Legal Backgrounder

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VICTORY IN TUNA TRIAL SIGNIFICANT FOR ALL PROPOSITON 65 DEFENDANTS

By

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On May 11, 2006, the Honorable Robert L. Dondero of the San Francisco County Superior Court dealt the State of California a stunning blow in a Proposition 65 lawsuit brought by the State against manufacturers of canned tuna.[1] Following a bench trial that proceeded fully on the merits, Judge Dondero ruled against the State on all key issues – federal preemption, the application of the "Maximum Allowable Dose Level" ("MADL"), and the meaning of "naturally occurring" – as they pertained to the State's claim that defendants exposed, and continue to expose, individuals to methylmercury in canned tuna without a clear and reasonable warning. Methylmercury is identified as a reproductive toxin under Proposition 65.

At the time of this writing, the parties are briefing the State's objections to the court's Findings of Facts and Conclusions of Law ("Decision"), but it is unlikely that the court will modify its fundamental rulings. Unless reversed on appeal, the court's consideration of and ultimate conclusions regarding these key issues will have broad implications on compliance decisions and on how future Proposition 65 lawsuits might be litigated or settled.

Preemption. The primary issue in the case was whether the State's claims were preempted. The Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301, *et seq*., prohibits the introduction in commerce of food that is adulterated or misbranded within the meaning of the statute. Pursuant to the FFDCA, the Food and Drug Administration ("FDA") is authorized to regulate food labeling and is charged with the protection of food. In the last few decades, the FDA has devoted considerable resources to the issue of methylmercury in seafood, establishing an action level for the chemical of 0.1 parts per million, maintaining a monitoring and evaluation program, and targeting the issue as part with a nuanced approach that includes consumer advisories – rather than product or shelf labeling. Decision at 3, 6-11.

The FDA's nuanced approach recognizes the benefits that eating seafood confers on individuals, including women of childbearing age and pregnant women.[2] *Id.* at 4-5. Uniquely qualified to determine how to convey information to consumers about food, the FDA crafted its advisory informing consumers of both the benefits ***and*** risks of eating seafood. *Id.* at 8.

As a general agency policy matter, the FDA shuns food warnings unless exceptional circumstances exist, such as when food has been adulterated or misbranded. *Id.* at 6. Too many warnings might lead to consumers ignoring all warnings, thereby creating a larger problem than the one sought to be solved. *Id.* at 7. Given the

[1]Findings of Fact and Conclusions of Law Re: Preemption, MADL and Naturally Occurring, entered on May 11, 2006 in *People v. Tri-Union Seafoods, LLC, et al.*, S.F. County Sup. Ct. Consolidated Case Nos. CGC-01-402975 and CGC-04-432394.

[2]Former federal HHS Secretary Dr. Louis Sullivan testified at trial, explaining that pregnant women who eat "less fish have a higher incidence of low birth weight preterm babies and babies born with complications." Decision at 4-5. According to Dr. Sullivan, canned tuna is a low-cost, low-calorie seafood option for improving and sustaining American health, especially among the poor. *Id*. at 5.

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benefits of eating seafood, the FDA is particularly concerned that unnecessary warnings would discourage consumers from eating this overall beneficial category of food. *Id.* at 8.

Following its own examination of exposures to methylmercury in canned tuna, the State sought to require a warning that was a "condensed" version of the FDA's advisory. *Id.* at 9. Drafted by the State's expert (about whose qualifications the court was dismissive, *see, e.g., id.* at 13), the warning would appear on shelf signage, with an even more condensed version, containing the word "WARNIING," on product labeling. *Id.* at 13-14.

Alerted to the State's claims by a group of companies that included defendants, the FDA reprimanded California Attorney General Bill Lockyer in a strongly worded letter (the "FDA Letter") asserting the agency's authority to regulate food labeling:

> [T]he agency believes California cannot legally require Proposition 65 warnings on tuna products because they are preempted under federal law, for two principal reasons. First, FDA has been given broad authority to regulate the labels of food products, and has deliberately implemented its regulatory authority with a nuanced approach…and only under exceptional circumstances, requiring manufacturers to provide warnings on their labels.
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> Second, the Proposition 65 warnings purport to convey factual information, namely that methylmercury is known to cause cancer and reproductive harm. However, it is done without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm.[3]

Thus, the FDA helped to set the stage for defendants' conflict preemption argument – one with which the court ultimately agreed. Noting that the California Supreme Court had accorded "significant deference" to the FDA's informal letter to defendants in *Dowhal v. SmithKline Beecham* (2004) 32 Cal.4th 910 (in which the Court held that the FFDCA preempted Proposition 65 as to warnings for over-the-counter nicotine patches), the court accorded similar deference to the FDA's articulated reasons for finding Proposition 65 preempted as to warnings for seafood: (1) Proposition 65 warnings frustrate the FDA's carefully considered approach to advising the public about both the benefits ***and*** risks of eating canned tuna; (2) point of purchase warnings conflict with the FDA's longstanding opposition to warning signs in connection with the sale of food; and (3) Proposition 65 warnings conflict with federal law because such warnings on canned tuna would be misleading under 21 U.S.C. § 343. Decision at 92. Largely agreeing with the FDA's reasons, the court concluded that defendants could not comply with both Proposition 65 and the FFDCA, and that therefore the State's claims were preempted.[4] *Id.* at 96.

Of course, what the State proposed by way of warning text was not the usual Proposition 65 warning discussed by the court. Rather, the State had proposed a "condensed" version of the FDA consumer advisory for mercury in seafood, which did not even state that methylmercury was known to the State of California to cause birth defects and reproductive harm, the message that renders a Proposition 65 warning legally "clear." *Id.* at 100. Instead of saving the State from preemption, however, the State's proposed warning was its downfall, for the court found that the State's proposed warning did not comply with Proposition 65 at all. *Id.* In its complete rejection of the State's warning, the court neatly boxed the State in a perfect Catch-22: the State's proposed warning was legally insufficient, and a legally sufficient warning would be preempted.

The court found the State's proposed warning legally insufficient for three reasons: (1) it did not contain the core and mandatory language "WARNING" and "this product contains a chemical known to the state of California to cause birth defects or other reproductive harm"; (2) even if the core and mandatory language appeared in the warning, there is no basis for the State to add it by condensing the FDA consumer advisory; and (3) even if the core and mandatory language appeared in the warning, the proposed text added language to the

[3]Letter from Commissioner of Food and Drugs Lester M. Crawford to California Attorney General Bill Lockyer, Aug. 12, 2005.

[4]The fact that the FDA sent its letter at the request of defendants was of no moment, the court further concluded, because that request was protected by the First Amendment right to petition and did not undermine the legitimate and compelling points raised by the FDA. Decision at 94.

core message that diluted the actual warning and made it difficult to understand. *Id.* at 99-100.

The court's holding in this regard, however, could have a significant impact in Proposition 65 settlements. Parties negotiating a settlement sometimes will negotiate a variation of the "core and mandatory" language, usually by adding text to that language. Without exploring all the reasons why, such variations prove mutually beneficial to the parties, and sometimes settlements cannot be achieved without them. Courts reviewing settlements rarely comment on them. Following this decision, will courts now scrutinize such language?

This aspect of the court's decision also could have broad implications in the acrylamide-in-food cases pending in Los Angeles County Superior Court.[5] Although the FDA has not yet stepped into that fray, those cases raise the same issues of FDA's regulation of food as were resolved in this case – and that does not bode well for the State and the private plaintiffs prosecuting those enforcement actions. In contrast to the canned tuna case, however, the products targeted in those cases – French fries and potato chips – have not been identified by the FDA as having specific benefits, as for seafood. On that basis, the State and/or the private plaintiffs may well argue that the principles articulated in the court's decision here are not applicable. Setting aside whether such an argument is tenable, query whether California citizens voted for the Attorney General in order to have that office decide for them what is "beneficial" food and what is not.

In any event, one thing is now clear. Where there is even a breath of a chance that a federal statute can preempt Proposition 65 in a particular case, it is worth talking to the federal agency charged with implementing that statute, to see if it will take a position in writing, articulating why Proposition 65 should be preempted.

Maximum Allowable Dose Level. The court did not stop at finding preemption. Next, it tackled the scientific issues involving the MADL for methylmercury and the calculation of exposure. The court confirmed that it is defendants' burden to prove that exposures, if any, to methylmercury in canned tuna is below the MADL for that chemical. After undertaking an exhaustive review of the parties' expert evidence regarding the appropriate MADL for methylmercury (and finding that it is 0.3 micrograms per day), *id.* at 31-42, 105, the court turned to the calculation of the level of exposure to the chemical in canned seafood – and once again attacked the State's scientific premises.

In other cases, the State and private plaintiffs long have argued that one cannot average an exposure to a reproductive toxin over time. In other words, an exposure above the MADL, even for one day in a lifetime, requires a warning irrespective of the mode of action of the chemical. The regulated community has taken a different view, at least in litigation, arguing that an exposure to a reproductive toxin should be averaged based on the nature of its reproductive effect and the chemical's half-life (*i.e.*, how long it stays in the body). Thus, for example, an exposure to thalidomide should not be averaged, because scientific evidence shows that even a one-day exposure can cause birth defects and the chemical has a short half-life. Methylmercury, on the other hand, does not have a similar reproductive effect, and it has a relatively long half-life of two months. Applying all of these principles, and noting that the regulations refer to "exposures to ***average*** users of the consumer product," the court concluded that exposures to methylmercury in canned tuna, if any occurred, are below 0.3 micrograms per day.[6] *Id.* at 46-53, 105-108. From a compliance standpoint the court's conclusion that exposures to reproductive toxins appropriately may be averaged represents a significant departure from the way Proposition 65 defense lawyers have advised their clients, and may well mean that some products will no longer need to bear warnings.

"Naturally Occurring". In its final blow to the State's case, the court examined whether the methylmercury in canned tuna is "naturally occurring" within the meaning of Title 22, California Code of Regulations, Section 12501. Under that section, a defendant is not responsible for exposures to listed chemicals in food that are "naturally occurring." A listed chemical "is naturally occurring only to the extent that the chemical did not result from any known human activity" and "only to the extent that it was not avoidable by good

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[5] *People v. Frito-Lay, Inc.. et al.*, Los Angeles County Superior Ct. Case No. BC338956; *Environmental Law Foundation v. Procter and Gamble Co.*, Los Angeles County Superior Ct. Case No. BC338895; *Environmental Law Foundation v. Lance, Inc.*, Los Angeles County Superior Ct. Case No. BC338896; *Environmental Law Foundation v. Kettle Foods, Inc.* Los Angeles County Superior Ct. Case No. BC338898; *Environmental Law Foundation v. Frito-Lay (Pepsico, Inc.)*, Los Angeles County Superior Ct. Case No. BC338897; *Council for Education and Research on Toxics v. McDonalds Corp., et al.*, Los Angeles County Superior Ct. Case No. BC280980.

[6] Contrary to what most fourth-graders know, the State insisted that "average" means the median, and not the arithmetic mean, forcing the court to conduct an arduous exercise into the meaning of that term. Decision at 50-52, 106-107.

agricultural or good manufacturing practices." 22 CCR § 12501(a)(3), (4).

The phrase "naturally occurring" has been interpreted strictly by plaintiffs to mean that the chemical cannot be present in food as a result of ***any*** human activity. Thus, for example, lead in food resulting from the deposition of lead from gasoline emissions by vehicles driven near a farm would not be "naturally occurring," even if the farmer, processor, distributor or retailer did nothing to add lead to that food. This interpretation effectively has put the protections afforded by this regulation out of reach of defendants, who are left having to prove a negative, *i.e.*, that no human activity ***at all*** could have resulted in the chemical being present in the food.

The court's decision has clarified that this interpretation is far too strict. Focusing on the word "known," the court determined that the regulation's drafters "intended on only exempting chemicals in food that are naturally occurring or the result of *uncontrollable human activity.*" Decision at 111 (emphasis in original). Moreover, "Proposition 65 is designed to be directed to conduct that the defendant can ***control***." *Id.* at 115 (emphasis added). Thus, if "the manufacturer or producer could avoid altogether or decrease the amount of that chemical in the food product, then that chemical is not exempt under section 12501." *Id.* at 111.

The court found further support for this interpretation in *Nicolle-Wagner v. Deukmajian* (1991) 230 Cal.App.3d 652, 656. In that case, the Court of Appeal reviewed a challenge to Section 12501 shortly after it was promulgated. In holding that the regulation was consistent with the statute, the court examined voters' intent in passing Proposition 65 and determined that the law "sought to regulate toxic substances that are *deliberately added or put into the environment by human activity.*" *Id.* at 659; Decision at 113 (emphasis in original).

Applying these concepts to the expert evidence presented at trial, the court in the canned tuna case found that that "virtually all methylmercury in canned tuna is naturally occurring" and "is almost exclusively absorbed from the ocean environment independently of human pollution." Decision at 115. Because the canned tuna manufacturers do not put methylmercury in tuna, and there is no way for them to remove the chemical from their products – or, put another way, because the manufacturers cannot ***control*** the methylmercury in tuna – the court concluded that the methylmercury is "naturally occurring" within the meaning of the statute. *Id.* Thus, the manufacturers were not legally liable for any exposures to methylmercury in their products.

This aspect of the Decision could have a significant effect on the pending acrylamide cases. Acrylamide is not found in potatoes, or indeed in any other raw food. Rather, acrylamide is formed naturally upon cooking potatoes and other carbohydrate-rich foods, *i.e.*, it becomes a natural constituent of these foods. The cooking temperature, cooking time and cooking method (*e.g.*, frying) has some effect on the levels of acrylamide, but there is only so much flexibility available in cooking potatoes, if you really want French fries or potato chips. Thus, the product manufacturers – who do not put the acrylamide in the food – have no way to remove the acrylamide from the cooked products, thereby fitting neatly into the paradigm created by the court here.

Conclusion. This case is one of the few Proposition 65 lawsuits to proceed to trial fully on the merits. Most cases are settled in the absence of any challenge to plaintiff's allegations. Moreover, Proposition 65 defendants tend to avoid a head-to-head confrontation with the State, fearing that courts might be unduly swayed by the weight of the Attorney General's authority. This particular lawsuit was not exactly a battle between David and Goliath; defendants are major corporations which were well-represented by major law firms. Nevertheless, the court's decision in this case acknowledges that even in the topsy-turvy world of Proposition 65 litigation, the law and the science stand on their own merits. Defendants should take this message to heart, and – assuming they have the necessary financial wherewithal to hunker down for an expensive fight – should think twice before settling unfounded claims.

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