

## Industry Responds to California Fish Oil Lawsuit

Jason Phillips March 3rd, 2010

Eight dietary supplement manufacturers and marketers were named in a California lawsuit filed on March 2 that alleges some fish oil supplements have been sold containing illegally undisclosed and unnecessarily high levels of contamination with polychlorinated biphenyl (PCB) compounds. The eight companies named in the lawsuit are: **CVS Pharmacy Inc., General Nutrition Corp. (GNC), Now Health Group Inc., Omega Protein Inc., Pharmavite LLC, Rite Aid Corp., Solgar Inc., and TwinLab Corp.** The lawsuit alleges that the companies sold fish oil, shark oil, fish liver oil and shark liver oil supplements that have PCB contamination above the so-called “safe harbor” limits set for human PCB consumption under California’s Proposition 65. That law requires companies to warn consumers about contaminant exposures. Proposition 65, passed as a ballot initiative in 1986, was passed to force consumer products to eliminate toxic chemical ingredients or reduce them below published safe harbor limits in the past.

U.S. consumers spent \$739 million on fish and animal oil supplements in 2008, making it the eighth most popular dietary supplement on *Nutrition Business Journal*’s list of the top 100 selling supplements in the United States. Many within the industry are wondering what the potential implications this lawsuit could have on the fish oil supplement market. *NBJ* reached out to two industry trade associations, as well as to legal experts with the **Goodwin Procter** law firm to determine what effect this might have on the industry; their responses are included below along with a statement from one of the defendants, TwinLab Corp.

• **Forrest Hainline, attorney at the San Francisco office of Goodwin Procter:** This threatened lawsuit highlights an essential problem in applying Proposition 65 to foods or supplements. The evidence is uncontroverted that omega-3 fatty acids are not only beneficial but essential for health. The evidence is overwhelming that Americans in general do not eat enough fish to obtain the appropriate amounts of omega-3 fatty acids. This might be due in part to the campaign to frighten people away from eating fish for fear of methyl mercury.

As the **California Supreme Court** recognized in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal.4th 910 (2004), “even if scientific evidence supports the existence of a risk, a warning is not necessarily appropriate: The problems of over warning are exacerbated if warnings must be given even as to very remote risks.” This is particularly true where the benefit of the product folks would be warned against outweigh the potential harm. This was true in the [Tuna Case](#), which I tried and won. The benefits of

eating fish (because of omega-3 fatty acids, among other benefits) far outweighed the remote and even theoretical risk of exposure to the minute amounts of methyl mercury.

The **Food and Drug Administration (FDA)**, not a bounty hunter law firm under Proposition 65, should determine whether warnings on foods or supplements are appropriate, and what form they should take.

Note: Hainline also obtained a judgment for restaurants that Proposition 65 warnings concerning grilled chicken were preempted by federal law.

**Joanne Gray, attorney at the New York City office of Goodwin Procter:** I have provided legal advice to a number of dietary supplement companies over the years and have been continually disappointed at the number of frivolous lawsuits that have been filed against the industry, including Proposition 65 claims, consumer class actions claims and products liability lawsuits. It is important to mount a strong defense to these actions right from the start.

It is unfortunate that dietary supplement companies and retailers have faced Proposition 65 lawsuits, even when minute amount of substances hold no real risk of harm to the consumer. These lawsuits are a real threat to the survival of the smaller companies in the industry, and they also increase costs to consumers.

- **Council for Responsible Nutrition (CRN):** CRN believes the suit was filed in California in order to take advantage of a state law, Prop 65, which has conservative standards that are not law in the rest of the nation. Further, the information disclosed during the press conference danced around the details, offering a lack of specificity to the general public about the levels of polychlorinated biphenyl (PCB) compounds found in the fish oil products that were tested. Though the lawyers suggest that the levels of PCBs found in these products far exceed what is acceptable by Prop 65 standards, the actual levels of PCBs found in the majority of these products do not appear to exceed the Prop 65 limit (90 ng/day). Furthermore, they fail to mention that the Food and Drug Administration's (FDA) tolerance level for PCBs in fish (2,000 parts per billion) far exceeds the levels of PCBs found in fish oil...

The bottom line is that consumers, whether they live in California or elsewhere, should continue to feel confident in the safety and efficacy of their fish oil supplements. This lawsuit does nothing to change the strong science supporting the many health benefits of fish oil, which range from cardiovascular health to cognitive development of infants and young children, and the very low thresholds of PCBs which apparently trigger a labeling requirement in California cannot be extrapolated to demonstrate any actual risks at those levels. The health benefits for fish oil far outweigh any suggested, and unsupported, risks." Read the entire statement [here](#).

- **Global Organization for EPA and DHA Omega-3 (GOED):** In response to a lawsuit being filed against eight dietary supplement brands and retailers, the Global Organization for EPA and DHA Omega-3s (GOED) is reassuring the industry and consumers that fish

oils manufactured by its members, and the market in general, meet the highest quality standards available. “We have complete confidence in the safety of the fish oil supplement market, which has been validated through multiple third-party reviews by industry watchdogs on thousands of products,” said Adam Ismail, Executive Director of GOED. “In fact, this industry is among the highest quality and most transparent of all consumer products,” he added.

There are multiple resources in the public domain where consumers can get more information on the quality of their products, including the International Fish Oil Standards program ([www.ifosprogram.com](http://www.ifosprogram.com)). Furthermore, a recent report by Frost & Sullivan found that 93% of the refined fish oils on the market in the United States are produced from anchovy and sardine oils. However, the plaintiffs unfortunately only tested one of these types of oils, which actually had PCB content well within the Safe Harbor provisions of Proposition 65. “While the plaintiffs raise an important issue,” said Ismail, “it is unfortunate that they are implying that most fish oils are unsafe and that the industry is hiding information on such vital nutrients.” Read the entire statement [here](#).

• **Greg Grochoski, Twinlab’s chief science officer:** “Twinlab’s fish oil products are all molecularly distilled and quality tested for purity. These processes are especially effective for reducing impurities such as PCBs found in oceans, lakes, rivers and streams and common to fish and fish-based products.” Twinlab’s statement went on to say that the company cannot comment on the validity or accuracy of the tests referenced by the plaintiffs, though its products were reported as having among the lowest level of impurities.