defendant must be told unambiguously what conduct has violated the statute; and,
27 2) the defendant must be presumed innocent until *proven guilty*. The Act is *intentionally structured to*
28 *allow private parties an unfettered right to sue*, and to place the burden of proving innocence on the

1 defendant. In the case of foods, the plaintiff's burden of production is almost non-existent, since it is
2 undisputed that most foods contain detectable levels of listed chemicals. (*Nicole-Wagner v Duekmejian*
3 (1991) 230 Cal.App.3d 652, 660; FSR, 27 C.C.R. §25501, Sullivan Decl. ¶55.)

4 A bedrock principal inherent in the Rule of Law, is that a defendant is considered innocent until
5 **proven** guilty by its accuser. (*Coffin v. United States* (1895) 156 U.S. 432, 454). Proposition 65 subverts
6 this principal by artifice – an artifice without precedent and wholly unjustified. It is the defendant, not
7 the prosecutor, who must prove it is “innocent.” It must do so by both deriving *and* quantifying the
8 standard, and then prove by a preponderance of the evidence that exposures from its products fall below
9 the standard. (*Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333, 345-347.) The defendant
10 must carry the burden of proof even though the regulations are obtuse, at times contradictory, and at other
11 times non-existent. (Embree Decl. ¶11-16.) Courts have recognized that there is no way short of a full
12 blown trial for a defendant to dispose of a Proposition 65 case. (*Rental Housing* at 1215-16.) Even a
13 cursory read of three recent opinions confirms how complex, burdensome and ruinously expensive a
14 defense is. (See *Tri-Union*, *DiPirro v Bondo* (2007) 153 Cal. App. 4th 150; and *Baxter, supra*, 120
15 Cal.App.4th 333.) Clearly, such vindication of a decision not to warn is a luxury afforded the largest
16 companies or defense groups, and beyond the means of smaller businesses.

17 Third, if the defendant fails to carry its burden of proof, this *penal* statute imposes mandatory
18 penalties of up to \$2,500 per violation per day. (*Shamsian v. Atlantic Richfield Company*, 107
19 Cal.App.4th 967, 976 (2003).) These are truly punitive in that the potential levy may easily exceed the
20 net worth of the business. **This is especially egregious considering the fines imposed without**
21 **regard to any showing of harm or injury to anyone, and are not remedial.** Potential fines of this
22 magnitude are clearly excessive, and as such may violate the prohibition against “excessive fines” in
23 the Eighth Amendment. The possibility of an award close to the statutory maximum is exploited by
24 plaintiffs as another tool in their potent arsenal to compel lucrative settlements for themselves.

25 **b. Proposition 65 Cannot Withstand Strict Scrutiny**

26 When a law is challenged as a violation of individual liberty under the Due Process Clause, the
27 court's scrutiny depends upon the right infringed. (*United States v. Carolene Products Company*
28 (1938) 304 U.S. 144, fn. 4.) Here, the governmental action infringes upon a confluence of three

1 fundamental rights – two guaranteed in the Bill of Rights and one integral to our judicial system.
2 Thus, the highest level of review – strict scrutiny – must be used. (*Adarand Constructors v. Pena*
3 (1995) 515 U.S. 200 (equal protection); *Sherbert v. Verner* (1963) 374 U.S. 398 (First Amendment).)

4 (i) **Proposition 65 does not serve a compelling governmental
5 interest – nor even a substantial interest**

6 Proposition 65’s stated purpose is to provide notice to consumers before exposure to “known”
7 and “significant” exposures. (*See* Ballot Argument in Favor of Proposition 65 (RJN Ex 5).)
8 (“**Proposition 65 does not apply to insignificant (safe) amounts of chemicals.**”) As the *Nicole-*
9 *Wagner* court observed when finding the naturally occurring exception to be consistent with the
10 purposes of the Act:

11 [T]he ballot argument in favor of Proposition 65 explains that “[Proposition 65] will
12 not take anyone by surprise. [It] applies only to businesses that *know* they are putting
13 one of the chemicals out into the environment. . . .” (Italics in original.) A chemical is
14 not “put” into the environment if it is naturally occurring in, for example, fruits and
vegetables. The ballot argument against Proposition 65 also includes strong language
indicating that **naturally occurring substances are not intended to be controlled by
the proposed statute. . . .**

15 (*Nicole-Wagner*, 230 Cal.App.3d at 660 (emphasis added).) Thus, even though the ballot measure
16 assured voters that overwarning would not occur – the statute and its implementing regulations apply
17 *contrary* to the ballot argument, and compel *overwarning* for foods.

18 Indeed, overwarning is anathema to a “clear and reasonable” warning. In support of its
19 decision to preempt Proposition 65, the *Dowhal* Court addressed the problems of overwarning:

20 “[E]ven if scientific evidence supports the existence of a risk, a warning is not
21 necessarily appropriate: **The problems of overwarning are exacerbated if warnings
22 must be given even as to very remote risks. . . .**” (citations omitted) “Against the
23 benefits that may be gained by a warning must be balanced the dangers of overwarning
and of less meaningful warnings crowding out necessary warnings, the problems of
remote risks, and the seriousness of the possible harm to the consumer.”

24 (*Dowhal, supra*, 32 Cal.4th at 932-933.) There is no compelling state interest; in fact, there is no state
25 interest whatsoever, in preserving a statute that is ineffective in achieving its own *stated purpose*.

26 (ii) **Proposition 65 is not *narrowly tailored* and does not achieve its
27 ends by the *least restrictive means***

28 Proposition 65 is not narrowly tailored to achieve the State’s interest in providing clear and

1 reasonable warnings – it is not even reasonably related to this objective. It fact, the reverse is true.

2 **The Act as a whole and each provision is intentionally crafted to diminish defendants’ rights and**
3 **grant plaintiffs unheard of “new” rights.**

4 Most egregious is the statute’s reversal of the burden of proof. As noted in *Rental Housing*:

5 The critical part is in the burden shifting provision of Health and Safety Code section
6 25249.10, which states that “In any action brought to enforce Section 25249.6, the burden of
7 showing that an exposure meets the criteria of this subdivision shall be on the defendant.”
8 Leaving aside the problem of “knowing and intentional” as an element of the statute, **the**
9 **burden shifting provisions make it virtually impossible for a private defendant to defend**
10 **a warning action on the theory that the amount of carcinogenic exposure is so low as to**
11 **pose “no significant risk” short of actual trial.**

12 (*Rental Housing* at 1214, (emphasis added), *Consumer Cause, Inc. v. Smilecare* (2001) 91 Cal.App.4th
13 454 (dissent).) Even if sanctioned by voters and expedient for public prosecutors, a law that sanctions
14 vigilantism to achieve its ends is unjust – and cannot be made so under any credible reasoning.

15 The reversal of proof is even more unjustified for foods, because 27 C.C.R. §25501 excludes
16 naturally occurring contaminants *from the definition of “exposure”*⁹ In a lawsuit, plaintiff must plead
17 a detectable “exposure,” but is not required to show that any part of the chemical was man-made or
18 even that its presence is avoidable. Section 25501(a) requires *defendants* to prove these things. Put
19 another way, the defendant, not the plaintiff, must prove that no Proposition 65 *exposure* occurred –
20 *i.e.*, that the statute does not even apply in the first place.

21 Proposition 65 is much more oppressive than necessary – or reasonable. First, Proposition 65 is
22 over-inclusive – and therefore impacts free speech rights more than necessary, because it compels
23 warnings at the level of detection. Since the level of detection is well below any level shown to cause
24 harm, it ensures overwarning – and also contradicts the ballot initiative. Second, the enforcement
25 mechanism is overly broad in that there are insufficient mechanisms to *prevent* meritless actions, and
26 to ensure consistency of result. Further, the unique private enforcer provision allows anyone to sue,
27 bypassing all of the time-honored protections of judicial standing. (H.S.C. §25249.7(d).) There is no
28 compelling state interest to grant access to the court to plaintiffs who have suffered no injury to person

⁹ 27 C.C.R. § 25501 provides: “Human consumption of a food shall not constitute an ‘exposure’ for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food.”

1 or property. This open access has fostered industry-wide litigation and astonishing abuses.

2 **c. Other Options to Insure Food Safety**

3 Finally, it is worth noting that aside from properly delegating the issue of food warnings to
4 FDA, there are much better and constitutional ways to protect the public with respect to potential
5 dangers in foods. For example, California could establish discrete standards for lead in food under the
6 Sherman Act,¹⁰ or work collaboratively with FDA to set a tolerance. Alternately, the Sherman Act
7 expressly authorizes warnings for dietary supplements – *to the extent that such statements comply*
8 *with federal law*. (H.S.C. §110422 (c).) Additionally, the Sherman Act and the FDA both have the
9 power to actually prohibit the sale of dangerous food, which Proposition 65 does not have. (See fn 10.)

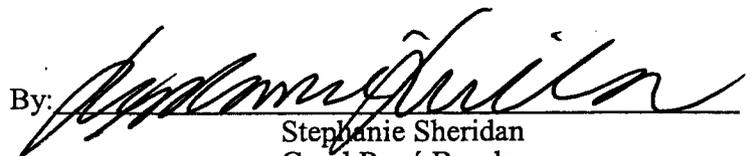
10 Although both FDA and the Department of Health Services banned ephedra, H.S.C. §110423
11 provide examples of the state warnings for this ingredient that were required before the total ban. This
12 also illustrates both the seriousness of concern needed to trigger warnings, and the appropriate
13 tailoring of the text to properly affect the warning. Because the Sherman Act is consistent with
14 FFDCFA, and administered by individuals with expertise in medicine, nutrition, and food science
15 (unlike Proposition 65 “enforcers”), the chance of conflicting with federal law would be lessened, and
16 regulation could be tailored to meet the articulated goals. More important, any standards or warning
17 regulations adopted would comply with due process, and provide clear and adequate notice to the
18 public. Not only are Proposition 65’s process-based standards indeterminant until ratified or revised
19 by a court, they are simply unfair to the business community and unjust.

20 **IV. CONCLUSION**

21 For the reasons above, Swanson’s Motion for Summary Judgment should be granted.

22 Dated: July 25, 2008.

SEDGWICK, DETERT, MORAN & ARNOLD LLP

23
24 By: 

Stephanie Sheridan

Carol René Brophy

Attorneys for Defendant

SWANSON HEALTH PRODUCTS, INC.

25
26
27 ¹⁰ Health & Safety Code § 110070 authorizes the California Department of Health Services to set tolerances, which are
28 absolute limits on the amount of a deleterious substances that may be present in food. Under state law, as well as the
FFDCFA, foods that exceed the tolerance level are banned from commerce.

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
CITY AND COUNTY OF SAN FRANCISCO

AS YOU SOW,

Plaintiff,

v.

SWANSON HEALTH PRODUCTS, INC.,

Defendant.

CASE NO. CGC-07-466-169

DECLARATION OF LOUIS W. SULLIVAN, M.D. IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Hearing : Select Any Day M-F
Time : 9:30 a.m.
Dept. : 301
Judge : Hon. Peter Busch
Action Filed : August 14, 2007
TRIAL DATE : August 3, 2009

1 I, Louis W. Sullivan, M.D., declare as follows:

2 1. I am giving this declaration as an expert in the field of regulation of foods and
3 dietary supplements by the U.S. Food and Drug Administration ("FDA") under the Federal Food,
4 Drug, and Cosmetic Act ("FFDCA"). The basis for my expertise follows.

5 2. *Professional background and experience.* I hold an M.D. from Boston
6 University and a B.S. from Morehouse College. Over the past forty-five years I have taught in
7 the medical field at Virginia Commonwealth University, The Morehouse School of Medicine,
8 Morehouse College, Boston University School of Medicine, New Jersey College of Medicine,
9 and Harvard Medical School. I served as Dean and Director at the School of Medicine at
10 Morehouse College. Additionally, I have served as President and Dean at The Morehouse
11 School of Medicine, where I am currently President Emeritus. A copy of my most recent
12 curriculum vitae is attached as Exhibit 1A.

13 3. Since 1958, I have worked as a physician and conducted medical research at
14 numerous hospitals and medical schools.

15 4. From 1989 until 1993, I served as Secretary of the U.S. Department of Health and
16 Human Services ("HHS"). Under my tenure, the Food and Drug Administration implemented its
17 new food labeling regulations.

18 5. Over the past 40 years I have held over 40 advisory and consulting positions,
19 including positions with the National Cancer Advisory Board, National Cancer Institute and the
20 Board of Scientific Counselors, and the Agency for Toxic Substances and Disease Registry. I
21 have served as a member of the Advisory Committee to the Director of the National Institutes of
22 Health, and presently, I am a member of the Advisory Committee to the Director of the Center
23 for Disease Control and Prevention, and the Institutes of Medicine's Committee on the
24 Organizational Structure of the HHS, and the Health Disparities Technical Expert Panel of the
25 Centers for Medicaid and Medicare Services. My public committee memberships as Secretary,
26 HHS (Ex-Officio), include National Advisory Child Health and Human Development Council
27 and National Heart, Lung, and Blood Advisory Council, among at least 19 others.

28 6. I have authored numerous publications, at least 64 of which are scientific, and 37

1 of which are public-policy related.

2 7. I testified as an expert witness on federal food labeling regulations during the
3 Proposition 65 trial of *People of the State of California, et. al. v Tri-Union Sea-Foods, LLC*, San
4 Francisco County Superior Court, Nos. CGC-01-402975, CGC-04-432394 (filed June 21, 2004).

5 8. I am familiar with California's Proposition 65, and have been aware of the
6 requirements imposed by this law since its early implementation.

7 9. I am making this declaration on the basis of my own personal knowledge, my
8 experience, and information from documents available from the public record.

9 10. **Summary of testimony.** The purpose of this declaration is to demonstrate my
10 conclusions that:

- 11 a) Through the FFDCA, Congress has delegated to FDA the authority to
12 regulate food and dietary supplements (hereinafter "foods"), and to
13 implement the labeling (misbranding) and food safety (adulteration)
14 provisions of the FFDCA.
- 15 b) FDA has implemented a comprehensive regulatory scheme for foods,
16 which includes carcinogens and reproductive toxins, such as lead. The
17 relevant history and background are complex and extensive. FDA has
18 been examining this issue for many years and has compiled substantial
19 data concerning background levels of contaminants in foods.
- 20 c) Accurate, and not misleading, labeling is critical to achieve the purposes
21 and goals of the FFDCA, and to the success of FDA's regulatory
22 programs.
- 23 d) FDA has developed a thorough understanding of Proposition 65's
24 provisions, and is "uniquely qualified" to comprehend the likely impact of
25 a Proposition 65 warning on foods. The subject matter is technical, and
26 FDA has substantial expertise in analyzing the scientific issues involved,
27 as well as the consumer education aspects of the matter.
- 28 e) Since its regulations were adopted during my administration, as US
Secretary of HHS, FDA and other federal agencies have repeatedly
advised California that Proposition 65 conflicts with the federal regulatory
scheme for foods, as well as other FDA-regulated products.
- f) Proposition 65 and its implementing regulations conflict irreconcilably
with the FFDCA and FDA's long time and well-considered policy for
regulating foods. The conflict is two-fold:

First, Proposition 65 warnings applied to product labels and/or food

1 labeling, frustrates *both* the statutory prosecution against false and
2 misleading labeling, *and* the purposes of and goals of the FFDCA.

3 Second, Proposition 65 warnings on foods are inaccurate and misleading.
4 It is impossible to provide a Proposition 65 warning, and also comply with
5 the FFDCA prosecution against misbranding. Simply, the provision of a
6 Proposition 65 “warning” misbrands foods that are in compliance with
7 federal law; if the foods are not in compliance, they are “adulterated” and
8 may not be sold at all, regardless of whether a warning is given or not.

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I.
OVERVIEW OF THE STATUTORY AND REGULATORY SCHEME FOR THE
REGULATION OF FOODS

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A. **AS AUTHORIZED BY CONGRESS IN THE FFDCA, FDA COMPREHENSIVELY**
REGULATES FOODS

11 11. The Food and Drug Administration (“FDA”), part of HHS, employs about 10,000
12 employees, including physicians, scientists, health professionals and technical staff.¹ Although
13 headquartered in the Washington D.C. area where product review and regulatory functions are
14 focused, the Agency also operates field offices and laboratories throughout the nation. There are
15 11 offices in California.

16 12. Significantly, 20% of each consumer dollar is spent on FDA-regulated products –
17 or about \$1.5 trillion annually.² In Fiscal Year 2009, October 2008 through September 2009,
18 FDA will spend \$2.4 billion to protect and promote public health.³ Over one quarter of this
19 amount, \$660 million, will be spent on food safety, regulation and enforcement.

20 13. The FFDCA establishes a comprehensive statutory and regulatory scheme for the
21 regulation of food, drugs, cosmetics, and medical devices. Its approach is to establish
22 requirements for safety and effectiveness for these articles and to prevent products that do not
23 meet those requirements from entering the channels of trade. In the FFDCA, Congress
24 designated FDA to implement the Act.

25 14. FDA has been the primary guardian of the safety of the nation’s food and drug

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¹ FDA’s website has a number of informative articles about FDA’s history, its mandates and the programs it oversees.

² For more information *see*, <http://www.fda.gov/oc/opacom/fda101/sld002.html>.

³ For more information *see*, <http://www.fda.gov/oc/oms/ofm/budget/2009/TOC.htm>.

1 supply since 1906. FDA's mission is:

- 2 • to promote and protect the public health by helping safe and effective products
- 3 reach the market in a timely way,
- 4 • to monitor products for continued safety after they are in use, and
- 5 • to help the public get the accurate, science-based information needed to improve
- 6 health.

7 15. The Food and Drug Act of 1906 was the first nationwide consumer protection law
8 that made it illegal to distribute misbranded or adulterated foods, drinks, and drugs across state
9 lines. It was reissued in 1938, and has undergone a number of modifications and additions since,
10 including the Fair Packaging and Labeling Act, the Nutrition Labeling and Education Act of
11 1990, and The Dietary Supplement Health and Education Act of 1994.⁴ From its inception, the
12 FFDCA has focused on labeling as a principal means of communicating accurate information
13 about foods and dietary supplements.⁵

14 16. With regard to foods and dietary supplements, the FFDCA grants FDA broad
15 authority to establish food safety standards and good manufacturing practices, to regulate labels
16 for food products, and to issue food advisories as warranted.⁶ This authority is grounded in the
17 misbranding provisions of the FFDCA set forth in §§ 403(a)(1) and 201(n). Misbranding occurs
18 when food labeling is "false or misleading in any particular."⁷ This prohibition against
19 misleading statements applies to point-of-sale signs, brochures, or packing slips, as well as to
20 product labels.⁸

21 17. FFDCA § 342 also prohibits placing adulterated foods in commerce.⁹

22 ⁴ 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.*).

23 ⁵ See generally, Samia Rodriguez, *Food Labeling Requirements*, THE FUNDAMENTALS OF
LAW AND REGULATION 238-256 (Robert E. Brady et al. ed. 1997).

24 ⁶ 21 U.S.C. § 341; FFDCA § 401.

25 ⁷ 21 U.S.C. § 343; FFDCA § 403 (m).

26 ⁸ 21 U.S.C. § 321(m); The Act defines labeling: "The term "labeling" means all labels and
other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers,
or (2) accompanying such article."

27 ⁹ FFDCA § 402 [21 U.S.C. 342] – "(a) A food shall be deemed to be adulterated... (1) If it
bears or contains any poisonous or deleterious substance which may render it injurious to health;
but in case the substance is not an added substance such food shall not be considered adulterated
28 under this clause if the quantity of such substance in such food does not ordinarily render it

1 18. In addition, FDA is empowered to promulgate labeling rules to achieve the policy
2 and purposes of the FFDCFA, as well as its express provisions. This statutory structure provides
3 FDA with the tools to ensure all ingredients used in foods are safe, and that food is free of
4 contaminants, including chemicals, disease-causing organisms, and other harmful substances.

5 19. A principal tool for achieving food safety and improving human health is
6 consumer awareness of the nutritional properties of foods. A structured, consistent, scientifically
7 based, but easy to understand, labeling and risk communication scheme is at the heart of FDA's
8 program for regulating foods and educating consumers.

9 20. As seen by a brief overview of the FFDCFA, scientifically based labeling, with its
10 twin prohibitions against misbranding and adulteration, are central provisions, which have been
11 strengthened and clarified over the past 40 years.

12 21. ***Fair Packaging and Labeling Act ("FPLA")***. Congress adopted the Fair
13 Packaging and Labeling Act of 1966 during the Johnson administration to provide consumers the
14 information they need to choose among competing products.¹⁰ All businesses engaged in
15 producing and distributing consumer products must comply with the FPLA, which requires
16 businesses to disclose information truthfully. Among other things, the FPLA requires that labels
17 include basic information, such as, ingredients and contents, quantity, and maker of the product.
18 Although the FPLA falls under the consumer-protection charge of the Federal Trade
19 Commission, the authority to promulgate regulations with respect to foods, drugs, medical
20 devices and cosmetics is vested in the Secretary of Health and Human Services ("Secretary").
21 The Secretary also bears the primary responsibility for making sure that such labeling is not false
22 and misleading.¹¹

23 22. ***Nutrition Labeling and Education Act of 1990 ("NLEA")***. Shortly before the
24 NLEA was enacted by Congress, federal policy makers determined that it it was time to reform
25 food labeling to provide consumers with accurate and useful information about the foods they

26
27 injurious to health."

¹⁰ 15 U.S.C. § 1451, *et. seq.*

¹¹ 15 U.S.C. § 1454.

1 eat, and to educate them concerning the health benefits of a nutritionally adequate diet. The stage
2 for reform was set by C. Everett Koop's 1988 *Surgeon General's Report on Nutrition and*
3 *Health*, which was the federal government's first formal statement of the role of diet in certain
4 chronic diseases.

5 23. During my tenure as Secretary,¹² several HHS divisions under my direction,
6 including FDA and the National Institutes for Health ("NIH"), worked collaboratively to
7 comprehensively study all relevant aspects of the issue, and then to craft a proposed labeling
8 program that would achieve the goals.

9 24. Building on the work of my predecessors including Surgeon General Koop, FDA
10 and the National Research Council of the National Academy of Sciences jointly issued a
11 comprehensive report in 1989: *Diet and Health: Implications for Reducing Chronic Disease*
12 *Risk*, which presented additional evidence of diet as a factor in the development of chronic
13 diseases, such as coronary heart disease and cancer. Under contract to FDA and the U.S.
14 Department of Agriculture's Food Safety and Inspection Service ("FSIS"), the Food and
15 Nutrition Board of the National Academy of Sciences convened a committee to consider how
16 food labels could be improved to help consumers adopt or adhere to healthy diets. These
17 recommendations were summarized in *Nutrition Labeling: Issues and Directions for the 1990s*.¹³

18 25. In 1989, based upon the above evaluations and interagency consultation, HHS
19 proposed extensive food labeling changes, which included mandatory nutrition labeling for most
20

21 ¹² The U.S. Department of Health and Human Services ("HHS") is a Cabinet department of
22 the United States government with the goal of protecting the health of all Americans and
23 providing essential human services. HHS, led by the Secretary of Health and Human Services,
24 includes staff offices (e.g., general counsel, and Assistant Secretaries for Health, for Legislation,
25 for Planning and Evaluation, for Public Affairs, and for Management and Budget, and Director of
26 the Office of Civil Rights) and 12 operating divisions: (1) Administration on Aging; (2)
27 Administration for Children and Families; (3) Center for Medicare and Medicaid Services; (4)
28 Program Support Center; and the eight divisions that together constitute the U.S. Public Health
29 Service: (1) Agency for Health Care Quality and Research; (2) Agency for Toxic Substances and
30 Disease Registry; (3) Centers for Disease Control and Prevention; (4) Food and Drug
31 Administration; (5) Health Resources and Services Administration; (6) Indian Health Service; (7)
32 National Institutes of Health; and (8) Substance Abuse and Mental Health Services
33 Administration.

¹³ Donna V. Porter and Robert O. Earl, ed., *NUTRITION LABELING: ISSUES AND DIRECTIONS FOR THE 1990S*, National Academy Press, Washington, D.C., 1990.

1 foods, standardized serving sizes, and uniform use of health claims.¹⁴ On August 8, 1989, FDA
2 published an advance notice of proposed rule-making on food labeling and, with FSIS
3 participating, held a series of four public hearings around the country.¹⁵ The scope of the
4 recommendations was thoughtfully limited, for clarity and simplicity, so that consumers would
5 understand the format and use the information provided. (A more detailed discussion of
6 interagency consultation and the factors considered in developing and implementing the NLEA
7 labeling scheme is discussed below at III.A.)

8 26. These reports and other information provided by HHS to the Congress, formed the
9 nucleus of the NLEA, which reaffirmed the basis for, and structure of, FDA's labeling initiative.

10 27. Thus, when Congress enacted the NLEA,¹⁶ it ratified FDA's regulatory program,
11 requiring standard-format nutrition labeling for manufactured food products. The NLEA
12 achieved national uniformity by preempting state nutritional labeling standards, including
13 nutrition content and health claims,¹⁷ and by authorizing states to cooperate in enforcing the
14 standards with FDA.

15 28. In the NLEA, Congress did not authorize states to adopt labeling requirements for
16 foods that frustrated the primary purpose of the NLEA, which was to make labeling clear and
17 easily understood by consumers. Congress' purpose was to strengthen FDA's authority to
18 require nutrition labeling on foods, and to establish circumstances when claims may be made
19 about a food's nutritional content.

20 29. The NLEA was also a congressional response to the increased role of the states in
21 regulating food labeling and advertising. Moreover, the food industry is no longer local, but truly

22
23 ¹⁴ 56 Fed. Reg. 28592 (June 21, 1991).

24 ¹⁵ Fed. Reg. Vol. 54, No. 151/ Tuesday, August 8, 1989/ Proposed Rules [Announcement
25 from the] Department of Health and Human Services Food and Drug Administration 21 C.F.R.
26 Ch.1 [Docket No. 89N-0226] RIN 0905-AD08 Food Labeling [as requested by the] Food and
27 Drug Administration [concerning] Advance notice of proposed rulemaking; request for public
28 comment. (As extended in Fed. Reg. September 20, 1989.)

26 ¹⁶ Pub. L. No. 101-535, 104 Stat. 2353 (1990); 21 U.S.C. § 343-1.

27 ¹⁷ 21 U.S.C. § 343-1(a)(4). See generally, 55 Fed. Reg. 5191 (Feb. 13, 1990); Hearings on
28 S. 1425 Before the Senate Comm. on Labor and Human Resources, 101st Cong., 1st Sess. 164
(1989) (statement of Sen. Hatch). Craig Jordan, *Preemption and Uniform Enforcement of Food
Marketing Regulations*, 49 Food & Drug L. J. (1994).

1 international. Consequently, state regulations, especially those that depart markedly from FDA's
2 regulatory format, increase the probability of conflicts with national regulations and international
3 treaties. Further, with the publication and dissemination of information showing a direct
4 correlation between consumer dietary habits and the prevalence of disease, consumers have
5 become increasingly concerned about the accuracy of nutrition information.¹⁸

6 30. In adopting NLEA, Congress recognized the disruptive impact that conflicting
7 state labeling laws may have on the interstate commerce of foods, as well as the consumer
8 confusion that may result from conflicting state standards. Thus, one of the goals of the NLEA
9 was to give industry the relief from inconsistent state-imposed requirements that interfere with
10 the ability to market products in all 50 states in an efficient and cost effective manner.

11 31. It is well known that the NLEA included legislative compromises, including the
12 provisions on national labeling uniformity that impinged state labeling requirements. **It is my
13 opinion, based upon my role working closely with Congress on NLEA, that *Congress did
14 not intend that Proposition 65 apply if it frustrated the purposes and goal of the FFDCFA, its
15 implementing regulations and FDA policies.* Thus, to the extent that any state law,
16 including Proposition 65, conflicts with federal law and/or frustrates federal policy, it must
17 give way to the federal scheme.**

18 32. My view is further supported by the legislative history of the NLEA. Recognizing
19 the preemption provisions in the NLEA, Senator Hatch spoke to the issue, expressing his concern
20 that inconsistent state food warning requirements "undermin[e] the credibility and effectiveness
21 of Federal policy in this area" and "frustrate food safety and nutrition education efforts by
22 presenting consumers with varying and inconsistent information and warnings. In sum, we
23 simply must remember that a warning on everything means a warning on nothing." Further, he
24 characterized the limited preemption in the NLEA as "only one step toward expanding
25 uniformity of labeling laws and food safety requirements through existing law as well as future
26 legislation." (136 Cong. Rec. S16611 (daily ed. Oct. 24, 1990). Request for Judicial Notice
27

¹⁸ The comments of Representative Madigan illustrates this point. Rep Madigan, 136 Cong. Rec. H12954 (October 26, 1990).

1 (“RJN”) Exhibit 5B.)

2 33. In fact, the record shows that Congress intended for “conflicts preemption” to
3 retain its full force and vitality. As Senator Hatch explained:

4 [A]lthough the provisions of this bill may not preempt a state warning
5 requirement . . . , that very same state warning may be preempted by virtue of *the*
6 *Constitution, another statutory provision, or agency action*. This result is an
7 essential element of the compromise embodied in the uniformity provisions of this
8 legislation. The decision of the Congress in this legislation to specifically
9 preempt certain State or local requirements is not evidence, one way or the other,
10 of any congressional view about the existence of preemption which may arise
11 from other existing legal authorities or actions.

12 (136 Cong. Rec. S16611 (daily ed. Oct. 24, 1990) (emphasis added).)

13 34. Although the NLEA preempts many state labeling requirements for foods, it
14 allows states to establish and enforce safety standards exceeding those of FDA where the state
15 does so in a manner that is consistent with FDA’s regulatory structure, such that there is no
16 irreconcilable conflict or a frustration of federal policy.

17 35. *Dietary Supplement Health Education Act of 1994 (“DSHEA”)*. Recognizing
18 “the importance of nutrition and the benefits of dietary supplements to health promotion and
19 disease prevention,” Congress passed the Dietary Supplement Health and Education Act of 1994
20 (“DSHEA”).¹⁹ The DSHEA recognizes that dietary supplements are foods, and regulates them as
21 such, creating a new category within the framework of food. The DSHEA includes the following
22 provisions: 1) definitions of dietary supplements and dietary ingredients; 2) safety provisions; 3)
23 statements of nutritional support; 4) dietary supplement labeling requirements; 5) new dietary
24 ingredients regulations; and 6) dietary supplement good manufacturing practices.²⁰

25 36. In adopting the DSHEA, Congress made significant findings that emphasize the
26 importance of diet and nutrition, including dietary supplement use, in promoting health and
27 reducing the risk of disease. Building on the important principal embodied in the NLEA, that
28 clear and understandable labeling is critical for consumers to make use of nutritional information,
the DSHEA provides for broad access to dietary supplements for consumers and also recognizes

¹⁹ Pub. L. No. 103-417, 108 Stat. 4325 (1994) (hereinafter “DSHEA”)(codified as amended in various sections of 21 U. S. C.) (quote at § 2.).

²⁰ *Id.* (codified at 21 U. S. C. § 342).

1 that there is a need for a rational regulatory framework that provides FDA authority to remove
2 from the market products that pose a “significant or unreasonable” risk to consumers or that are
3 otherwise adulterated, and to require that labeling for dietary supplements be accurate.

4 37. Congress defined “dietary supplement” to mean products that are intended to
5 supplement the diet that contain one or more of certain dietary ingredients, such as:

- 6 • a vitamin or a mineral,
- 7 • an herb or other botanical,
- 8 • an amino acid,
- 9 • a dietary substance for use by man to supplement the diet by increasing the total
10 dietary intake, a concentrate, metabolite, constituent, extract, or
- 11 • combination of the preceding ingredients, and, that meet other criteria specified in
12 § 201(ff)(2)-(3).²¹

13 38. Congress found dietary ingredients marketed prior to passage of the DSHEA to be
14 safe, just like regular foods (e.g., fresh fruits and vegetables). If a new supplement contains a
15 new dietary ingredient, the DSHEA requires the manufacturer to notify FDA at least 75 days
16 before it is first marketed, and to include in the notification the manufacturer’s basis for its
17 conclusion that a dietary supplement containing the ingredient will reasonably be expected to be
18 safe. This provision recognizes that, although supplements are regulated as foods, they are used
19 by consumers to address specific nutritional purposes.

20 39. Like the NLEA, the DSHEA defines any dietary supplement that creates a
21 “significant or unreasonable” risk to consumers to be “adulterated,” thereby subjecting it to FDA
22 enforcement action.²² In particularly compelling cases, the DSHEA allows the Secretary to ban a
23 dietary supplement if he finds it to be an “imminent hazard.”²³ Significantly, Congress requires
24 that the burden of proving the supplement is adulterated and an imminent hazard be borne by
25 FDA.²⁴

26 40. Congress recognized that with regard to supplements, which concentrate or
27 contain a specific nutrient, consumers may need more and different kinds of information to

28 ²¹ *Id.* (codified at 21 U.S.C. 321(ff)).

²² *Id.* § 3 (codified as 21 U.S.C. 342(f)(1)(A)).

²³ *Id.* § 4 (codified as 21 U.S.C. 342(f)(1)(C)).

²⁴ *Id.* § 4 (codified as 21 U.S.C. 342(f)).

1 educate them about the nutritional effect of the supplement, including its benefits and any risks.
2 Thus, Congress specially tailored requirements for ingredient labeling and nutrition labeling for
3 supplements, including a special provision that allows articles, abstracts or other publications
4 addressing the health effects of dietary supplements or nutrients to be provided to consumers
5 under strictly specified conditions, including that they do not promote a particular brand of
6 supplement. Above all, the information provided must be accurate and based upon sound
7 science.²⁵

8 41. Unlike conventional foods, which require all health claims to be approved by
9 FDA before being used in labeling, the DSHEA allows manufacturers to make certain claims
10 about how the supplement affects the structure or function of the body, claims of general well-
11 being from consumption of a nutrient or dietary ingredient, and claims of benefits related to
12 classical nutrient deficiency diseases. However, the manufacturer must notify FDA within 30
13 days after marketing and must substantiate the claims. In addition, a claim must be accompanied
14 by the disclaimer: "This statement has not been evaluated by the FDA. This product is not
15 intended to diagnose, treat, cure, or prevent any disease."

16 42. Congress considered the accurate labeling of dietary supplements of sufficient
17 importance to establish an independent Commission on Dietary Supplement Labels ("CDSL"),
18 with seven members appointed by the President.²⁶ The Act charged CDSL to determine how
19 best to provide *truthful, scientifically valid, and straight forward information to consumers* so
20 that they may make informed and appropriate health care choices.²⁷ CDSL issued its final report
21 in 1997.²⁸ The report emphasized the need for clarity – finding that label statements should "not
22 be false or misleading" and should provide scientifically valid information to the consumer so
23 that consumers can make informed decisions.²⁹ To ensure that regulations and labels are based

24 _____
25 ²⁵ *Id.* § 5 (codified as 21 U.S.C. 403B(a)).

26 ²⁶ *Id.* § 12.

27 ²⁷ *See*, Letter from Malden C. Nesheim, Ph.D. Chairman, CDSL, to President Clinton,
November 24, 1997, transmitting the CDSL Final Report. RJN Ex 50.

28 ²⁸ *Report from the Commission on Dietary Supplement Labels*, November 1997, available at
<http://web.health.gov/dietsupp/cover.htm>. RJN Ex 50.

²⁹ *Id.* at Chapter III.

1 on science, the DSHEA created an Office of Dietary Supplements within the National Institutes
2 of Health to direct and coordinate research on dietary supplements and serve as an advisor to
3 FDA.³⁰

4 43. It should be emphasized that, although Congress expanded supplement labeling
5 vehicles available to supplement manufacturers, *it did so within the same regulatory framework*
6 *it established in the NLEA*. It further appointed the CDSL to determine the parameters to guide
7 supplement labeling in light of the expanded labeling provisions. CDSL confirmed, reiterated
8 and applied the same fundamental principals to supplements that FDA had relied upon in
9 developing its labeling program for conventional foods. Specifically, statements about foods and
10 supplements must always be easily understood and not confusing, accurate and not misleading,
11 and above all based upon sound science and medical relevance.

12 44. Before the DSHEA, dietary supplement manufacturers could not add any
13 information to labels other than authorized for foods under the NLEA. Congress believed that
14 consumers needed additional information about the nutrients in supplements, as well as more
15 extensive directions for use. Thus, Congress added two provisions to affect this: §201(g)(1)
16 allows companies to make health claims and explanations about the risks and benefits of specific
17 dietary nutrients without FDA prior approval, and §343(s) provides that manufacturers may
18 provide “directions for use and warnings” without this misbranding the product. These changes
19 were intended to encourage the balanced presentation about the *specific nutrient content of the*
20 *supplement*. They were not intended to change FDA policy that warnings directed at *de minimis*
21 amounts of common and unavoidably present contaminants should not be given, and that false
22 and misleading statements misbrand both conventional foods and dietary supplements.

23 45. It is noteworthy that Congress did not alter FFDCA § 201(n), which explains that
24 labeling will be considered misleading if it fails to reveal a material fact.³¹ Obviously, FDA
25 retains the authority to prosecute dietary supplement manufacturers if their labeling statements
26 are misleading and inaccurate.

27 ³⁰ DSHEA § 13 (codified at 42 U.S.C. § 287c-11).

28 ³¹ 21 U.S.C. § 321(n).

1 46. Seen in light of the DSHEA as a whole, § 343(s) is not a license to add inaccurate
2 and misleading statements to supplement labels, or to misbrand products with impunity.
3 Considering the lengths to which Congress went to ensure that the labeling provisions in the
4 DSHEA would be based upon sound science and would assist, rather than confuse, consumers, it
5 is absurd to read the DSHEA, including § 343(s), as granting states, or private plaintiffs, a license
6 to impose Proposition 65 warnings on supplements themselves or in their other labeling.

7 47. Finally, Congress requires dietary supplement manufacturers to comply with
8 current good manufacturing standards, and granted FDA explicit authority to establish current
9 good manufacturing practice regulations.³² These requirements are extensive, and violations are
10 enforced by FDA administratively, by the US Attorney General's Office, and also by the states.³³

11 48. On June 22, 2007, FDA issued its Current Good Manufacturing Practice
12 requirements ("CGMPs") for dietary supplements, which among other things requires ingredient
13 testing, quality verification and manufacturing recordkeeping. In addition, the industry is
14 required to receive and maintain records of adverse reports, and must report all serious events to
15 FDA. Thus, FDA is able to inspect facilities, review manufacturing records, evaluate adverse
16 incidence reports, seize adulterated or misbranded products, and take other action as needed.

17 49. CGMP regulations establish a mechanism to help assure purity and consistency in
18 dietary supplement products. The regulations aim to ensure that dietary supplements do NOT
19 have: 1) wrong ingredients; 2) too much or too little of a dietary ingredient; 3) improper
20 packaging; 4) improper labeling; or 5) contamination due to natural toxins, bacteria, pesticides,
21 glass, lead, or other deleterious substances.³⁴

22 50. The CGMPs require process controls at each step of the manufacturing process.
23 Thus, the quality of the dietary supplement is built into the product throughout the manufacturing
24 process; it begins with the initial ingredients and continues with the product being manufactured

25 _____
³² DSHEA § 9 (codified at 42 U. S. C. § 342 (g)).

26 ³³ FFDC Chapter III, Prohibited Acts and Enforcement. 21 U.S.C. §301, *et. seq.* See also,
27 72 Fed. Reg. 34751-34958 (June 25, 2007) (Final CGMP Rule for dietary supplements, discussing
at length the Rule's requirements for testing, inspections, recordkeeping and enforcement against
products not manufactured in accordance with the CGMPs as misbranded and/or adulterated.)

28 ³⁴ The CGMPs are found at 21 C.F.R. Part 110. 72 Fed. Reg. 34751-34958 (June 25, 2007).

1 in a reproducible manner according to established specifications.

2 51. The CGMPs are carefully crafted to establish a comprehensive system of process
3 controls, including documentation of each stage of the manufacturing process, that can minimize
4 the likelihood of, or detect, problems and variances in manufacturing as they occur and before
5 the product is in its finished form. **I share FDA's view that manufacturers who comply with
6 the CGMPs will deliver safe, wholesome and effective products, and in the process will
7 have reduced contaminants to the lowest level feasible.**

8 52. One of FDA's primary concerns in adopting the CGMPs was to prevent the
9 dietary supplement from being "adulterated" due to the presence of contaminants if it contains
10 any *unintentionally* added poisonous or deleterious substance.³⁵ During FDA's 10 year
11 consultative process during which the CGMPs were developed, FDA was asked to set a zero
12 tolerance policy for "unavoidably present" chemicals, such as lead, but declined to do so –
13 reaffirming its commitment to a flexible scientifically based regime. As FDA stated in its response to
14 comments on the CGMPs:

15 We do not have a 'zero tolerance' policy for such unavoidable contaminants but
16 we have issued some regulations and guidance to address certain common
17 contaminants. We also have issued a booklet entitled "Action Levels For
18 Poisonous Or Deleterious Substances In Human Food And Animal Feed" (Ref.
19 30; available at <http://www.cfsan.fda.gov>). The booklet is a useful resource for
20 manufacturers who seek information about common contaminants that may
21 adulterate a dietary supplement product or lead to adulteration. (Another resource
22 is the Foods Chemical Codex, which includes monographs on many substances,
23 such as salts that are used as sources of minerals used in both dietary supplements
24 and conventional food. These monographs include limits on common
25 contaminants, such as lead or other heavy metals. In addition, the regulations in
26 21 C.F.R. part 109 provide information about certain contaminants.)³⁶

22 II.

23 **FDA HAS CONSIDERED, BUT SOUNDLY REJECTED, WARNINGS FOR 24 FOODS CONTAINING TRACES OF CARCINOGENIC AND OTHER 25 DELETERIOUS SUBSTANCES**

26 A. **FDA HAS A LONG-STANDING POLICY AGAINST WARNINGS ON FOODS**

27 53. As illustrated above with respect to the NLEA deliberations concerning warnings,
28 FDA consistently has taken the position that warnings should be used on FDA-regulated products

³⁵ FFCDA §402(a) (1-3).

³⁶ 72 Fed. Reg. 34751, 34840 (July 25, 2007). RJN Ex 5C.

1 very rarely, and only in cases where they represent a serious health risk to a specific segment of
2 the population. FDA's decisions concerning warnings not only reflect well-reasoned scientific
3 determinations, but balance the benefits as well. Further, decisions about whether to require a
4 particular warning are coupled with a fundamental decision about whether the product is
5 sufficiently safe to be marketed at all. Thus, FDA controls risk in food by prohibiting the
6 marketing of a food that may pose a risk to health, or by limiting the amount of a potentially
7 dangerous substance in food by setting a tolerance level.

8 **54. FDA has repeatedly expressed its strong concern about proliferation of**
9 **warnings on foods:**

10 **A requirement for warnings on all foods that may contain an inherent**
11 **carcinogenic ingredient or a carcinogenic contaminant . . . would apply to**
12 **many, perhaps most foods in a supermarket. Such warnings would be so**
numerous they would confuse the public, would not promote informed
consumer decision-making, and would not advance the public health.

13 (44 Fed. Reg. 59509, 59513 (Oct. 16, 1979).) In adopting an exception to its policy against
14 warnings, in the case of unpasteurized juice, FDA confirmed that "too many warning labels on
15 foods could result in loss of consumer credibility and effectiveness." (63 Fed. Reg. 37030,
16 37035 (July 8, 1998). RJN Ex 5E.)

17 **B. FDA HAS CONSIDERED, BUT SOUNDLY REJECTED, WARNINGS FOR FOODS**
CONTAINING CARCINOGENIC AND OTHER DELETERIOUS SUBSTANCES

18 55. First and foremost, virtually all foods contain detectable amounts of one or more
19 deleterious substances. This fact is universally recognized by the scientific and medical
20 community. Because the amount of such substances are known to vary from source to source,
21 from year to year, and even from lot to lot, FDA has evaluated these variations and studied the
22 cumulative effect of these contaminants in the American diet for over forty years.

23 56. Since 1961, FDA has conducted the so-called Total Diet Study, or Market Basket
24 Survey ("TDS"), which is an ongoing FDA program that determines levels of various
25 contaminants and nutrients in foods. From this information, FDA estimates the dietary intake of
26 the analytes over time, as well as marks current trends – whether a contaminant or nutrient is
27 increasing or decreasing. FDA makes the results of the TDS available to the public and
28 researchers. (See, www.cfsan.fda.gov/~comm/tds-toc.html. RJN Ex 5K.)

1 57. A unique aspect of the TDS is that foods are prepared as they would be consumed
2 (table-ready) prior to analysis, so the analytical results provide the basis for realistic estimates of
3 the dietary intake of the analytes.

4 58. To the extent that these contaminants have been present at low levels over time,
5 FDA monitoring has shown no adverse impact to human health. Consequently, FDA has
6 consistently considered and rejected the notion that FDA should regulate unavoidably present
7 contaminants.

8 59. In 1977, FDA responded to and rejected a suggestion that warnings should be
9 required on foods containing low levels of carcinogenic substances:

10 The Commissioner advises that tolerances and action levels will be established at
11 levels intended to ensure that food marketed is not hazardous to health. The
12 suggested *warnings would therefore be unnecessary and inappropriate. If any food is found to be hazardous to health, FDA will not permit it to be distributed in interstate commerce.*

13 (42 Fed. Reg. 52814 (Sept. 30, 1977). RJN Ex 5D.) This policy remained in force during my
14 administration, and remains in force today.

15 60. FDA has revisited this policy not to regulate at the level of detection as recently as
16 October of 2007. When it issued Good Manufacturing Practices for dietary supplements, FDA
17 considered and rejected a regulatory scheme that would establish a list of contaminants, similar
18 to Proposition 65. Specifically, FDA said: “It is impractical to provide an exhaustive list of
19 relevant types of contamination, and a list that is longer, but not exhaustive, is more likely to be
20 misunderstood as suggesting that the only types of contamination that are significant are the types
21 of contamination in the list. For that reason, we have eliminated the reference to contamination
22 to clarify that in any instance where it is appropriate quality control personnel must ensure that
23 the disposition decision is based on a scientifically valid reason and also approve the
24 reprocessing.” (72 Fed. Reg. 34751, 34860 (July 25, 2007).)

25 61. In sum, FDA has made sparing use of food product warnings, to ensure their
26 efficacy. (42 Fed. Reg. 22018 (April 29, 1977) (warning for fluorocarbons). RJN Ex 5F.) If the
27 product poses a serious risk, it simply is not allowed to be marketed at all. FDA has made clear
28 that the FFDCA “authorizes warnings and affirmative disclosures only with respect to *serious*

1 hazards.” (42 Fed. Reg. 22018 (April 29, 1977) (deciding that warnings are not appropriate for
2 fluorocarbons).)

3 C. **IN OVER 100 YEARS, FDA HAS AUTHORIZED FEW EXCEPTIONS TO ITS POLICY**
4 **AGAINST WARNINGS FOR FOOD – AND THESE ARE LIMITED AND TARGETED**

5 62. Where a warning is deemed necessary, FDA makes its decision formally, so that
6 the regulated community and consumers may be fully aware of it, and FDA carefully tailors the
7 message and the nature of delivery to the facts of each case. Because consumer education is vital
8 to ensuring that the information provided may be used effectively, FDA issues specific
9 requirements through interagency consultation and formal rule-making procedures.

10 63. In over 100 years, FDA has issued very few exceptions to its policy regarding
11 warnings for foods. Two require the use of the signal word “warning.” (21 C.F.R. § 101.17(d)
12 (certain proteins in very low calorie diets) and 21 C.F.R. § 101.17(g) (unpasteurized juice).) The
13 third does not, but advises the user about a specific risk to targeted individuals. (21 C.F.R.
14 172.804(c)(2) (phenylketonuria from aspartame).) The contours of FDA’s policy on food
15 warnings is clearly illustrated by examining these examples. In each case, the text is carefully
16 written to convey very specific and useful information. Moreover, FDA issued each label
17 warning to address very serious health risks, including death.

18 64. **Protein.** FDA determined that when individuals on a very low calorie diet
19 consume certain proteins, there is a serious health risk, including a risk of death After evaluating
20 the medical and scientific issues , FDA adopted 21 C.F.R. 101.17(d), which requires the
21 following statement:

22 WARNING: Very low calorie protein diets, below 400 calories a day, may cause
23 serious illness or death. Do not use for weight reduction in such diets without
24 medical supervision. Not for use by infants, children, or pregnant or nursing
25 women.

26 65. **Unpasteurized juices.** In 1977, FDA promulgated a regulation requiring a
27 warning on unpasteurized juices. Based upon serious adverse event reports, FDA determined the
28 warning was required to advise the public that the products had not been processed to eliminate
29 bacteria:

30 WARNING: This product has not been pasteurized and therefore may contain
31 harmful bacteria that can cause serious illness in children, the elderly, and persons

1 with weakened immune systems.³⁷

2 66. *Pherylalanine.* In 1974, FDA adopted a caution statement for the sweetener
3 aspartame, because of a known and specific risk to infants and others that cannot metabolize the
4 amino acid pheylalanine due to an enzyme deficiency³⁸ FDA's regulation requires that any food
5 containing the sweetener aspartame must bear the following statement:

6 Phenylketonurics: Phenylketonurics are those individuals affected by deficiency of
7 the enzyme phenylalanine. This contains phenylalanine.³⁹

8 67. In the case of pheylalanine, the risk information is only useful to phenylketonurics
9 - individuals with the specific enzyme deficiency – but for them, use of the product poses a
10 serious and substantial health risk. For most people, the information is simply not useful or
11 relevant. To avoid confusion and unnecessary alarm, FDA did not use the signal word
12 “warning,” but instead directed the notice to the specific category of individuals affected -
13 “phenylketonurics.” Most important, the text is crafted to be useful to those individuals.

14
15 **D. WITHOUT FDA PRIOR APPROVAL, SUPPLEMENT “DIRECTIONS FOR USE”**
16 **MAY APPROPRIATELY INCLUDE CAUTIONARY STATEMENTS, BUT, UNLIKE**
17 **PROPOSITION 65, SUCH STATEMENTS MAY NOT BE ALARMIST, OVERBROAD**
OR MISLEADING

18 68. For some active ingredients in dietary supplements, directions for use and
19 warnings may be appropriate – and even necessary. Note, these “directions for use and
20 warnings” are for the active ingredients or nutrients integral to the purpose of the product, not
21 unavoidable contamination present in all foods.

22 69. Consider the regulatory history of ephedra. Ephedra as an herbal supplement once
23 found in many over-the-counter products designed to help lose weight, enhance sports
24 performance, and increase energy. Although FDA banned ephedra entirely in 2004, prior to
25 taking this action, the substance went through several levels of regulation – both on a federal
26

27 ³⁷ 21 C.F.R. 101.17(g).

³⁸ See, 46 Fed. Reg. 38285 (1974).

³⁹ 21 C.F.R. 172.804(c)(2).

1 level and on a state level.

2 70. Under the DSHEA, FDA does not review dietary supplements for safety and
3 efficacy before they go on the market.⁴⁰ FDA does have authority, however, to regulate the
4 manufacturer's health claims and directions for use, and to require corrections if the statements
5 are inaccurate. FDA also has the power to require specific warnings, and to take the drug off the
6 market if it presents a significant risk. In the case of ephedra, FDA did all of these things.

7 71. Initially, these products were labeled in accordance with the manufacturer's
8 interpretation of the DSHEA's "health claims and "directions for use and warnings"
9 requirements. After receiving reports of injury and even deaths, in June 1997, FDA proposed
10 limits on use, including a required on-label statement warning that ephedra is hazardous and
11 should not be used for more than seven days. In 2002, FDA required a stronger, black box
12 warning on ephedra-containing products. In February 2003, the Agency announced a series of
13 measures that included strong enforcement actions against firms making unsubstantiated claims
14 about their ephedra products. On February 6, 2004, FDA banned the substance entirely.⁴¹

15 72. Like FDA, California also took action against ephedra under the State's Sherman
16 Act. Prior to the 2004 ban, California issued regulations mandating warnings. In addition, the
17 State modified the Sherman Act in late 2003 to prohibit sale of ephedra to individuals under
18 eighteen.⁴²

19 73. The case of ephedra illustrates the circumstances under which warnings may be
20 deemed necessary, and how the regulation of food safety under both the state and federal
21 schemes can be affected through the joint prohibitions of "misbranding" and "adulteration."

22 74. There is one other example of the DSHEA "directions for use and warnings" that
23 also illustrates how states, in this case California's Department of Health Services, may craft
24 meaningful and targeted consumer guidance for supplements and properly impose them under
25

26 ⁴⁰ The regulatory history of the Act makes it clear that Congress did not wish to frustrate the
27 consumer's ability to obtain supplements by subjecting these products to premarket review.
DSHEA Legislative History, S.Rep. 103-410 p. 37-38. RJN Ex 5A.

28 ⁴¹ See, http://www.fda.gov/oc/initiatives/ephedra/february2004/qa_020604.html.

⁴² HSC §110423.100.

1 FFDCA 343(s) without running afoul of federal misbranding prohibition.⁴³ In 1995, the FDA
2 Food Advisory Committee's 1995 special task group on stimulant laxative substances in food
3 agreed that dietary supplement teas containing stimulant laxatives can have adverse effects and
4 that a label statement would be helpful in warning consumers about the risks. The task force
5 proposed this label warning:

6 "NOTICE (or WARNING): Contains herbs (insert name of herbs) that can act as
7 stimulant laxatives. Prolonged steeping time can increase the risk of adverse
8 laxative effects, including: nausea, vomiting, abdominal cramps, and diarrhea.
9 Chronic use of laxatives can impair colon function. Use of laxatives may be
10 hazardous in the presence of abdominal pain, nausea, vomiting, or rectal bleeding.
11 Laxative-induced diarrhea does not significantly reduce absorption of food
12 calories. Acute or chronic diarrhea may result in serious injury or death."

13 75. Shortly thereafter, California adopted a regulation to require a similar warning on
14 all affected products.⁴⁴ FDA has issued guidance to industry supporting the use of the California
15 requirement, which it finds appropriate and narrowly tailored to assist consumers in using the
16 affected products safely.⁴⁵

17 76. As with ephedra, the "dieter's tea" example illustrates the appropriate scope of a
18 "directions for use and warnings." I believe these examples also illustrate how state and federal
19 partnerships under the FFDCA and the State's Sherman Act can work together to achieve
20 common health goals.

21 **III.**
22 **WHEN CREATING FFDCA ENFORCEMENT MECHANISMS, CONGRESS**
23 **ENVISIONED A STATE-FEDERAL PARTNERSHIP**

24 77. Congress intended the FFDCA to be administered and enforced in cooperation
25 with the states. In addition to various provisions that allow states to consult with FDA during the
26 development of policy and regulations on both state and federal levels, FFDCA provides express
27 authority for states to enforce federal laws under their own names.⁴⁶ Moreover, where the United
28 States is prosecuting a violation of federal law within a state, that state may intervene in the
action as of right. The practical effect of this provision is to allow California the right to

⁴³ For background *see*, http://www.fda.gov/FDAC/features/1997/597_tea.html.

⁴⁴ 17 C.C.R. §10750.

⁴⁵ *See*, http://www.fda.gov/FDAC/features/1997/597_tea.html.

⁴⁶ FFDCA § 310. (codified as 21 USC 337).

1 prosecute violations of any federal food regulation or policy in the state.

2 78. In at least one high-profile instance, California chose to prosecute what was a
3 clear cut example of food adulteration and misbranding under Proposition 65 as a “failure to
4 warn” action, rather than to proceed under either California’s Sherman Act or the FFDCa. In
5 *People v. Alpro Alimento Proteinicos, S.A. de C.V., et al.*, for example, the Office of the Attorney
6 General prosecuted certain manufacturers and distributors of Mexican-style candies under
7 Proposition 65 for allegedly failing to provide warnings under that statute.⁴⁷ This case could, and
8 should, have been prosecuted by the State as both a violation of the FFDCa and Sherman Act
9 adulteration provisions – not as a failure to warn case. It is notable that the evidence on which
10 the Office of the Attorney General proceeded stemmed from FDA’s 1995 notices to Mexican
11 candy makers concerning its findings that lead in packing as well as excessive lead in various
12 ingredients rendered these products adulterated and subjected them to seizure.⁴⁸

13 79. It is particularly troubling that standards for allowable lead in these products was
14 established through settlement agreements, negotiated in private by lawyers – not scientists,
15 qualified policy makers, or health professionals. *Establishing allowable tolerances for*
16 *contaminants by this method is not defensible from a public policy perspective*, even if it may
17 be warranted under California law. The fact that the standard negotiated may have been based
18 upon federal guidelines, and that the California legislature required the Department of Health
19 Services to formally adopt a regulation to set a tolerance (after the fact) is not exculpating.
20 Rather, the State’s after-the-fact adoption of standards illustrates that California had the legal
21 authority to do so *before* using Proposition 65 to prosecute. There is no reason, except perhaps
22 ease, expediency and the elimination of the need to bear the burden of proof, that California
23

24 ⁴⁷ *People v. Alpro Alimento Proteinicos, S.A. de C.V., et al.*, Los Angeles County Superior
Court, No. BC318207 (2004). RJN Ex 5T.

25 ⁴⁸ *Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy*
26 *Wrappers*, Fred R. Shank, Ph.D., Director, Center for Food Safety and Applied Nutrition, FDA
(June 13, 1995); *Letter to Manufacturers, Importers, and Distributors of Imported Candy*, Janice
27 F. Oliver, Deputy Director, Center for Food Safety and Applied Nutrition, FDA (March 25,
2004); *Supporting Document for Recommended Maximum Level for Lead in Candy Likely to be*
28 *Consumed Frequently by Small Children [Docket No. 2005D-0481]*, Center for Food Safety and
Applied Nutrition, FDA (November 2006).

1 could not have prosecuted under the Sherman Act and/or the FFDCFA.

2 **IV.**
3 **HHS, FDA AND OTHER FEDERAL AGENCIES HAVE A COMPREHENSIVE**
4 **PROGRAM FOR REDUCING LEAD AND OTHER TOXINS IN FOODS**

5 80. Lead is a toxic substance that has been recognized as a health hazard for centuries.
6 Lead is so pervasive -- in air, water and soil -- that some can be found in the bodies of most
7 people today, generally bound with calcium in the bones. There is no known nutritional benefit
8 from lead, and no established acceptable or "normal" body burden level.

9 81. For nearly a century, HHS, FDA, the Centers for Disease Control, the
10 Environmental Protection Agency, and other federal agencies, have identified significant sources
11 of lead contamination to the food supply and have taken action to eliminate them. In 1970, EPA
12 initiated a 25-year phase-out of lead in gasoline, which reached its goal in 1995. Lead was
13 banned from house paint in 1978. U.S. food canners stopped using lead solder in 1991.

14 82. In addition to banning lead solder in cans, preventing lead foil use, and removing
15 lead-based inks from packaging materials, FDA has taken proactive steps to limit lead in food
16 products, especially those intended for infants and young children. Beginning in 1972, FDA
17 gave first priority to infant food products – evaporated milk, infant formula, juices and other
18 foods. Working cooperatively with industry, manufacturers of condensed milk and ready to use
19 infant formula converted to lead free steel containers, and baby food manufacturers switched to
20 glass jars. FDA has also established standards for leachable lead from ceramic and other
21 containers. All manufacturers are required to use current good manufacturing practices to assure
22 that lead is reduced to the maximum extent practicable in raw products as well as processed
23 foods.⁴⁹ Between 1972 and the 1980's, lead levels in infant food products were reduced 80–90
24 percent.⁵⁰

25 83. Various standards for tolerable lead exposures have been issued by the
26 Environmental Protection Agency, the Centers for Disease Control and two components of the

27 ⁴⁹ See, 21 CFR 110-169 for Current Good Manufacturing Practices for Foods. As the name
28 implies, as technology progresses, FDA may revise these practices.

⁵⁰ See, <http://www.hhs.gov/news/press/2002pres/lead.html>.

1 World Health Organization. Each organization's standard varies, but generally seeks to limit
2 lead in foods to 10 to 18 micrograms a day for a child.⁵¹ FDA's TDS shows significant
3 continuous declines, proving that FDA's efforts to reduce lead levels are effective. Between
4 1976 and 1999, the National Center for Environmental Health determined that lead blood levels
5 in children fell from 16 ug/dl to 2.0 ug/dl.⁵²

6 84. Federal efforts are continuing to reduce these levels further. At present, HHS,
7 other agencies and consumer groups agree that exposures from residual lead paint and lead
8 soldered plumbing in older building remains the most intractable and significant source of lead
9 exposure today. Such exposure is not limited to infants ingesting lead paint chips, but also from
10 dust created when lead paint disintegrates over time in older homes. This very fine dust
11 circulates in homes and may cause exposure from a number of routes. HHS and many states,
12 including California, have programs in place to educate consumers about this source of lead
13 exposure, and to provide guidance to affected individuals concerning the steps they may take to
14 avoid, or at least reduce, this exposure.⁵³

15 85. It is well established that consumers are more likely to ignore important
16 advisories, such as the advice provided by EPA and California concerning actions they *can* take
17 to eliminate exposure to lead in their environment⁵⁴, if the needed advice is diluted by ubiquitous
18 warnings about exposures they can do little or nothing to avoid. From my extensive experience
19 as a policy maker and as Secretary of HHS, it is my view that Proposition 65 warnings for foods
20 hamper both federal and state efforts to educate consumers on the steps they can actually take to
21 protect their families and reduce lead exposure.

24 ⁵¹ *Id.*

25 ⁵² See, <http://www.cfsan.fda.gov/~dms/acrysink/sld003.html>.

26 ⁵³ EPA is the federal lead agency for this program, but works in cooperation with HHS and
other federal and state agencies. EPA's programs are available at: <http://www.epa.gov/lead>.

27 ⁵⁴ *Is Lead Toxicity Still a Risk to U.S. Children?*, Karrie Heneman and Sheri Zidenberg-Cherr,
CALIFORNIA AGRICULTURE, Vol. 60, No. 4, October-December 2006; also see, *HHS Helps in
Efforts to Eliminate Childhood Lead Poisoning*, United States Dept. of Health & Human
28 Services, March 4, 2002 (online at <http://www.hhs.gov/news/press/2002pres/lead.html>).

V.
**CALIFORNIA'S SHERMAN ACT GIVES THE STATE AUTHORITY TO
REGULATE FOOD, AND IS CONSISTENT WITH THE FFDCA**

86. California's Sherman Food and Drug Act ("Sherman Act") is one of several state statutes that established state authority over food safety.⁵⁵ The Sherman Act is also structured so that regulations promulgated by the State under its authority are not likely to conflict with federal law and policy. Specifically, the Sherman Act is focused on preventing contamination of foods by prohibiting "adulteration"⁵⁶ and "misbranding."⁵⁷ Although California has not established its own good manufacturing practices for foods or supplements, it has adopted a registration requirement for food handling, processing or storage facilities, and mandates that they follow rigorous guidelines.⁵⁸

87. The adulterated food provision of the Sherman Act closely tracks the analogous provision in the FFDCA. In addition, the Sherman Act expressly provides that "the food is not considered adulterated, if the substance is a naturally occurring substance, and if the quantity of the substance in the food does not render it injurious to health."⁵⁹ Significantly, the California Legislature has required the Department of Health Services ("DHS"), which administers the Sherman Act, to set a level for lead in candy above which the candy would be deemed adulterated.⁶⁰ Thus, California has exercised its independent state authority, consistent with federal law and constitutional assurances, to establish tolerances or standards for lead in certain foods. This shows conclusively that if California wishes to set standards for lead in foods, it can and should do so by adopting regulations or tolerances under authority of the Sherman Act.

88. The Sherman Act's misbranding provision *expressly* tracks federal law, and provides: "Any food is misbranded if its labeling is false or misleading in any particular."⁶¹ California goes further, however, and expressly makes it unlawful not only to misbrand food, but

⁵⁵ Sherman Food, Drug and Cosmetic Act, Health and Safety Code §109875, *et. seq.*

⁵⁶ HSC §110545-110655.

⁵⁷ HSC §110660-110805.

⁵⁸ HSC §110460-110495.

⁵⁹ HSC §110545.

⁶⁰ HSC §110552.

⁶¹ HSC §110660.

1 to receive and/or transfer misbranded food in commerce.⁶²

2 89. The Sherman Act also contains clarifications concerning the application of
3 warning statements on supplement labels.⁶³ It is notable that the misbranding provision expressly
4 states: "This section shall be implemented to the extent permitted by federal law." Thus, any
5 "warnings" permitted for dietary supplements under the Sherman Act are only permitted to the
6 extent they also comply with federal "directions for use and warning" requirements, *and* FDA
7 misbranding policy.

8 90. It is my opinion that Proposition 65 warnings applied to foods not only violates
9 the FFDCa proscription against misbranding, but also violates California's Sherman Act as well.

10 **VI.**
11 **FDA'S HAS DETERMINED THAT PROPOSITION 65 WARNINGS ON FOODS**
12 **ARE INAPPROPRIATE AND INTERFERE WITH AND FRUSTRATE FEDERAL**
13 **GOALS**

14 91. Since its inception, FDA has had grave concerns about the application of
15 Proposition 65 to foods, and has repeatedly voiced these objections to California through various
16 means. As early as 1987, then FDA Commissioner Frank Young submitted the following
17 statement to the California Scientific Advisory Panel:

18 It is my strong belief that FDA regulated products that are lawfully sold in
19 accordance with federal law do not pose a significant risk to human health. It is
20 my further view that warnings on products that do not pose such a risk are
21 unnecessary, are likely to be confusing and may be very costly to industry and
22 consumers.⁶⁴

23 As a result of his testimony and FDA's discussions, Commissioner Young received assurances
24 that California would accept compliance with FDA's requirements as proof that Proposition 65
25 exposures were below the levels requiring warnings.⁶⁵ In June 1988, he noted that the initial

26 ⁶² HSC §110760-110775.

27 ⁶³ HSC §110422.

28 ⁶⁴ Statement of FDA Commissioner Frank E. Young to the California Scientific Advisory
Panel (Dec. 11, 1987).

⁶⁵ Remarks by Frank E. Young, M.D., Ph.D., Commissioner of Food and Drugs, before the
Association of Food and Drug Officials, 92nd Annual Conference, Hartford, Connecticut, June
14, 1988 (online at <http://www.fda.gov/bbs/topics/SPEECH/SPE00008.htm>). RJN Ex 5L.

1 Proposition 65 regulations *appeared* to be consistent with the assurances he had received.

2 92. Initially, the Proposition 65 regulations included two provisions that FDA hoped
3 would prevent conflict with federal law and policy: Cal. Code Regs., tit. 27, §25501 (naturally
4 occurring exclusion from exposure), and 27 C.C.R. §25713(c)(d) (exposures from foods, drugs,
5 and medical devices).⁶⁶ As issued in 1988, §12713⁶⁷ *appeared* to provide that, until California
6 adopted specific standards for listed chemicals in FDA-regulated products, federal and state
7 standards imposed under other appropriate laws would apply, and proof of compliance with
8 qualitative regulations, such as FDA's current good manufacturing practices for foods, would
9 suffice to show that no Proposition 65 violation occurred⁶⁸. Section 12713 was revised in 1990,
10 and repealed altogether in 1993. Thus, during my administration, FDA was concerned about
11 Proposition 65, but other than these early assurances, had little evidence that the Act would grow
12 to present the impediment to federal policy that it does today.

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

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

24 ⁶⁶ Effective June 18, 2008, the Proposition 65 regulations were moved from Title 22 (Health
25 Services) to Title 27 (Cal/EPA) of the Code of Regulations. References herein to the Proposition
26 65 regulations are based on the existing Title 27 numbering. However, historical documents may
be listed under the old Title 22 numbering.

27 ⁶⁷ This regulation is referred to based on the old numbering system because it was repealed
before the new numbering system went into effect.

28 ⁶⁸ Final Statement of Reasons, 22 C.C.R. §12713. For the initial regulation, *see*,
http://www.oehha.ca.gov/prop65/law/pdf_zip/RegsArt7.pdf.

1 (Letter from FDA Commissioner Lester Crawford to California Attorney General Bill Lockyer,
2 dated August 12, 2005.)

3 94. In March 2006, FDA wrote a further letter opposing Proposition 65 warnings
4 concerning acrylimide, restating its concern that:

5 [T]he warnings may have the following adverse effects, among others:

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

10 (Letter from Terry C. Troxell, PhD., Director, Office of Plant and Dairy Foods, Center for Food
11 Safety and Applied Nutrition, to Joan Denton, Director, OEHHA, and Deputy Attorney General
12 Ed Weil, dated March 21, 2006. RJN Ex. 5N.)

13 95. FDA's statement of policy articulated in these letters – from Commissioner
14 Young's to Director Troxell's – applies equally Proposition 65's application to all foods, and
15 should not be construed as limited to tuna or fried foods.

16 **VII.**
17 **PROPOSITION 65 AND ITS IMPLEMENTING REGULATIONS CONFLICT**
18 **IRRECONCILABLY WITH THE FFDCA AND FDA'S LONG TIME AND WELL-**
19 **CONSIDERED POLICY FOR REGULATING FOODS**

20 96. For the same reasons articulated in the FDA letters, as well as my first hand
21 knowledge of the FFDCA and FDA's policies, goals and objectives, it is my opinion that
22 Proposition 65 and its implementing regulations irreconcilably conflict with federal law and
23 policy.

24 97. To supplement the many letters FDA written to California regulators and the
25 Office of the Attorney General discussed above, I also address the conflicts in four categories.

26 98. *First, Proposition 65 applies too broadly, and mandates warnings even where*
27 *there is no conceivable risk.* The overboard application begins with the list of chemicals

1 “known to the State of California to cause cancer and/or reproductive toxicity.”⁶⁹ The list
2 appears to have been created by a hodge-podge of sources: court decisions,⁷⁰ disparate
3 authoritative bodies, and a California Science Advisory Board.⁷¹

4 99. As a tool for regulating food, the listings are grossly overbroad. The Proposition
5 65 list contains approximately 800 chemicals, many of them “families of chemicals” (e.g. lead
6 and lead compounds, soots, tars, and mineral oils), hormones (e.g. estrogen and testosterone),
7 and even substances needed to preserve health (e.g., vitamin A,). Where chemical elements are
8 listed along with their compounds, the listing does not speciate or differentiate between
9 substances that are beneficial to life, chemically inert in the body, or hazardous. In the case of
10 food, such speciation is critical, as the form of the listed chemical may determine whether it is
11 biologically available, and to what degree. Moreover, chemicals are placed on the list based
12 upon data from high-dose animal tests, which may or may not be relevant to humans.

13 100. The Proposition 65 list is therefore overinclusive, and because it does not focus on
14 relevant harm to humans, it is deceptively inaccurate.

15 101. Even assuming a specific chemical is clearly and appropriately listed, Proposition
16 65 is overbroad because it triggers warnings at the level of detection – but only provides an
17 opportunity for the defendant to prove at trial an alternative higher warning threshold. This
18 provision virtually ensures that overwarning will occur, and that many, if not most, warnings will
19 be provided at levels where there is no reasonable expectation of harm.

20 102. Because Proposition 65 triggers a “warning” for every listed chemical at the level
21 of detection – and allows public and private enforcers to file an action for an injunction and
22 penalties at this low level - the statute establishes a zero tolerance for every listed chemicals,
23 which is simply not supported by sound science. On this basis alone, Proposition 65 is contrary
24 to federal law and policy that warnings shall not be provided except in cases of very serious risks,
25 and then, only to the extent that they are *very narrowly drafted* to inform the consumer of both

26 ⁶⁹ <http://www.fda.gov/bbs/topics/SPEECH/SPE00008.htm>.

27 ⁷⁰ See, *ALF-CIO v Deukmejian*, (1989) 212 Cal. App. 3d 425, which ordered that all
chemicals identified by OSHA be listed automatically.

28 ⁷¹ HSC §25249.8(b).

1 the benefits and risks.

2 103. ***Second, Proposition 65 “warnings” when applied to products lawfully marketed***
3 ***under federal law, misbrands them.*** It is impossible to provide a Proposition 65 warning, and
4 also comply with the FFDCA prosecution against misbranding. As noted above, the warnings
5 are alarmist, misleading, and undermine confidence in the nation’s food supply. Simply, the
6 provision of a Proposition 65 “warning” misbrands foods that are in compliance with federal law;
7 if the foods are not in compliance, they are “adulterated” and may not be sold at all, regardless of
8 whether a warning is given.

9 104. ***Third, Proposition 65 allows, even encourages, inconsistent standards to be***
10 ***applied to the same foods – and none of these levels are based upon science or medicine.***
11 Proposition 65 does not provide clear and understandable standards for listed chemicals in foods.
12 Virtually all foods have some detectable amount of Proposition 65 listed chemicals, including
13 lead. Although Proposition 65 provides a “naturally-occurring” exemption, it places the burden
14 of proof on the defendant to quantify the amount in an adversarial proceeding. Because lead is so
15 pervasive in the environment, both from natural and manmade sources over the centuries, and
16 because the source of food ingredients is no longer local, it is not reasonable to expect a food
17 manufacturer to be able to obtain data concerning the levels of lead in the environment where
18 ingredients are grown or raised. Consequently, the enforcement scheme “railroads”
19 manufacturers of wholesome foods, who are unable to effectively defend themselves.

20 105. The Proposition 65 enforcement scheme allows *anyone* to file suit against a food
21 manufacturer or retailer, and to set standards through settlement agreements brokered by the
22 Office of the Attorney General, without any oversight or input from California’s Department of
23 Health Services – California’s designated agency for regulating food. In this way, Proposition 65
24 allows lawyers and private individuals – without expertise or training in food safety, medicine, or
25 science – to set standards for foods.

26 106. Not only is this poor public policy, but it fosters inconsistent and arbitrary
27 standards. As a physician, and an individual who has spent most of my life in public service as
28 an advocate for improving human health, I am appalled by the reality that Proposition 65 permits

1 warnings about food to be crafted and tolerance levels to be set by private plaintiffs and lawyers,
2 rather than by California's public health agencies.

3 107. **Fourth, Proposition 65 interferes with and frustrates the goals and policies of**
4 **the FFDCA.** Above all, FDA has continuously striven make food labels clear, unambiguous and
5 useful. FDA's regulatory scheme is thoughtfully developed by the largest and most prestigious
6 public health agency in the world. Its requirements are grounded in well thought out public
7 policy and sound science. Its rules and standards are issued in advance so that the public may
8 know how to comply with them, and its enforcement practices are focused on compliance and
9 early correction of manufacturing difficulties, rather than burdensome litigation.

10 108. Proposition 65 is contrary to FDA's purpose and regulatory policy – not only
11 because the "warnings" are false and misleading, but because the inconsistent standards it fosters
12 are arbitrary and coerced by litigation necessity.

13 * * *

14 I declare under penalty of perjury, under the laws of the State of California, that
15 the foregoing is true and correct.

16 Executed this 29th day of July, 2008 at Atlanta, Georgia

17
18 
19 Louis W. Sullivan, M.D.

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7
8 SUPERIOR COURT OF THE STATE OF CALIFORNIA
9 CITY AND COUNTY OF SAN FRANCISCO

10
11 AS YOU SOW,

12 Plaintiff,

13 v.

14 SWANSON HEALTH PRODUCTS, INC.,

15 Defendant.

CASE NO. CGC-07-466-169

**DECLARATION OF DR. JAMES EMBREE
IN SUPPORT OF DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT**

Hearing : October 8, 2008
Time : 9:30 a.m.
Dept. : 301
Judge : Hon. Peter Busch
Action Filed : August 14, 2007
TRIAL DATE: August 3, 2009

16
17
18
19 I, Dr. James Embree, declare as follows:

20 1. I am giving this declaration as an expert in the fields of toxicology, human health
21 risk and exposure assessment, as well as the application of these disciplines to California's Safe
22 Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") and its implementing
23 regulations. The basis for my expertise is as follows:

24 **I. PROFESSIONAL BACKGROUND AND EXPERIENCE**

25 2. I am a Principal Toxicologist at AMEC Geomatrix ("AMEC"), an environmental
26 sciences and engineering consulting firm. I have held that position since 1992. I am also the
27 technical leader for AMEC's Health Risk Assessment Group. I received a Ph.D. in Comparative
28 Pharmacology and Toxicology from the University of California, San Francisco, School of

1 Medicine in 1976. I have been a Diplomat of the American Board of Toxicology since 1980. My
2 most recent recertification was completed in 2005 and is valid until 2010. A copy of my most
3 recent *curriculum vitae* is attached as Exhibit 4A.

4 3. I have over 30 years' experience evaluating the potential health impacts of chemical
5 substances released into the environment and communicating the significance of those impacts to
6 the general public. I have taught university courses in health risk assessment and toxicology and
7 have been invited to speak on health risk assessments at a number of environmental conferences.

8 4. I have conducted many assessments to determine the risk of exposure to chemicals
9 released into the environment and to assess whether various consumer products pose adverse
10 health risks. The Department of Health Services, Toxic Substances Control, the South Coast Air
11 Quality Management District, the California Air Resources Board, and other regulatory agencies
12 have relied on health risk assessments that I have conducted.

13 5. I am familiar with California's Safe Drinking Water and Toxic Enforcement Act of
14 1986 ("Proposition 65"), particularly with Health & Safety Code §§ 25249.6, 25249.8, 25249.10,
15 and 25249.12. I have detailed knowledge of Proposition 65's regulations (27 C.C.R. §§ 25001, *et*
16 *seq.*) and of the implementing agency's Statement of Reasons. I have an extensive working
17 knowledge of Proposition 65-required methods for determining exposures to listed chemicals.

18 6. I have conducted hundreds of health risk assessments to support Proposition 65
19 compliance efforts, including those in response to lawsuits alleging violations of the requirement
20 to warn of an exposure to listed chemicals in consumer products. I have assessed Proposition 65
21 warning obligations from exposure to numerous consumer products, including ingestion of
22 products containing trace levels of lead.

23 7. I have conducted exposure assessments that have been accepted, incorporated and
24 cited in court decisions, and I have testified as an expert witness in Proposition 65 cases including
25 *Environmental Defense Fund v. Parks Corp.* (S.F. Sup. Court Case No. 941291), *Mangini v. J.G.*
26 *Durand & Cie* (S.F. Sup. Court Case No. 952402), *DiPirro v. J.C. Penney* (S.F. Sup. Court Case
27 No. 407458) and *DiPirro v. Bondo Corporation* (2007) 153 Cal. App. 4th 150.

28 ///

1 8. I have been involved with California's Proposition 65 since its inception. I
2 participated in the development of Proposition 65's implementing regulations (27 C.C.R. § 25001,
3 *et seq.*) and their revisions. Thus, I have a detailed knowledge of them and the accompanying
4 Statement of Reasons. During the past 22 years since Proposition 65 was enacted, I have
5 participated in developing Proposition 65 safe use determinations, and have completed exposure
6 and warning evaluations for various products. As part of the exposure assessment process, I have
7 identified, interpreted and used required methodologies to determine risk and exposure, and have
8 overseen and conducted testing to evaluate and quantify safe exposure levels of a variety of
9 chemicals from numerous sources and routes. I have also conducted evaluation studies to
10 characterize and quantify human behavior as it affects exposure frequency and duration of
11 exposure to chemicals. Significantly, I conducted the risk assessment to support the risk-based
12 Proposition 65 interpretive guideline issued by the Office of Environmental Health Hazard
13 Assessment ("OEHHA"), the lead agency for Proposition 65, pursuant to 27 C.C.R. §25104.
14 (Public notice regarding the Hand to Mouth Transfer Factor for Lead appears online at
15 http://www.oehha.ca.gov/prop65/CRNR_notices/safe_use/sud031408.html, 3/14/2008.)

16 9. Based on my personal and professional experience, the above stated activities, and
17 review of the pleadings and document submissions in this matter, I have acquired personal
18 knowledge of the matters discussed herein, and can and will competently testify thereto.

19 **II. SUMMARY OF OPINIONS**

- 20 10. Summary of and basis for principal opinions:
- 21 (a) The Proposition 65 regulations, supporting documentation and agency guidance do
22 not provide the necessary background or bases by which a responsible entity can determine
23 whether a warning is required for listed chemicals naturally occurring in foods.
 - 24 (b) The Proposition 65 regulations provide that a company is not responsible for
25 consumer exposure to a chemical to the extent that the chemical occurs naturally in a food.
 - 26 (c) Technical information that could be useful in quantifying the naturally occurring
27 background of a chemical in foods is limited and available for only a limited number of
28 chemicals and is a source of controversy in its application. Companies responsible for a
potential exposure to a listed chemical in a food have no way of determining the
appropriate naturally occurring levels of that listed chemical in the food in a manner that
will provide assurance that their Proposition 65 compliance evaluation and decision to
provide a warning or not is appropriate or could withstand a challenge at trial.

1 (d) A variety of listed chemicals including volatile organic chemicals (e.g., benzene,
2 formaldehyde) and metals (e.g., lead, arsenic, cobalt) are found naturally in foods. While
3 these levels are generally well below those associated with adverse health effects, they can
4 be in excess of insignificant risk levels as defined under Proposition 65, due, in part, to the
5 fact that foods are eaten in large amounts; even very low concentrations of a listed
6 chemical in food will result in an intake above Proposition 65 warning levels.

7 (e) Because the natural presence of listed chemicals in food would represent an
8 obligation to provide a consumer warning, it is important to be able to define the naturally
9 occurring exemption. Otherwise, consumers would be exposed to warnings for exposure
10 to listed chemicals that: 1) would be without concern of adverse health effects; 2) would
11 be no different than exposures to other sources of the same food; and 3) would be no
12 different than exposures historically associated with the food. Further, the public health
13 goals of Proposition 65 would be negated by the meaningless application of warning labels
14 on nutritionally important dietary components.

15 (f) In my extensive experience developing exposure assessments and participating in
16 litigation as an expert assessor, the levels established in consent judgments often do not
17 equate with an exposure assessment presented by any assessor involved in the case. It is
18 my opinion that the numbers are often negotiated by the parties' attorneys and arrived at
19 not by science, but as a litigation-driven compromise.

20 (g) The Proposition 65 settlement for Mexican Style Candies that was finalized in June
21 2006 specified a maximum level of lead in these products that would not require a package
22 warning as 100 ppb. From my review of the settlement document, this was intended to
23 account for both the Maximum Allowable Daily Limit of 0.5 micrograms per day of lead
24 plus the "naturally occurring allowance." This same criteria, but for candy in general, had
25 been under development by the U.S. FDA for some time and was finalized shortly after the
26 signing of the Mexican Candy settlement agreement.

27 **III. OVERVIEW OF PROPOSITION 65'S UNIQUE SCIENTIFIC AND TECHNICAL** 28 **PROVISIONS**

29 11. From a scientific and regulatory public health point of view, Proposition 65's
30 warning provision is based on several unusual, if not unique, regulatory schemes for at least three
31 principal reasons.

32 12. First, it does not regulate the amount of a listed chemical in a media of exposure
33 (e.g., food, water, air, consumer product), but, rather, it regulates the *exposure*. Other regulatory
34 schemes place specified limits on amounts in an exposure media or an emission from a consumer
35 product and give specific guidance as to how these will be measured. For example, the Federal
36 drinking water action level for lead is 15 ug/l – an easily measured compliance point representing

1 the concentration of lead in water, which does not need to be extrapolated to an estimate of
2 exposure.

3 13. Second, Proposition 65 does not establish *any* exposure level below which it does
4 not apply; there is no *de minimis* exposure level of concern.¹ Without a quantification of an
5 exposure to a specific media or consumer product, followed by a positive demonstration of the
6 insignificance of the risk, *all exposures* require a warning. In other words, Proposition 65 goes
7 into effect at the level of detection, but contains a provision that allows the defendant to avoid
8 liability by establishing the following at trial (as an affirmative defense). The defendant must:

- 9 • First: identify *and* quantify a higher exposure level meeting certain requirements
10 described in the statute (H.S.C. §25249.10(c).) and;
- 11 • Second: show that the exposure from the specific product (or products) at issue is
12 below the level.

13 14. Third, Proposition 65 and its implementing regulations require that the individual
14 responsible for the exposure (e.g., the manufacturer of the consumer product) is required to
15 technically support the demonstration of insignificant risk. Without adequate clarity or specific
16 guidance to allow the regulated community to do so with reasonable certainty, the ability to safely
17 conclude that no warning is required becomes infeasible; the company has no assurance that they
18 have eliminated liability due to complaints brought under Proposition 65. In response to requests
19 from industry for specific guidance concerning how exposures are to be measured, tested and
20 quantified, OEHHA has *declined* to do so, stating that it is not feasible.²

23 ¹ In risk assessment, “*de minimis*” refers to a level of risk that is too small to be concerned with.
24 The United States National Library of Medicine, National Institute of Health, defines *risk de minimis*:
25 *risk de minimis*: Risk that is negligible and too small to be of societal concern (usually
26 assumed to be a probability below 10⁻⁵ or 10⁻⁶); can also mean ‘virtually safe.’ In the USA,
this is a legal term used to mean “negligible risk to the individual.”
(Available online at: <http://sis.nlm.nih.gov/enviro/glossaryr.html> (accessed June 17, 2006).)

27 ² See, Final Statement of Reasons (“FSR”) Repeal of 22 C.C.R. § 12901 (Methods of Detection)
28 (when repealing the “Methods of Detection” regulation, OEHHA told industry to *use the rules of
evidence* to decide which tests are appropriate.)

1 15. Proposition 65's warning provision requires:

2 **25249.6. Required Warning Before Exposure to Chemicals Known to Cause**
3 **Cancer or Reproductive Toxicity.** No person in the course of doing business shall
4 knowingly and intentionally expose any individual to a chemical known to the state to
5 cause cancer or reproductive toxicity without first giving clear and reasonable warning
6 to such individual, except as provided in Section 25249.10.

6 (H.S.C. § 25249.6.)

7 16. To make clear that Proposition 65 does not recognize *de minimis* exposure levels,
8 its implementing regulations confirm that the warning provision is triggered at the level of
9 detection. Although businesses are not required to do testing, the regulations expressly provide
10 that the *only* way that a defendant can prove that an enforcement action is improper (e.g. allow a
11 plaintiff to sue to require the defendant to present a exposure assessment to the court for its
12 determination), is by conducting a test for each listed chemical at least once a year, and ***if all of the***
13 ***results are negative.***³ (27 C.C.R. § 25900(a).)

14 **IV. THE "NATURALLY OCCURRING ALLOWANCE" FOR FOODS IS UNCLEAR**
15 **AND IMPRACTICAL TO APPLY**

16 17. The "Naturally Occurring Allowance" for foods is an important concept in the
17 Proposition 65 regulations. As provided in the regulations (§ 25501. Exposure to a Naturally

18 ³ Use of Specified Methods of Detection and Analysis as a Defense to an Enforcement Action:

19 (a) . . . (F) or purposes of Section 25249.6 no knowing and intentional exposure occurs if a
20 person in the course of doing business, otherwise responsible for an alleged release, discharge
21 or exposure can show all of the following:

21 (1) That he or she has properly applied a method of detection and analysis as defined in
22 subsection . . . (g) below for the chemical in question at any time within the year prior to
23 the service or filing of a notice or complaint concerning an alleged discharge, release or
24 exposure to the chemical in question;

23 (2) That such method of detection and analysis was applied to the same matrix as defined
24 in subsection (g) below, in which the discharge, release or exposure is alleged to have
25 occurred or to be occurring;

25 (3) That the method of detection and analysis was conducted by a laboratory certified by
26 the State of California or accredited by the State of California, a federal agency, the
27 National Environmental Laboratory Accreditation Program or similar nationally
28 recognized accrediting organization to perform the particular method of detection and
analysis in question; and

(4) That all the reported results show that the chemical in question was not detected.
(27 C.C.R. § 25900(a).)

1 Occurring Chemical in a Food):

2 “(a) Human consumption of a food shall not constitute an “exposure” for purposes of
3 Section 25249.6 of the Act to a listed chemical in the food to the extent that the person
4 responsible for the exposure can show that the chemical is naturally occurring in the food.”

5 18. This provision importantly allows for the natural presence of a number of listed
6 chemicals in food with the clear intention that companies should not be held responsible for
7 providing warnings for chemicals in their products when the chemical is naturally present in food.
8 Similarly, there is also a provision in the regulations (§ 25502. Exposure to a Listed Chemical in
9 Drinking Water) that applies the same concept to products that incorporate drinking water with
10 listed chemicals present.

11 19. While the concept is clear, the implementing regulations do not supply sufficient
12 specificity required for a company to know with reasonable certainty that it complies with the
13 regulations. §25501(a)(2) provides:

14 The “naturally occurring” level of a chemical in a food may be established by determining
15 the natural background level of the chemical in the area in which the food is raised, or
16 grown, or obtained, based on reliable local or regional data.

17 20. There is no additional guidance provided by the regulations for conducting this type
18 of analysis. For many companies that provide food-based products (e.g., nutritional supplements),
19 there is no means for obtaining or generating this type of quantitative data; individual components
20 may come from numerous, unknown locales. Even if data could be developed, the definition of
21 “reliable local or regional data” is not established and the data gathered with good intentions
22 would be open to attack. As another example, some of the food-based components may be in the
23 form of a concentrate. In this situation, a large amount of fruit or vegetable material is extracted or
24 dried, such that the resulting quantity of material is greatly diminished (e.g., frozen orange juice
25 concentrate). Because the volume of material is decreased, the concentration of listed chemicals
26 would increase, even if the concentration in the original material was at the “naturally occurring”
27 level. This type of process, however, is just one of many examples that is not defined in the
28 regulations and adds great uncertainty to whether a food containing an extract product would
29 require a warning.

///

1 21. It is my experience that the Attorney General's office (Attorney General) has
2 interpreted § 25501 to require that the food in question must have the "lowest feasible level" of the
3 listed chemical in order to meet the naturally occurring exemption. The means for determining
4 whether or not the food in question has, in fact, the "lowest feasible level" has not been described
5 (beyond the very different description and more readily achievable method presented in the
6 regulations) and from the technical perspective may be impossible given the natural fluctuations in
7 raw materials from even the same source. Fluctuations over time may not be that different than
8 geographical fluctuations and adds another confounding factor.

9 22. The Attorney General's interpretation, while inconsistent with my technical
10 interpretation of the regulatory language, introduces another, much larger level of uncertainty into
11 the process of determining consumer exposure. With this interpretation, a company might be
12 required to not only determine typical background rates in the area in which the product is grown (or
13 extracted), but also to compare those levels to materials from other areas to ensure they are the
14 lowest levels possible. The logical extension of this process is that the determinations would need
15 to be made with regularity and a company's buying decisions would have to be dependent upon
16 recent analytical results of component materials, so there might never be certainty that the source
17 with the lowest level of a listed chemical was being used in every case.

18 23. There are other likely unintended consequences to interpreting the "lowest feasible
19 level" to mean the lowest possible single source of supply -- even if it were possible. For example,
20 if corn from Iowa generally had a lower concentration of lead than corn from Kansas, even if the
21 difference was of no importance for public health, it would be impossible to use the corn from
22 Kansas in preparing food products unless a Proposition 65 warning was applied. From a practical
23 perspective, compliance with this type of requirement would be impossible.

24 24. The Proposition 65 settlement for the presence of lead in calcium supplements⁴
25 (including antacids) provides a very illustrative "case history" of the difficulty, if not impossibility,
26

27 ⁴ *People v. Warner-Lambert Co., et. al.*, San Francisco Co. Super. Ct. , Case # 984503,
28 (Stipulation for Consent Judgment dated April 18, 1997). Request for Judicial Notice ("RJN")
Exhibit 5U.)

1 imposed in attempting to meet the requirements of Proposition 65 for naturally occurring materials
2 in foods. I provided technical support to one of the defendants in the action and was involved in
3 many of the technical deliberations.

4 25. In that calcium supplement case, low levels of lead were detected in calcium
5 supplement products. Because of the large amounts of the products used by consumers for
6 beneficial health effects (antacid or calcium supplementation), the levels of ingested lead were in
7 excess of the Proposition 65 Maximum Allowable Daily Limit of 0.5 microgram per day, although
8 less than the FDA criteria and substantially below levels associated with adverse health effects.
9 Sound technical arguments regarding the decreased absorption of lead with the presence of
10 calcium were ignored by the Attorney General. Further, the Attorney General mandated the level
11 of lead that was to be considered to be “naturally occurring “ (i.e., the naturally occurring
12 exemption of 1 ug of lead per milligram of calcium to a maximum of 1,500 milligrams of calcium)
13 based on a review of the available commercial sources of calcium and selecting the lowest
14 available level without consideration of the ultimate source or local conditions. The fact that a
15 large source of calcium is mined calcium carbonate and therefore all of the lead in the material is
16 naturally occurring (e.g. was deposited in the geological past) was ignored. Finally, the settlement
17 requires that six lots of a product be tested for lead and that warning requirements are based on the
18 statistical upper-bound of the mean of the results.

19 26. The complexity and lack of reasonable interpretation of Proposition 65
20 requirements within the framework of “naturally occurring” demonstrated by the above example of
21 the calcium supplement settlement set a precedent for private enforcers as well as the Attorney
22 General. For food companies, it is a virtual impossibility to comply with Proposition 65 because
23 the interpretation and process used by the Attorney General are impossible to follow for other
24 products with any assurance of compliance.

25 27. A similar process was established for the multi-vitamin settlement⁵ in that naturally
26 occurring limits were established for several mineral sources (e.g., magnesium) without

27
28 ⁵ *People v. Warner-Lambert Co., et. al.*, San Francisco Co. Super. Ct. , Case # 984503,
(Stipulation for Consent Judgment filed November 18, 1998). RJN Ex 5V.

1 consideration of the technical merits.

2 **V. IT IS WELL-DOCUMENTED THAT FOODS CONTAIN DETECTABLE - BUT**
3 **BENIGN - LEVELS OF NATURALLY OCCURRING CHEMICALS**

4 28. As a threshold matter, all foods contain detectable levels of one or more
5 Proposition 65 listed chemicals. This is widely recognized, and can be verified by using data from
6 the Total Diet Study ("TDS"), or Market Basket Survey conducted continuously by FDA since
7 1961. The TDS survey studies the cumulative effect of dozens of contaminants and nutrients in
8 the American diet. FDA makes the results of the TDS available to the public and researchers.⁶

9 29. One of the chemicals that FDA continuously monitors in food is lead. Of the foods
10 tested, the great majority have at least one sample with detectable levels of lead. The results for
11 milk are informative -- 48 samples were tested and five had detectable levels of lead with a
12 maximum level of 11 micrograms per kilogram (ppb). (See, [www.cfsan.fda.gov/~comm/tds-](http://www.cfsan.fda.gov/~comm/tds-toc.html)
13 [toc.html](http://www.cfsan.fda.gov/~comm/tds-toc.html).) One kilogram of milk is roughly equal to four cups of milk. Since the Proposition 65
14 insignificant risk level (Maximum Allowable Daily Limit) for lead is 0.5 ug/day, ingestion of less
15 than one cup (240 grams) of milk (containing 2.64 micrograms of lead) would exceed the
16 Proposition 65 level by a factor of over five. Even the mean concentration of lead reported in milk
17 (1 ppb) would result in an exposure of 0.24 ug of lead per serving. Two servings of milk would
18 exceed the Maximum Allowable Daily Limit. In fact, the detection limit for lead in foods from the
19 FDA program is approximately 10 ppb as inferred from the TDS data. (See,
20 www.cfsan.fda.gov/~comm/tds-toc.html.) This means that the milk samples without detectable lead
21 might, in fact, actually have levels of lead that would result in exposures greater than the no
22 significant risk level and day to day variability would cause detections in dairies previously
23 without detectable lead. In fact, the detection limit of 10 ppb may be inadvertently deceptive,
24 because it suggests that a number of food samples have no lead when they actually may have at
25 least some lead. It certainly biases the calculated mean levels lower.

26
27
28 ⁶ (See, www.cfsan.fda.gov/~comm/tds-toc.html.)

1 30. The FDA data demonstrates the uncertainty that would be associated with trying to
2 generate data to support the “naturally occurring level” of a listed chemical. A random inspection
3 of other data in the TDS shows the same relationship. Canned corn was seen to have a maximum
4 lead level of 16 ppb and a mean lead level of 5 ppb. With a serving size of one-half cup (82
5 grams), this equates to a possible exposure to lead of 1.31 ug/serving and a mean exposure of 0.41
6 ug/ serving. Therefore, a single serving of corn with the maximum detected level of lead would
7 exceed the Maximum Allowable Daily Limit by over a factor of two. Even corn with the mean
8 level of lead would almost reach the Maximum Allowable Daily Limit after a single serving. The
9 dried raisin data indicates a possible exposure of 0.4 ug/serving (miniature box) and a mean
10 exposure of 0.1 ug/serving. Raisins, being a dried product, also illustrate the problems related to a
11 concentration of lead levels – grapes have a lower concentration than raisins because the removal
12 of water in essence concentrates the lead. Finally, some foods appear to have a higher likelihood
13 of higher levels of lead. For example, the average concentration of lead in a sweet cucumber
14 pickle was 27 ppb with a maximum of 131 ppb. For a serving size of one spear (1.3 oz or
15 approximately 36 grams) the average exposure would be 0.97 ug of lead, almost two times the
16 maximum allowable daily limit, while a pickle with the maximum level of lead detected would
17 lead to an exposure of 4.7 ug after a single serving. In this example, lead might be contributed by
18 other food components, including spices which presumably would also need to be evaluated for
19 the naturally occurring contribution.

20 31. The FDA data, in describing naturally occurring levels of several listed chemicals
21 in food, clearly show that the presence of these chemicals in foods at the levels detected do not
22 represent a public health threat. Yet, compliance with Proposition 65 requires that warnings be
23 provided for products with these illustrated results, unless a company was willing to run the risk of
24 defending their technical position in an adversarial setting.

25 ///
26 ///
27 ///
28 ///



1 32. Another Proposition 65 case history relevant to my opinion involves the Attorney
2 General's action regarding Mexican Style Candy.⁷ As finalized in June 2006, the settlement
3 provides a warning exemption for Mexican candy containing less than 100 ppb lead. My technical
4 reading of the settlement shows that the basis for this exemption includes consideration of both the
5 Proposition 65 Maximum Allowable Daily Limit as well as an allowance for the naturally
6 occurring lead in the food components. This settlement was portrayed in a press release from the
7 Attorney General as a "tremendous advancement in protecting our children."⁸ In fact, the FDA in
8 1995 had established an allowable limit for lead in candy at 500 ppb based on the Food Chemical
9 Codex limit for the expected level of lead in sucrose, the major component of candy, of 500 ppb.
10 In March 2004, the FDA announced that they were in the process of lowering the allowable
11 amount based on newer data on lead levels and in November 2006 they recommended a new,
12 lower level of 100 ppb based on new data on lead levels in sucrose and incorporating information
13 available on the concentration of lead that might be found in other components of candy, including
14 Mexican-style ingredients.⁹ The FDA program was well underway before the Proposition 65
15 settlement was finalized and the supporting analysis and documentation was extensive, reflecting
16 the scientific analysis necessary to determine the appropriate level. Of course, the FDA effort did
17 not incorporate any consideration of the Proposition 65 Maximum Allowable Daily Limit of 0.5
18 ug/day. Of importance to my opinion is the level of effort required to demonstrate a naturally
19 occurring level.

20 **VI. CONCLUSIONS**

21 33. The ability to comply with the Proposition 65 warning obligations with respect to
22 the exemption for naturally occurring listed chemicals in food are unclear, and not capable of
23 being ascertained with reasonable certainty. As a scientist with over two decades experience in
24

25 ⁷ *People, et.al. v. Alpro Alimento Proteinicos, et.al.*, Los Angeles Co. Superior Court, Nos.
BC318207, BC 318216, & BC321570, filed July 9, 2004, Consent Judgment June 2006. RJN Ex
26 5T.

27 ⁸ <http://ag.ca.gov/newsalerts/release.php?id=1317>

28 ⁹ US Food and Drug Administration. *Supporting Document for Recommended Maximum Level
for Lead in Candy Likely To Be Consumed Frequently by Small Children.* [Docket No. 2005D-
0481] RJN Ex 5Q.

1 conducting exposure assessments, it is my opinion that it is not only beyond the capability of a
2 company to understand what the statute requires, but is also beyond the ability of such a company
3 to design and undertake the necessary studies to support their compliance effort.

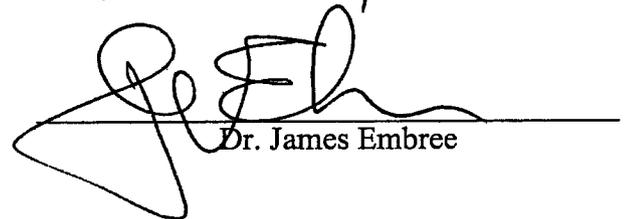
4 34. Because virtually all foods contain detectable amounts of listed chemicals, any
5 decision not to provide warnings, may be challenged by a lawsuit under Proposition 65 -- even
6 milk, as demonstrated above. Even if a business were to spend considerable money and other
7 resources to perform the most rigorous quantitative exposure assessment with the best intentions to
8 comply with the regulation, it could still be challenged and every element attacked. At the end of
9 the day, it is only after the court rules that the defendant can know whether a warning was
10 required.

11 35. As a result, it is not possible to conduct an analysis of potential exposures that
12 incorporates information on the naturally occurring levels of a listed chemical in food in a manner
13 that can be known to be valid prior to marketing the product. The lack of guidance within the
14 regulations, supporting documentation and methodology precludes effective compliance.

15 * * *

16 I declare under penalty of perjury under the laws of the State of California that the foregoing
17 is true and correct.

18 Executed this 24th day of July, 2008 at NEWPORT BEACH, CA.

19
20 
21 Dr. James Embree

**CONSENT JUDGMENTS IN DIETARY SUPPLEMENT PROPOSITION 65 CASES:
MONETARY PENALTIES, REFORMULATION REQUIREMENTS, AND OTHER TERMS¹**

CASE	COURT	CASE NUMBER	SETTLEMENT DATE	ATTORNEYS FEES PAID TO PLAINTIFF'S ATTY	CIVIL PENALTIES	OTHER	TOTAL MONETARY PAYOUT	TERMS
The Following Five of the Highest Paying Defendants get the Highest Allowance of Lead in Their Products:								
AYS v. Botanical Laboratories, Inc.	San Francisco Superior Court	429563	05/09/05	121,000	30,000	104,000	259,000	<ul style="list-style-type: none"> • 4.0 lead level allowed = 3.5 micrograms, plus 0.5 allowance; • Ban on 14 micrograms or over (after 60 days from effective date)
AYS v. Nature's Way Products, Inc.	San Francisco Superior Court	422848	05/09/05	105,000	45,000	165,000	315,000	<ul style="list-style-type: none"> • 4.0 lead level allowed = 3.5 micrograms, plus 0.5 allowance; • Ban on 14 micrograms or over (after 60 days from effective date)
AYS v. Threshold Enterprises, Ltd.	San Francisco Superior Court	422847	09/08/05	165,000	45,000	190,000	400,000	<ul style="list-style-type: none"> • 4.0 lead allowance = 3.5 micrograms, plus 0.5 allowance; • Ban on 14 micrograms or over (after 60 days from effective date)

¹ This chart covers representative enforcement actions brought by As You Sow ("AYS") against manufacturers and distributors of dietary supplements as well as several brought by Stephen D. Gillett. AYS and Gillett are represented by Andrew Packard. A complete list of 60-day notices of intent to sue issued by these and other private enforcers, is available on-line at <http://proposition65.doj.ca.gov/default.asp>

CASE	COURT	CASE NUMBER	SETTLEMENT DATE	ATTORNEYS FEES PAID TO PLAINTIFF'S ATTY	CIVIL PENALTIES	OTHER	TOTAL MONETARY PAYOUT	TERMS
AYS v. Irwin Naturals	San Francisco Superior Court	429279	06/15/05	120,000	5,000	55,300	180,300	<ul style="list-style-type: none"> • 4.0 lead level allowed = 3.5 micrograms, plus 0.5 allowance; • Ban on 14 micrograms or over (after 60 days from effective date)
AYS v. Nature's Sunshine Products, Inc.	San Francisco Superior Court	437196	05/17/05	140,000	5,000	95,000	240,000	<ul style="list-style-type: none"> • 4.0 lead level allowed = 3.5 micrograms, plus 0.5 allowance; • Ban on 14 micrograms or over (after 60 days from effective date)
AYS v. Mayway Corp.	N/A	N/A	2001	80,000	10,000	120,000	210,000	<ul style="list-style-type: none"> • warnings at level of detection; • warnings in Chinese language required
AYS v. 99 Ranch Markets et al.	N/A	c. 1999	N/A					<ul style="list-style-type: none"> • CJ not obtained; no details of settlement reported on AG's public information database
AYS v. Tawa & Welcome Supermarkets	San Francisco Superior Court	317970	03/28/01	19,500	0	36,250	55,750	<ul style="list-style-type: none"> • action against retailers; retailers agreed to discontinue sale of identified products
AYS v. Herba Enterprise, Inc. & Kwok Shing Import-Export, Inc.	San Francisco Superior Court	313637	05/25/01	65,000	5,000	60,000	130,000	<ul style="list-style-type: none"> • warnings at level of detection; • warnings in Chinese language required
AYS v. ADG Concerns, Inc. (Defendant Bio Essence)	San Francisco Superior Court	323070	05/01/02	19,000	3,500	17,500	40,000	<ul style="list-style-type: none"> • warnings at level of detection; • warnings in Chinese language required

CASE	COURT	CASE NUMBER	SETTLEMENT DATE	ATTORNEYS FEES PAID TO PLAINTIFF'S ATTY	CIVIL PENALTIES	OTHER	TOTAL MONETARY PAYOUT	TERMS
AYS v. ADG Concerns, Inc. (Defendant Lotus Herbs)	San Francisco Superior Court	323070	05/01/02	45,000	15,000	90,000	150,000	<ul style="list-style-type: none"> warnings required on all products warnings in Chinese language required
AYS v. ADG Concerns, Inc. (Defendant K'AN Herbs)	San Francisco Superior Court	323070	05/01/02	25,000	7,500	32,500	65,000	<ul style="list-style-type: none"> CJ not obtained; only information reported on AG's public information database
AYS v. ADG Concerns, Inc. (Defendant Tai Sang Trading)	San Francisco Superior Court	323070	05/01/02	17,500	5,000	50,000	72,500	<ul style="list-style-type: none"> warnings required on all products warnings in Chinese language required
AYS v. Pharmabotanixx								<ul style="list-style-type: none"> dismissed w/o prejudice on 8-16-02
AYS v. Nuherbs, Inc.	San Francisco Superior Court	403172	01/29/03	19,500	5,000	25,000	49,500	<ul style="list-style-type: none"> warnings at level of detection; warnings in Chinese language required
AYS v. Brion Herbs Corp; Sun Ten Laboratories	San Francisco Superior Court	409222	06/02/03	140,000	5,000	200,000	345,000	<ul style="list-style-type: none"> Defendants may submit to binding arbitration to determine whether "naturally occurring" exemption from the warning requirement is applicable to products

CASE	COURT	CASE NUMBER	SETTLEMENT DATE	ATTORNEYS FEES PAID TO PLAINTIFF'S ATTY.	CIVIL PENALTIES	OTHER	TOTAL MONETARY PAYOUT	TERMS
								<ul style="list-style-type: none"> warnings required on 2 products sale of 1 product prohibited unless relabeled with lower recommended daily dose of one tablet
AYS v. General Nutrition Corp.	San Francisco Superior Court	415739	08/20/03	35,000	5,000	45,000	85,000	<ul style="list-style-type: none"> sale of 3 products prohibited
AYS v. Rainbow Grocery Cooperative, Inc.	San Francisco Superior Court	417175	09/16/03	25,000	5,000	25,000	55,000	<ul style="list-style-type: none"> warnings at level of detection; action against retailer
AYS v. Lotus Brands, Inc.	San Francisco Superior Court	429591	08/12/04	34,875	5,000	11,125	46,500	<ul style="list-style-type: none"> warnings at level of detection;
AYS v. Twinlab	San Francisco Superior Court	422845	08/24/05			8,326	8,326	<ul style="list-style-type: none"> Defendant filed for bankruptcy; paid 18% of reduced \$46,000 claim
Gillett v. Institute for Traditional Medicine & Preventative Health Care, Inc.	San Francisco Superior Court	460692	03/28/07	15,000	8,000	12,000	35,000	<ul style="list-style-type: none"> warnings at level of detection; action v. distributor
Gillett v. Shen Herb, Inc.	San Francisco Superior Court	461057	07/02/07	40,000	30,000		70,000	<ul style="list-style-type: none"> warnings at level of detection; action v. distributor
Gillett v. Nexgen Pharma, Inc.	San Francisco Superior Court	465289	09/19/07	14,750	25,000	60,000	99,750	<ul style="list-style-type: none"> Warnings required; no "naturally occurring" level set

CASE	COURT	CASE NUMBER	SETTLEMENT DATE	ATTORNEYS FEES PAID TO PLAINTIFF'S ATTY.	CIVIL PENALTIES	OTHER	TOTAL MONETARY PAYOUT	TERMS
AYS v. Idea Sphere, Inc.	San Francisco Superior Court	468381	03/28/08	47,000	35,000	215,000	297,000	<ul style="list-style-type: none"> • 2.25 micrograms plus 0.5 allowance; • Ban on 10 micrograms or over (after 60 days from effective date) • Defendant also to purchase product testing equipment for at least \$242,000 • 50% of "Other" fees will go to CA non-profit groups to reduce exposures; remainder to AYS Foundation Environmental Enforcement Fund



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