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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

**PUBLIC MEDIA CENTER,**

Plaintiff,

v.

**TRI-UNION SEAFOODS, LLC., DEL MONTE CORPORATION (formerly sued as H.J. Heinz, Co.), BUMBLE BEE SEAFOODS, LLC (formerly sued as Bumble Bee Seafoods, Inc.), and DOES 1 through 499,**

Defendants.

**PEOPLE OF THE STATE OF CALIFORNIA, ex rel. BILL LOCKYER, Attorney General of the State of California,**

Plaintiff,

v.

**TRI-UNION SEAFOODS, LLC., DEL MONTE CORPORATION, BUMBLE BEE SEAFOODS, LLC, and DOES 1 through 100,**

Defendants.

Consolidated Case Nos.: CGC - 01- 402975; CGC - 04- 432394

**PEOPLE'S OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS**

Date: September 30, 2005
Time: 2:30 p.m.
Place: Department 206
Judge: Hon. Robert A. Dondero

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## INTRODUCTION

It is undisputed that methylmercury is a potent neurotoxin that crosses the placenta of the pregnant woman and enters the brain of the fetus. The various states, the federal government, and even the defendants agree that consumers of canned tuna, in particular pregnant women, nursing mothers, women of childbearing age, and mothers of small children, must be warned about the risk of methylmercury in fish. The only question is how to do it. Rather than litigate the case, including the issue of what is an appropriate warning, the defendants now ask the Court to dismiss the case based solely upon a letter that the Commissioner of the U.S. Food and Drug Administration (FDA) sent to the Attorney General at the eleventh hour, expressing his view that federal law preempts the People's claims. The letter appears to be the result of *ex parte* contacts and behind-the-scenes pressure by industry groups, who successfully misled the FDA about the nature of the People's claims and the remedy they seek in this case, and persuaded it to set up a straw man argument by attacking Proposition 65's "safe harbor" warning, a warning that is not at issue here. The FDA made no effort to consult the Attorney General, and states no opinion on any warning the People actually seek, or on the myriad other potential warnings the Court could require. Ultimately, the FDA's statement that the safe-harbor warnings "are preempted under federal law" is simply irrelevant.

Furthermore, to the extent that Defendants argue that the FDA has prohibited the People from giving *any* information to consumers, even truthful information consistent with the FDA's warning, the argument misreads the FDA letter and far exceeds the scope of FDA authority. Quite to the contrary, the FDA has acknowledged elsewhere that the FDA advisory efforts are intended to supplement, not supplant, state efforts to provide information about the risks and benefits of eating fish.

Finally, this motion is procedurally improper. A determination whether a conflict exists between Proposition 65 and the FDA fish advisory efforts can only be made after the Court considers facts not currently in the record, not on a judgment on the pleadings. The People therefore request that this Court deny Defendants' motion for judgment on the pleadings and allow this important matter to proceed to trial.

## STATEMENT OF FACTS

On June 21, 2004, the People sued three of the country's largest canned tuna producers for selling canned tuna fish in California without a warning that the product contains mercury and mercury compounds.[1] The complaint alleges violations of Proposition 65 (Health & Saf. Code, § 25249.6) and the Unfair Competition Law (Bus. & Prof. Code, § 17200). The People seek penalties and injunctive relief to compel Defendants to provide "clear and reasonable warnings, as plaintiffs shall specify in further applications to the court." (Compl. p. 6, Prayer for Relief 2.) To date, the People have not specified to the Court what "clear and reasonable warnings" they seek. That will be part of the case they present at trial. (Declaration of Susan S. Fiering ("Fiering Decl.") ¶ 5.)[2]

The People filed the lawsuit three months after the FDA, together with the Environmental Protection Agency, issued an advisory about mercury in fish and shellfish, called "What You Need to Know About Mercury in Fish and Shellfish." (Fiering Decl. ¶ 3; see also Defendants' Request for Judicial Notice ("Def. RJN") Ex. F ("FDA 2004 Advisory").) The FDA 2004 Advisory, for the first time, specifically identified canned light tuna and albacore ("white") tuna as among the types of fish that contain mercury. While the advisory affirms that fish and shellfish are "an important part of a healthy diet," it recommends that, due to the risks of mercury exposure, women who might become pregnant, women who are pregnant, nursing mothers, and young children follow certain guidelines when consuming seafood, including:

> . . . 2. Eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury.
>
> • Five of the most commonly eaten fish that are low in mercury are shrimp, *canned light tuna*, salmon, pollock, and catfish.

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1. The People's case was consolidated with the similar case filed by private enforcer Public Media Center on December 30, 2001. (S.F. Super. Ct. No. CGC 01-402975.)

2. Copies of the warnings the People's expert is developing and evaluating are attached to the Fiering Declaration as Exhibits A and B. The Court may consider such evidence when evaluating a motion for judgment on the pleadings. (*Cloud v. Northrop Grumman Corp.* (1998) 67 Cal.App.4th 995, 999 [denying motion for judgment on pleadings because facts raised in opposition declaration "highlight the factual nature of the inquiry necessary" to decide the issue].)

- Another commonly eaten fish, *albacore ("white") tuna* has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (one average meal) of albacore tuna per week.

(Fiering Decl. ¶ 2; Def. RJN Ex. F [emphasis added].)

Nothing in the 2004 Advisory suggests that it is intended to supplant state efforts to advise citizens about the risks of mercury in fish. In fact, in December 2004, six months after the People had filed this litigation and three months after a law firm representing industry had asked FDA to send the preemption letter to California (Fiering Decl. ¶¶ 12, 15, Exs. I-K), the Director of Food Safety and Security and Chief Medical Officer of the FDA, David Acheson, M.D., along with an officer from the EPA, sent a letter to the Maine Department of Health assuring the State agency that it was always the federal agencies' intention to collaborate with the states in providing advice to women and children on eating fish: "In this age of limited public health resources available at both the State and Federal level, it is our hope and expectation that the national efforts will only supplement whatever activities are taking place in the various States." (People's Request for Judicial Notice ("People's RJN") Ex. 1.)

Nevertheless, on August 12, 2005, the Commissioner of the FDA wrote to the California Attorney General that "the agency believes that Proposition 65 is preempted by federal law with respect to the proposed warnings concerning mercury and mercury compounds in tuna." (Fiering Decl. ¶ 10, Ex. G at p. 6 ["FDA Letter"].) The FDA Letter, however, addressed only the safe harbor warning: "**WARNING**: This product contains a chemical known to the State of California to cause birth defects and other reproductive harm" (*id.* at p. 1), which is not the warning the People seek in this case. The People attempted to gain a better understanding of how the FDA developed its letter, and came to misunderstand the nature of the People's case, by serving on the FDA a Code of Civil Procedure section 2025.230 person-most-qualified subpoena (with document demand) concerning the information available to the FDA when it wrote its Preemption Letter. (Fiering Decl. ¶ 8, Ex. E.) Simultaneously, the People followed the FDA's own regulations for requesting this testimony (*id.*, Ex. D; see 21 C.F.R. § 20.1(c) (2004)), and filed a request for documents under the Freedom of Information Act ("FOIA") (Fiering Decl. ¶ 6,

Ex. B; see 5 U.S.C. § 552).

The FDA responded on September 8, 2005, to the properly-served subpoena by asserting that this Court has no power to compel it to testify or produce government records or other evidence. (Fiering Decl. ¶ 9, Ex. F.) The FDA also rejected the People's request for testimony, explaining that the Court could simply decide for itself what weight to give to the FDA letter:

> Your stated purpose for deposing FDA employees about the August 12th letter is to determine whether FDA was aware of all relevant facts of the *Tri-Union* case before it issued the letter. You have FDA's letter and its reasoning therein and it would neither be in the public interest nor promote the objectives of the FDCA to divert FDA employees from their official duties to provide testimony for the sole purpose of searching beyond the letter for what FDA did or did not know, consider, or rely upon when it composed the letter. . . . [T]he court can assess the weight FDA's letter should be given if the defendants do file a motion based upon it.

(*Ibid.*) The FDA responded to the FOIA request that it "will respond as soon as possible," but to date it has produced no documents. (*Id.* ¶ 7, Ex. C.)

While the FDA itself has declined to provide testimony about the basis for its letter and has not yet responded to the People's FOIA request, a few days before this brief was to be submitted Defendants handed over an unsigned copy of a 2004 letter from the law firm of Covington & Burling to the Chief Counsel for the FDA that was in the possession of the United States Tuna Foundation, and two related legal memoranda. (Fiering Decl. ¶¶12, 15, Exs. J, K, and L.)[3] The letter and memoranda ask the FDA to issue a letter that Defendants could use to support a preemption defense in this very case, and thus to short-circuit the litigation. The Covington & Burling letter explains that, without a letter from the FDA, a court is not likely to conclude that the People's lawsuit is preempted:

> While the above-mentioned statutory provisions and expressions of federal policy, standing alone, are likely to be held *insufficient* to preempt state law on this subject, FDA could assert its authority and intent to preempt state-imposed warnings for mercury in tuna in a manner that *a court would likely accept and defer to the agency's determination* of preemption. Accordingly, we urge FDA to present such an expression of preemptive intent in a letter from the Acting Commissioner to appropriate California officials responsible for administering Proposition 65.

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3. According to the deposition testimony of the head of the United States Tuna Foundation, Covington & Burling represented either the Food Processors Association or a member of the United States Tuna Foundation. (Fiering Decl. ¶ 15, Ex. M.)

(*Id.* Ex. I at p. 2 [emphasis added].) The accompanying legal memorandum explains exactly what the FDA should say in the requested letter "to be persuasive" – including laying out for FDA the exact elements that the letter should contain – and concludes that "it is likely a court would find persuasive an FDA assertion along the lines set forth above." (*Id.* Ex. J at pp. 6-7, 13.)

After receiving the FDA letter, on August 30, 2005, the Attorney General sent a response to the FDA that corrected the FDA's erroneous assumptions about the advisories at issue in this case and described the Attorney General's understanding of the scope of the FDA letter, including his understanding that the FDA had not reviewed the warnings being sought by the State; the FDA was not claiming that every possible state warning would conflict with federal law; and the FDA did not contend that language consistent with the FDA advisory would conflict with federal law. (*Id.* ¶ 11, Ex. H.) The Attorney General requested that the FDA notify him if his understanding was not correct. To date there has been no response. (*Id.* ¶ 11.)

Two weeks after the FDA sent its letter concerning preemption to the Attorney General, the Defendants filed a motion to dismiss based upon the FDA's assertion that "Proposition 65 is preempted by federal law with respect to the proposed warning concerning mercury and mercury compounds in tuna." (Def. Mem. at p. 1.)

## ARGUMENT

### I. THE FDA LETTER IS IRRELEVANT BECAUSE IT EXPRESSES NO OPINION ABOUT THE WARNINGS THAT THE PEOPLE WILL SEEK IN THIS CASE.

The FDA makes a telling concession on the first page of its August 12 letter. It has absolutely no idea what warning the People seek in this litigation. Rather than contact the People to ask, it assumed, incorrectly, that the People seek the so-called "safe harbor" warning provided in the Proposition 65 regulations. According to the FDA letter,

> [t]he warnings that would be required on the defendants' products if the lawsuit is successful are some derivation of the following: "WARNING: This product contains a chemical known to the State of California to cause cancer," and "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(Fiering Decl. ¶ 10, Ex. G at p. 1.)

This assumption is wrong. Proposition 65 requires only that a person who knowingly and intentionally causes an exposure to a listed chemical provide a "clear and reasonable" warning. (Health & Saf. Code, § 25249.6.) It does not specify what the warning must say, and the regulations set forth only the minimum requirements for a warning. (See 22 Cal. Code Reg. § 12601, subd. (a) [requiring a warning to "clearly communicate that the chemical in question is known to the state to cause . . . birth defects or other reproductive harm," but not prescribing what other information can, or cannot, be provided].) Under the regulations, the safe harbor warnings that the FDA considered are deemed to be clear and reasonable, but there are myriad other possibilities for warning language that will satisfy Proposition 65.

As the Defendants know, the People do not seek to impose the safe harbor warning in this case. (Fiering Decl. ¶ 4.) Rather, the People will seek a warning that borrows heavily from the FDA 2004 Advisory. The People have disclosed to Defendants two of the warnings that their expert is developing, and a third warning that he is evaluating. (*Id.* ¶ 5, Exs. A and B.) There are two shelf signs, and one label warning. All three explain that eating fish has many benefits, but that certain individuals (pregnant and nursing women, women who may become pregnant, and young children) should follow guidelines to minimize exposure to mercury. All three derive the consumption guidelines directly from the FDA 2004 Advisory. And the shelf signs refer persons to the FDA website and toll-free number for additional information.[4/]

Apparently, the FDA was not aware that the safe harbor warnings are not at issue in this case. Therefore, the FDA's analysis of the effect of the safe harbor warnings on its approach is irrelevant and should be disregarded.

## II. DEFENDANTS' READING OF THE FDA LETTER IS INCONSISTENT WITH THE VIEWS EXPRESSED BY THE FDA.

Ignoring the fact that the FDA Letter was focused on the safe harbor warning, Defendants suggest that the FDA intends to preempt every conceivable warning or advisory that is not

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4. The Court is not limited by the Attorney General's submissions and can fashion an alternative warning that would comply with Proposition 65 and be consistent with information contained in the federal advisory.

identical to the FDA warning and not delivered in the same manner. For example, Defendants state that the FDA Letter and other federal actions establish a policy of prohibiting "Proposition 65 warnings and confirm that Proposition 65 warnings would have a negative effect on the health of Californians." (Def. Mem. at p. 1.) Since the FDA Letter addressed only the safe harbor warning, however, the Defendants necessarily overstate the FDA's conclusions. Moreover, if Defendants are correct, then the FDA would also have to preempt the numerous advisories issued by other states. Indeed, under Defendants' view, even printing out the FDA advisory from the FDA's web site and handing it out to grocery store patrons would be preempted. Such a reading of the FDA letter leads to absurd results, is not in keeping with FDA's behavior toward other states' warnings, and would be beyond the scope of FDA authority.

In fact, unlike the consumption advice in the advisories proposed by the People, which follows the FDA guidelines, many states have fish advisories that are different from the FDA advisory. The following language from other states' advisories contrasts and differs from the FDA advisory, but apparently is acceptable to the FDA:

| State | Warning | Advice |
|---|---|---|
| Connecticut | "[C]ertain types of fish bought in stores or restaurants have elevated levels of mercury. . . . If you eat too much of these fish, your unborn baby may be affected." | "When buying canned tuna, you should look for 'light' tuna; it has less mercury than 'white' tuna." |
| Minnesota | "Too much mercury may affect a child's behavior and lead to learning problems later in life." | "If you eat one 6 oz. can of white (albacore) tuna, then wait two weeks before eating another meal of *any* type of fish." |
| New Jersey | "You can build up harmful levels of . . . mercury . . . in your body without being aware of it. These contaminants can especially harm a developing child during pregnancy because the mother can pass them on to the baby." | "It is also safe for an expectant mother to eat up to eight ounces of canned tuna each week provided she has not eaten any other fish known to be contaminated with mercury that week." |
| Rhode Island | "If you eat fish with mercury, the mercury can act as a poison and harm you and your baby." | "If you eat tuna, make sure you choose **light tuna**, not other types of tuna." |

| | | |
|---|---|---|
| Washington | "Too much mercury can have health impacts on everyone, but women of childbearing age and children under six are especially at risk." | "Limit the amount of canned tuna you eat, based on your bodyweight. . . . . A woman who weighs less than 135 pounds should eat less than one can of tuna per week." |

(People's RJN Exs. 5-9.)

At least one state expressly has objected to the FDA advisory and instructed its health providers not to distribute it. (*Id.* Ex. 1 [letter from Maine Department of Health and Human Services expressing "how disillusioned we are that your agencies decided not to work with us on the delivery of advice to Maine families on eating fish"].) Rather than seek to preempt different advice, however, the FDA stated that it regretted sincerely that its program had caused concern, and responded to Maine that, "[i]t was always our expectation that the [FDA/EPA advisory] would be supplemented by local activities" and that "it is our hope and expectation that the national efforts will only supplement whatever activities are taking place in the various States." (*Id.* Ex. 2 [letter from FDA and EPA officials to Maine State Health Officer].) In addition, the letter continues, "combining our efforts with the outreach activities of the States will enhance our capability to reach our common goal: reaching the greatest number of people possible with important information about methylmercury in fish." (*Ibid.*) Such remarks hardly bespeak an agency intent on preempting every possible warning or advisory that differs from its own.

Finally, the mere fact that California may choose a different mechanism to communicate information similar to the FDA advisory (relying on a shelf sign instead of a website advisory) is not a sufficient basis on which to deem state law in conflict with federal law. (See *New York State Pesticide Coalition v. Jorling* (2d Cir. 1989) 874 F.2d 115, 120 [state requirement that warnings contained on EPA-approved labels also be distributed to residents at homes where pesticides were being used was not preempted].) Therefore, the Court should reject Defendants' expansive reading of the FDA letter. The FDA has never stated that every local effort to distribute information about the risks and benefits of eating fish is preempted.

## III. THE FDA LETTER IS NOT ENTITLED TO DEFERENCE.

Even if the opinions contained in the August 12th letter were relevant, they do not deserve

deference from the Court. First, an agency's legal opinion about whether its own regulations preempt state law is not entitled to deference. Furthermore, the FDA Letter resulted from *ex parte* and ill-informed contacts with the FDA, and the agency issued the letter without consulting with the Attorney General about the litigation. (Fiering Decl. ¶¶ 10, 12.) Opinion letters such as this are entitled to little deference.

**A. An Agency's Legal Opinion On Preemption Is Entitled To No Deference.**

While an agency's interpretation of its own regulations may be entitled to deference in some circumstances, an agency's legal opinion as to whether its own regulations preempt state law is not entitled to deference; it is up to the courts to find preemption. (See *Smiley v. Citibank (South Dakota), N.A.* (1996) 517 U.S. 735, 744 [assuming that the question of the preemptive effect of a statute "must always be decided *de novo* by the courts"].) Furthermore, "[b]ecause a preemption determination involves matters . . . more within the expertise of the courts than within the expertise of an administrative agency, we need not defer to an agency's opinion regarding preemption." (*BankWest, Inc. v. Baker* (11th Cir. 2005) 411 F.3d 1289, 1300-01 [citing *Colorado Public Utilities Commission v. Harmon* (10th Cir. 1991) 951 F.2d 1571, 1579] [internal punctuation omitted].)

Defendants rely on cases that do not support their argument that this Court must merely adopt the FDA's opinion that the safe harbor warnings are preempted. In *Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, the Court did not accept as binding an agency's litigation-inspired legal opinion of preemption, as defendants urge here, but instead reviewed years of agency explanations promulgated in the Federal Register to understand the regulatory scheme at issue and then decided for itself that a preemption conflict existed. (*Id.* at 874-81, 884.) Instead of the complete deference defendants suggest, the *Geier* Court explained that it did "place *some weight* upon DOT's interpretation" that state laws would be obstacles to the accomplishment of its objectives. (*Id.* at 883 [emphasis added].) In no sense does *Geier* stand for the proposition that an agency opinion letter is binding on this Court.

Other cases Defendants cite are similarly off point. In *Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 67-68, the Court simply agreed with briefing by the government that the express

preemption provisions of the Federal Boat Safety Act did not bar state tort suits, but it did not say that it was bound by such an opinion. In *Auer v. Robbins* (1997) 519 U.S. 452, 461, at the Court's request, the Secretary of Labor submitted a legal brief explaining its interpretation of a regulation used to determine which employees were exempt from the Fair Labor Standards Act. In *McCarthy v. Option One Mortgage Corp.* (7th Cir. 2004) 362 F.3d 1008, 1013, the court took into account the Office of Thrift Supervision's interpretation of its regulations in the absence of any evidence to contradict that interpretation. And in *Bank of America v. City and County of San Francisco* (9th Cir. 2002) 309 F.3d 551, 563 fn. 7, the court looked to an agency's interpretation of the scope of its regulations, as explained in an agency letter and *amicus* briefs because they were "entitled to respect." In none of these cases did a court defer to an agency's own legal interpretation of preemption.

### B. The FDA Letter Was Produced in Response to An *Ex Parte* Industry Contact Intended to Derail This Litigation

Not all agency legal interpretations are entitled to deference. Thus, legal interpretations "contained in an opinion letter, not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking. . . do not warrant Chevron-style deference. . . . Instead, interpretations contained in formats such as opinion letters are 'entitled to respect,' . . . but only to the extent that those interpretations have the 'power to persuade.'" (*Christensen v. Harris County* (2000) 529 U.S. 576, 587, 120 S.Ct. 1655, 1662-63 [internal citations omitted]; see *Wabash Valley Power Association Inc. v. Rural Electrification Administration* (7th Cir. 1990) 903 F.2d 445, 454 [regulatory letter from agency is not sufficient to preempt state law].)

Whether the FDA Letter has any "power to persuade" depends on how its analysis was carried out. Not only is it informal and not the result of an administrative process, it appears to have been solicited for the express purpose of its use in this litigation. The arguments it expresses are not based on an independent analysis by the FDA, but rather they parrot the arguments that a private law firm advanced on behalf of its industry clients. (See, e.g. Fiering Decl. ¶ 12, Ex. J at p. 6 ["[i]n order to be persuasive, such a letter should contain the following elements. . ."].) As noted by the California Supreme Court in another Proposition 65 case, "the

views of an administrative agency that are the product of a nonadversarial, *ex parte* process, conducted at the request of an organization that exclusively represents the interests of a private industry group are entitled to less deference than administrative decisions made after formal proceedings in which adversarial views are aired." (*People v. Superior Ct. (American Standard)* (1996) 14 Cal.4th 294, 311 [internal punctuation omitted].) Indeed, the FDA letter stands in stark contrast to the *amicus* brief that the Supreme Court found to be persuasive in *Geier*, where there was no reason to suspect that the Solicitor General's view "reflects anything other than the agency's fair and considered judgment on the matter." (*Geier v. American Honda Motor Co.*, *supra*, 529 U.S. at p. 884 [punctuation omitted].) The FDA Letter's power to persuade is severely compromised by the context in which it was produced, and it is entitled to no deference from this Court.

## IV. THE SUPREME COURT DECISION IN *DOWHAL* MANDATES THAT THERE BE NO PREEMPTION HERE.

While Defendants purport to rely on the California Supreme Court's decision in *Dowhal v. Smithkline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, that decision militates against a finding of preemption on this motion. In *Dowhal*, a private enforcer sought to require defendants to place Proposition 65 warnings on the labels of nicotine patches and other smoking cessation devices that use nicotine. The Proposition 65 warning would have stated that nicotine can cause reproductive harm. (*Id.* at p. 918.) Previously, however, following extensive agency review, the FDA had determined that these products must be sold with a warning that does *not* state that nicotine can cause reproductive harm. (*Id.* at pp. 918-19.) Moreover, the FDA had instructed manufacturers not to add to, or otherwise modify, its warning or the product would be misbranded: "*[a]ny additional or modified warning may render the product misbranded.*" (*Id.* at p. 921 [emphasis added by Supreme Court].) The *Dowhal* Court considered this instruction to impose a duty on the defendants not to add the Proposition 65 language. (*Ibid.*)

If, however, as a result of this case Defendants must provide a clear and reasonable warning about methylmercury, the warning would not conflict with any federal duty *not* to provide that information. Nor could the FDA prohibit the canned tuna companies from doing so by calling it

"misbranding," because the information is derived from the FDA's own advisory. (See 2004 DFA Advisory, Def. RJN Ex. F ["some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system"].) There can be no conflict with a Proposition 65 advisory that provides the same information.

A further difference between this case and *Dowhal* is that the Supreme Court in *Dowhal* based its decision only on a formal agency action that could be challenged in court, i.e., a ruling on a citizen petition. (*Dowhal v. Smithkline Beecham Consumer Healthcare*, *supra*, 32 Cal.4th at pp. 919-20, 922 and appendix). There is no such formal action here, only an informal letter from the FDA that does not constitute final agency action. (See *Biotics Research Corp. v. Heckler* (9th Cir. 1983) 710 F.2d 1375, 1378 [regulatory letters finding products in violation of federal law and threatening enforcement action do not constitute formal administrative determinations and final agency action].) Such letters cannot preempt state law.

Defendants have suggested that the FDA took formal action on the issue when, in 2003 (and thus prior to issuance of the revised FDA 2004 Advisory), it denied a citizen petition to require that information about the risks of methylmercury be provided with any qualified health claim about the benefits of omega-3 fatty acids. (Def. Mem. at p. 8.) While the FDA denied the petition, however, it did not prohibit companies from providing such information. The FDA decided only that "it is preferable not to use a label statement about mercury. . . *as a condition for the agency's enforcement discretion* for the omega-3 fatty acid qualified health claims." (Def. RJN Ex. C at p. 6 [emphasis added].) In other words, the agency would not require companies to provide information about mercury as a condition not to take enforcement action against a misleading health claim. Unlike the agency statements in *Dowhal*, which imposed a duty *not* to describe the toxicity of nicotine on the label of anti-smoking treatments, the Omega-3 ruling does not prohibit Defendants from providing analogous information about their products.

## V. THE DEFENDANTS' MOTION IS PROCEDURALLY IMPROPER.

### A. The Determination Of Actual Conflict With Federal Law Is A Factual Inquiry That Cannot Be Decided On A Motion For Judgment On The Pleadings.

While there are three ways in which federal law can preempt state law, the only arguable

basis for preemption here is conflict preemption, which occurs when state law conflicts with federal law, either because it is impossible for a party to comply with both sets of requirements, or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (*Dowhal v. Smithkline Beecham Consumer Healthcare*, *supra*, 32 Cal.4th at pp. 923-24 [quoting *English v. General Electric Co.* (1990) 496 U.S. 72, 79 [110 S.Ct. 2270, 110 L.Ed.2d 65].) The courts, however, should not find preemption too readily in the absence of clear evidence of an actual conflict. (*Geier v. American Honda Motor Co.*, *supra*, 529 U.S. at p. 885; *English v. General Electric Co.*, *supra*, 496 U.S. at p. 90.) It is generally recognized that the proper approach to preemption is to "reconcile the operation of both statutory schemes with one another rather than holding [that one has been] completely ousted." (*Chemical Specialties Manufacturers Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 949 [quoting *Ray v. Atlantic Richfield Co.* (1978) 435 U.S. 151, 183].)

Defendants do not cite a single case in which a court did what defendants are asking this court to do: base a finding of conflict preemption – as a matter of law – solely on an agency's letter stating that state law was preempted because a conflict existed with federal purposes. Instead, a finding of conflict preemption "turns on the identification of 'actual conflict.'" (*Geier v. American Honda Motor Co.*, *supra*, 529 U.S. at p. 884). This is necessarily a factual inquiry, because whether there is conflict depends on the warning that is imposed and its impact on the federal regulatory program. At trial, the Court surely must avoid imposing a warning that conflicts with federal law. However, in order for the Court to find a conflict between Proposition 65 and FDA's regulatory scheme *now*, on this motion for judgment on the pleadings, every possible Proposition 65 warning must conflict with federal law. (*Committee of Dental Amalgam Manufacturers & Distributors v. Stratton* (9th Cir. 1996) 92 F.3d 807, 810; *Chemical Specialties Manufacturers Ass'n, Inc. v. Allenby*, *supra*, 958 F.2d at p. 943; *People ex rel. Lungren v. Cotter & Co.*, (1997) 53 Cal.App.4th 1373, 1393.)

In fact, in the California Supreme Court's more recent decision on preemption, the court sets out in detail the type of analysis that must be undertaken in order to determine if a federal law, regulation, or agency action preempts state law. (*Bronco Wine Company v. Jolly* (2004) 33

Cal.4th 943.) Ultimately, the court must discern congressional intent based on the legislative history of the federal enactment, the intent of the responsible federal agency vis-a-vis state regulation, and whether the state statute stands as an obstacle to the "accomplishment and execution of the full purposes and objectives of Congress." (*Id.* at p. 956.) The Supreme Court in *Bronco Wine* devoted literally pages to examining the history of the state regulation, the federal regulation, the federal statute, and the relationship between the enactments, in order to determine congressional intent. Ultimately, the court concluded that, based on the relevant history, "neither Congress nor the BATF [federal agency] intended to preempt" the state laws. (*Id.* at p. 989.) Furthermore, the court declined simply to accept the argument that the federal regulations were preemptive because they reflected a careful balancing of federal policy objectives. Rather, the court noted that preemption required the finding of a specific federal purpose with which the state law interfered. (*Id.* at pp. 990-991.) As noted by the Supreme Court, "[t]o infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." (*Id.* at p. 992.)

Here, where the FDA has not issued a regulation and has not expressed its intention in a formal manner to preempt all forms of non-FDA warnings and advisories, the Court must not infer total preemption just because the FDA has developed its own advisory. Ultimately, in order to determine whether the FDA has the authority or the intent to preempt every Proposition 65 warnings requires "a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." (*Bronco Wine Company v. Jolly*, *supra*, 33 Cal.4th at p. 992 [quoting *Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 373].) This simply cannot be done on a motion for judgment on the pleadings.

**B. The Court Cannot Take Judicial Notice Of The Facts In The FDA Letter.**

On this motion for judgment on the pleadings, there are only two ways the Court could have before it facts about the FDA's fish advisory efforts that Defendants rely on: they must appear in the complaint or be judicially noticed. (Code Civ. Proc., § 438, subd. (d); see also *Executive Landscape Corp. v. San Vicente Country Villas IV Ass'n* (1983) 145 Cal.App.3d 496, 499.) They

are not in the complaint, however, and the Court may not take judicial notice of them. As set forth in the People's accompanying Objections to Defendants' Request for Judicial Notice, the proper scope of judicial notice is critical on a motion for judgment on the pleadings. While the Court can take judicial notice that the FDA's opinions are as set forth in the FDA letter and other documents, it cannot merely accept as true the Defendants' factual allegations about the history, purpose, scope, and impact of the federal advisory program. Requesting the Court to judicially notice such evidence does not make up for its absence. *(Bach v. McNelis* (1989) 207 Cal.App.3d 852, 865-66 [judgment on the pleadings must be denied where there are material factual issues that require evidentiary resolution].)

## CONCLUSION

This trial has been in preparation for years. The People are prepared to present their evidence to the Court and to provide the Court with one or more proposed warnings that will comply with state law and convey information derived from the FDA advisory. Defendants' argument that the FDA intends to, and has the power to, preempt every conceivable Proposition 65 warning about their product is inconsistent with the FDA position, not supported by the FDA letter, and beyond the scope of FDA authority. For the above reasons, the People respectfully request that this Court deny Defendants' motion and permit the parties to proceed to trial.

Dated: September 16, 2005

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