May 13, 2014

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Re: Pre-regulatory draft; Amendments to Cal Code of Regs., 25601 et seq. Clear and Reasonable Warnings.

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 250,000 consumer-advocate members. 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 take personal responsibility for their health.

Comment

ANH-USA is 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 reveal that private plaintiffs, not the public at large, are benefiting the most. Almost all Prop 65 case are brought by small handful

“Promoting sustainable health and freedom of healthcare choice through good science and good law”
of private plaintiff firms profiting from the law. Beside the exorbitant attorney costs and fees, they are able to extract further bounty through “payment in lieu of penalties,” ostensibly to further the intent of the law, but in actuality there is not accounting for how this money is spent. At the same time, many private plaintiffs choose to limit the civil penalties as much as possible because they are only allowed to keep 25% of the amount, while the other 75% is for the AG’s office to put toward enforcing prop 65 and other environmental laws. Therefore, private plaintiffs apportion a greater share of the settlement agreement toward “payment in lieu of penalties,” and attorney costs and fees, which have no limitation.

The distribution of penalties in 2012 paint this picture clearly: Attorney costs and payment 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.

<table>
<thead>
<tr>
<th></th>
<th>Attorney Fees</th>
<th>Civil Penalties</th>
<th>Payment in Lieu of Penalties</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>State of California (75%)</td>
<td>Plaintiffs (Bounty Hunter) (25%)</td>
<td></td>
</tr>
<tr>
<td>Amount</td>
<td>$14,579,592.53</td>
<td>$2,265,014.66</td>
<td>$755,004.89</td>
<td>$20,435,771.60</td>
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<tr>
<td>Percentage</td>
<td>71.34%</td>
<td>11.08%</td>
<td>3.69%</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

Breakdown of costs from 39 cases brought by private enforcers.

<table>
<thead>
<tr>
<th></th>
<th>Amount</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakdown of costs from 33 cases brought by AG/District Attorneys</td>
<td>$829,674.00</td>
<td>46.62%</td>
</tr>
<tr>
<td></td>
<td>$1,005,576.00</td>
<td>54.79%</td>
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*Naturally occurring Prop 6 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 allowance 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 allows 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 over 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.

**Recommendations**

- **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 payment in lieu of penalties:** There should be limits to the percentage of the settlement that is apportioned towards 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 6 threshold. 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.

- **Streamlined process to qualify for the Warner-Lambert threshold levels:** There should be a process in place to allow supplement companies that are able to document their manufacturing processes to preemptively apply for inclusion in the higher Warner-Lambert threshold levels for lead.

- **Develop “safe harbor levels” for all Prop 65 chemicals:** OEHA should develop safe harbor levels for all Prop 65 chemicals. OEHA should further work with industry and the public to ensure that the safe harbor levels protect public safety, while also avoiding ubiquitous warnings that dilute their meaning by making the safe harbor levels too low.

- **Eliminate bounty hunter fees:** The majority of all “bounty hunters” that file Prop 65 notices are associated with the law firms that file cases and receive fees. 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 maintain the true intent of the law to provide effective warning to consumers and the public at large regarding hazardous exposures to cancerous and reproductive toxins. However, we urge OEHA to address all our concerns to ensure comprehensive Prop 6 reform. This will protect companies from unnecessary enforcement via frivolous 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.