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Re: Request for Public Participation on Potential Regulatory Actions

The Alliance for Natural Health USA (ANH-USA) hereby submit comments in response to the California Office of Environmental Health Hazard Assessment (OEHHA) request in regard to the above mentioned pre-regulatory draft.

ANH-USA is a grassroots membership-based organization consisting of healthcare practitioners, natural product companies and over 350,000 consumer-advocate members, of which over 44,000 members are located in California. ANH-USA protects and promotes citizen access to information concerning the interaction between health and the environment, and the benefits of foods, dietary supplements, and lifestyle choices. Through public education, ANH-USA arms consumers with the tools they need to make informed, individualized decisions and to take personal responsibility for their health.

Comment

ANH-USA appreciates the opportunity to provide input regarding amendments to Proposition 65 (Prop 65).

We are highly supportive of the intent of Prop 65, to warn the public of exposures to carcinogenic and reproductive toxins, but we are cognizant of the problematic implementation and enforcement of the law.

Opportunistic Private Plaintiffs:

While the intent of the law is commendable, our concern is that private plaintiff attorneys are exploiting the law. An analysis of the distribution of costs from Prop 65 settlements reveals that private plaintiffs, not the public at large, are benefiting the most. Almost all Prop 65 cases are brought by a small handful of private plaintiff firms profiting from the law.

While the intention behind allowing private parties to bring suit under Prop 65 was to empower private citizens to protect the public, certain provisions in the law have given opportunistic private plaintiffs and attorneys the incentive to file lawsuits simply in order to make money. This occurs in the following ways:

- **Bounty hunter fees:** Prop 65 entitles the individual bringing the lawsuit to 25% of any civil penalties by settlements or through a court appointed fine. Even though in the statute, the civil penalties amount to \$2,500 per violation per day, however in reality this amount is negotiable between the two parties. This is because a “violation” under Prop 65 would mean, for example, every time an individual ingests a supplement that contains a Prop 65 chemical over the safe harbor level. Clearly this would be impossible to calculate across all consumers who use the supplement. The end result is that a private plaintiff may be able to negotiate 25% of a very high civil penalty.
- **High attorney costs:** The defendant is responsible for paying all attorney fees if they are found in violation of Prop 65. Therefore, the longer the case drags out, the higher the attorney fees. In total, attorney fees made up 73% of settlement costs from Prop 65 cases in 2013. Consequently this was not money used to protect the public from toxic exposures, or further the intent of the law in any way.
- **Payments in-lieu of penalties:** In addition to exorbitant attorney costs and fees, private plaintiffs are able to extract further money through “payments in lieu of penalties.” Private plaintiffs prefer to apportion a greater share of the settlement agreement toward a “payment in lieu of penalties,” and attorney costs and fees, which have no limitation, unlike the civil penalties (bounty hunter fees) that are subject to a 25% cap for private plaintiffs. Ostensibly payments-in-lieu of penalties are funds that plaintiffs can use to further the intent of the law. However, there is no actual accounting of how this money is spent, and there is very little evidence that consumers are better informed or protected by money distributed via these means.

The distribution of penalties in 2013 paints this picture clearly: Attorney costs and payments in-lieu of penalties make up a disproportionate share of the private plaintiff agreement, especially as compared to cases settled by the AG and district attorneys.

	Attorney Fees	Civil Penalties		Payment in Lieu of Penalties	Total
		State of California	Plaintiffs (Bounty Hunter)		
Breakdown of costs from 397 cases brought by private enforcers.					
Amount	\$12,426,052	\$17,909,32	\$596,977	\$1,998,435	\$16,812,396
Percentage	73%	10.65	3.55%	11.89%	100.00%
Breakdown of costs from 33 cases brought by AG/District Attorneys					
Amount	\$305,210	\$292,150			\$597,360
Percentage	51%	49%			100.00%

Naturally occurring Prop 65 chemicals

In particular, nutritional supplement companies have been disproportionately targeted by opportunistic Prop 65 lawsuits. They make up a significant percentage of the Prop 65 notices (indicating potential enforcement action) issued each year:

- In 2013, 61 of 1094 notices total were sent to supplement companies.
- In 2012, 86 of 911 notices.
- In 2011, 132 out of 1079 notices.
- In 2010, 172 out of 788 notices.

The most commonly cited Prop 65 chemical for dietary supplements is lead, which made up 96% of all enforcement actions between 2005 and 2012. Unfortunately, lead is highly prevalent in the natural environment, and unavoidably ends up in high quality supplements (often at very low levels) that contain natural ingredients. This makes even the most conscientious dietary supplement company an easy target for Prop 65 enforcement action.

While there is an exemption for exposures resulting from Prop 65 chemicals that naturally occur in food (including dietary supplements), the evidentiary bar is very high, and the burden is on the food company. In fact, the prevalence of lead in the natural environment has been recognized in a number of settlements, including the "Warner-Lambert" settlements, in which the AG fixed naturally occurring allowances for lead above the very low Prop 65 threshold. However, only supplement companies party to the settlement can rely on the higher thresholds, and while some prosecutors allow non-parties to employ the allowances, others do not. The AG has insisted that only parties to a consent judgment may rely on the allowances.

Consequently, many supplement companies face the unhappy choice of placing a warning on their product and deterring their health-conscious customer base or making themselves vulnerable to a lawsuit. Our concern is that consumers may avoid high quality supplements because of a generic Prop 65 warning without realizing that most natural ingredients contain lead, and that in many cases the benefits of supplementation may in fact outweigh the risks.

Safe harbor levels and uncertainty for businesses and consumers:

Of the 800+ Prop 65 chemicals listed, OEHAA has established safe harbor levels for only about half. So companies are expected to know whether they are exposing the public to any listed contaminants in dangerous levels, but the state doesn't know what those safe levels are. This creates uncertainty for business and dilutes the meaningfulness of warnings for consumers in the absence of an established standard.

Since companies are uncertain of the threshold levels required by the law, they are even more vulnerable to lawsuits by plaintiffs. Given that plaintiffs do not have to disclose the studies or data supporting their allegations of Prop 65 violations, companies do not know if the suit is justified or not. Consequently, they may be drawn into unnecessary and expensive legal proceedings when they may in fact not actually be in violation of the law. This does not benefit the public or industry.

Appropriate Warning:

The statute requires that the warnings be “clear and reasonable.” This standard means that a company cannot use a modifier in the statement that might dilute or undermine the warning. However, this has often been interpreted very strictly to the extent that it has prevented companies from providing context for their warnings.

For example, as mentioned above, lead occurs at high levels in the natural environment, and despite attempts by companies to lower levels of lead in their products containing natural ingredients, they still might occur at levels above the Prop 65 threshold. Many supplement companies are targeted for not providing a Prop 65 warning even though their levels, though slightly higher than the safe harbor level, are still very low.

Contextual language that would for example allow a supplement company to state that the level of lead in their product was less than x amount, where x is the federal limit, would both provide the requisite warning to the public, and yet would also help the consumer identify the product with the lowest amount of lead. Yet, under OEHHA’s current narrow interpretation of the law, such contextual language would be considered in violation of Prop 65.

While according to the recently released regulatory discussion draft, OEHHA is considering allowing companies to provide supplemental information in a pamphlet, this language will not appear on the label itself and therefore may not be sufficient in providing consumers with context. Further, OEHAA has stated that the language cannot contradict the warning, which while very important should not be interpreted so strictly as to have the practical effect of disincentivizing companies from choosing this option altogether.

Recommendations

- **Reassess the Safe Harbor Level for lead:** We are pleased that OEHAA is requesting comment regarding chemicals to give priority in the development or update of Safe Harbor levels. We strongly urge OEHAA to reconsider the Safe Harbor Level for lead. Currently, the level has been set at 0.5mcg. However, given the ubiquity of lead in the environment, from which many food products are derived (including dietary supplements), it is extremely difficult for even the most law-abiding food manufacturer to ensure that their natural ingredients contain less than 0.5mg of lead. In fact, federal allowances for lead are much higher; the FDA allows for a medium-sized pharmaceutical drug tablet to contain as much as 10mcg of lead. Many plaintiff lawyers have opportunistically targeted food manufacturers, in particular dietary supplement companies, recognizing that the 0.5mcg Safe Harbor Level is difficult, if not impossible, for many food manufacturers to meet. OEHAA should work with industry and the public to ensure that that a Safe Harbor Level for lead is reassessed to protect public safety and avoid the threat of frivolous lawsuits.

Additionally, while we are highly supportive of the OEHHA request for input regarding specific areas of Prop 65 regulation, we encourage the Agency to also consider amendments beyond the scope of the

Agency request. The following recommendations are offered to ensure that the intent of the law to protect consumers from harmful exposure to toxins is truly honored:

- **Cap or limit attorneys' fees:** Given that attorneys' fees make up a significant amount of the costs associated with Prop 65 cases, which is neither to the benefit of public or the environment, they should be capped, or at the very least, considered reasonable in light of the totality of the circumstances and subject to review by the court.
- **Accountability regarding payments in lieu of penalties:** There should be limits to the percentage of the settlement that is apportioned towards the payment in lieu of penalties, and there should be a transparent auditing system in place to track how these funds are utilized. These penalties should not be excessive and should be clearly connected to remediating the related exposure concern. They should never be utilized to pay attorney fees or bring additional legal actions.
- **Greater disclosure of plaintiff's information:** The plaintiff must agree to share information in good faith with the defendant upon request, including allegations of the notice, studies (or other data relevant to the allegations), and terms on which the action may be resolved or averted.
- **Contextual language surrounding warnings for lead:** Given the expense to prove that levels of lead are naturally occurring, supplement companies should be given the option to provide contextual language around the warning. For example, a company should be able to state the level of lead in the supplement and the amount it deviates from the Prop 65 threshold on the label itself. This will let consumers know if the levels of lead are only slightly above the already low Prop 65 threshold, and will also let discerning consumers choose between supplement products with different levels of lead.
- **Eliminate bounty hunter fees:** A majority of all "bounty hunters" that file Prop 65 notices are associated with the law firms that they file cases and receive fees. In 2013, three individual plaintiffs were responsible for over 40% of the cases settled. Private plaintiff bounty hunter fees should be eliminated entirely to honor the true intent of the law; it is about providing meaningful information to those who may actually be exposed to dangerous substances, not the vehicle for profiteering that it has become.

Conclusion

ANH-USA supports efforts to amend Prop 65 warning regulations in order to honor the true intent of the law, which is to provide effective warnings to consumers and the public at large regarding hazardous exposures to cancerous and reproductive toxins, further providing them a meaningful opportunity to avoid those exposures. However, we urge OEHA to address all of our concerns to ensure comprehensive Prop 65 reform. This will protect companies from opportunistic lawsuits, ensure that the distribution of settlements serve the intent of the law, and guarantee that the public is able to receive meaningful and accurate warning information to reduce exposure to environmental toxins.

