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August 12, 2004

MEMORANDUM

Re: Federal Preemption of Proposition 65 Warnings on Canned Tuna

The Attorney General of the State of California has filed suit under that state's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") against distributors of canned and packaged tuna, alleging that they failed to warn consumers that these products expose them to chemicals (mercury, mercury compounds, methyl mercury and methylmercury compounds) known to the state to cause cancer and birth defects or reproductive harm. The state seeks injunctive relief as well as civil penalties.

This state action conflicts with federal law and policy with respect to warnings on tuna, as expressed in the misbranding provisions of the Federal Food, Drug and Cosmetic Act (FDCA), the recently revised joint FDA/EPA consumer advisory entitled "What You Need to Know About Mercury in Fish and Shellfish" ("Consumer Advisory"),[1] and FDA's longstanding policy disfavoring warnings on food. While these 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.

This memorandum analyzes the applicable case law regarding preemption and discusses the criteria for an authoritative statement of preemption by FDA to which a court would likely defer. The memorandum describes three grounds for preemption of Proposition 65-compliant warnings on tuna. First, such warnings would be misleading in light of the Consumer Advisory and would therefore render the tuna misbranded under federal law, thereby making it impossible for manufacturers to comply with both federal and state labeling requirements. Second, a Proposition 65 warning on tuna would frustrate federal policy regarding advising vulnerable populations about the benefits and risks of seafood consumption, as expressed in the carefully-crafted language of the Consumer Advisory. Third, Proposition 65 warnings for canned tuna should be deemed preempted under the doctrine of negative preemption, for FDA has the authority to require such warnings but chose not to do so and has determined that no such warnings are appropriate.

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[1] Available at http://www.cfsan.fda.gov/~dms/admehg3.html.

An FDA statement that clearly sets forth the agency's authority and expertise regarding food safety and labeling, that states with specificity the agency's rationale for its policy with respect to mercury in seafood, and that declares FDA's preemptive intent would likely be deemed authoritative and as having preemptive effect. Such a statement should be presented in a letter to appropriate California officials responsible for administering Proposition 65.

I. Preemption Generally

The doctrine of federal preemption is derived from the Supremacy Clause of the United States Constitution, which provides that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI. "Under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation . . . ; and finally, when compliance with both state and federal law is impossible, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984) (internal citations and quotations omitted).

In considering whether a state requirement is preempted, it is necessary first to examine the governing federal statute to determine whether it expressly preempts state regulation of the type at issue. In this case, we look to the FDCA as amended by the Nutrition Labeling and Education Act of 1990 (NLEA). The NLEA added to the FDCA Section 403A, containing certain express preemption provisions relating to nutrition labeling, food standards of identity, and a number of other label requirements. The NLEA paragraph entitled "Construction" provides that while these provisions should not be construed to preempt state food warning requirements, nothing in the amendments should be construed to affect preemption, "express or implied," of any state requirement, which may arise under the Constitution, any provision of the FDCA not amended by the NLEA, or any other federal law. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535 § 6(c), 104 Stat. 2353, 2364 (1990). Thus, operative principles of conflict preemption remain unaffected as they relate to state food warning requirements.

The preemption provisions codified in the NLEA were the result of legislative compromise intended to assure national uniformity where it was most necessary, *i.e.*, concerning standards of identity, while leaving untouched the states' authority to adopt laws to protect the safety of their citizens. The legislative history makes clear, however, that Congress did not intend to alter the landscape of preemption analysis other than with respect to the express preemption provisions. Senator Hatch explained:

> [A]lthough the provisions of this bill may not preempt a State warning requirement . . . , that very same State warning may be preempted by virtue of the Constitution, another statutory provision, or *agency action*. This result is an essential element of

> the compromise embodied in the uniformity provisions of this legislation. The decision of the Congress in this legislation to specifically preempt certain State or local requirements is not evidence, one way or the other, of any congressional view about the existence of preemption which may arise from other existing legal authorities or actions.

136 Cong. Rec. S16611 (daily ed. Oct. 24, 1990) (emphasis added).[2] Accordingly, the NLEA clearly preserved the ability of FDA to preempt state food warning requirements that conflict with the agency's policy choices concerning labeling. As discussed below, the FDA Advisory coupled with an authoritative letter from the FDA Commissioner would likely be sufficient to preempt a Proposition 65 warning concerning mercury in tuna under the implied preemption doctrines of impossibility and frustration of purposes.

The Supreme Court has also recognized a kind of "negative" preemption of state law based on the *absence* of a federal law on a subject matter, explaining: A "federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated, and in that event would have as much pre-emptive force as a decision *to* regulate." *Arkansas Elec. Co-op. Co. v. Arkansas P.S.C.*, 461 U.S. 375, 384 (1983) (emphases in original); *cf. Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (States are prohibited from granting patent-like protection to an invention, after the period of its federal patent-protection expires: "To a limited extent, the federal patent laws must determine not only what is protected, but also what is free for all to use.") (citing *Arkansas Electric Co-op.*, 461 U.S. at 384).

The Supreme Court has held that when a federal agency has "properly exercised its own delegated authority [from Congress]" its substantive regulations will also have preemptive effect, *City of New York v. FCC*, 486 U.S. 57, 64 (1988), and that "[a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law," *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982). Accordingly, federal regulations can preempt state law in the same ways that federal statutes can.

Preemption by regulation is not likely to be a viable option with respect to mercury warnings on tuna, as no existing regulations appear to preempt Proposition 65 warnings on this subject, and FDA would not have time to promulgate a regulation that would have this effect before the matter is adjudicated. The question is therefore whether a less formal agency

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[2] Significantly, Senator Hatch expressly stated his concern that inconsistent state food warning requirements "undermin[e] the credibility and effectiveness of Federal policy in this area" and "frustrate food safety and nutrition education efforts by presenting consumers with varying and inconsistent information and warnings. In sum, we simply must remember that a warning on everything means a warning on nothing." Further, he characterized the limited preemption in the NLEA as "only one step toward expanding uniformity of labeling laws and food safety requirements through existing law as well as future legislation." 136 Cong. Rec. S16611 (daily ed. Oct. 24, 1990).

pronouncement, such as that expressed in a letter to California officials, could have the effect of preempting Proposition 65 warnings on tuna labeling.

The Supreme Court's cases discussing the preemptive effect of "regulations" do not specifically address whether more informal agency pronouncements, such as interpretive rules,[3] advisory opinions or letters, also preempt state law. Nevertheless, the language of the Supreme Court's decisions in *Fidelity Federal* and *de la Cuesta*, among others, suggests that only a so-called "legislative rule," that is, a binding rule of law promulgated pursuant to the agency's delegated rule-making authority from Congress, qualifies as a "Law of the United States" for purposes of preemption under the Supremacy Clause.

II. The Consumer Advisory Itself is Not Likely to Preempt a Proposition 65 Warning on Tuna, But a Properly-Crafted Authoritative Statement by FDA Would Likely Be Deemed Preemptive

A. Features of a Potentially Preemptive Agency Determination

In *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), the Supreme Court found "informal" agency determinations sufficient to preempt state regulation, and in doing so highlighted the features of an agency determination that would lead a court to find preemption. In *Geier*, a driver who was injured in a car accident sued the car's manufacturer alleging liability because the car lacked an airbag. The manufacturer argued that the claim was preempted by a Department of Transportation ("DOT") legislative rule, Federal Motor Vehicle Safety Standard 208. The majority opinion by Justice Breyer agreed with the manufacturer, holding that a tort suit claiming that only an airbag could have satisfied the manufacturer's duties to the driver "would have presented an obstacle to the variety and mix of [passive restraint] devices that the federal regulation sought." 529 U.S. at 881.

To assess the federal rule's objectives, the majority relied heavily on (1) the DOT's comments accompanying the rule's promulgation in 1984, *id.* at 874-75, 877-80; (2) the majority's own review of the history of airbag regulation, *id.* at 875-77; and (3) the Solicitor General's *amicus curiae* brief, *id.* at 881, 883-84.[4] The majority elaborated that it would place "some weight upon DOT's interpretation of FMVSS 208's objectives and its conclusion, as set forth in the Government's brief, that a tort suit such as this one would stand as an obstacle to the accomplishment and execution of those objectives." *Id.* at 883 (internal quotations omitted). The majority reasoned in support of this:

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[3] *See Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94-95 (D.C. Cir. 1997) (distinguishing an interpretive rule which "does not purport to modify [a legal] norm" and a "substantive" or "legislative" rule that "modifies or adds to a legal norm").

[4] It should be noted that *Geier* was a 5-4 decision, and that the dissent would have found these indicia of federal policy insufficient to preempt state law. Rather, the dissent would have required the Secretary of the Department of Transportation to specify her preemptive intent, and to do so through notice-and-comment rulemaking.

> Congress has delegated to DOT authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements. . . . And DOT has explained [the federal rule's] objectives, and the interference that 'no airbag' suits pose thereto, consistently over time. . . . In these circumstances, the agency's own views should make a difference. . . . We have no reason to suspect that the Solicitor General's representation of DOT's views reflects anything other than the agency's fair and considered judgment on the matter. . . . The failure of the Federal Register to address pre-emption explicitly is thus not determinative.

Id. at 883-84 (citations omitted).

The majority specifically rejected as unprecedented the dissent's argument that "would require a formal agency statement of preemptive intent as a prerequisite to concluding that a conflict exists." *Id.* at 884. "To insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be in certain cases to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended." *Id.* at 885.

While a formal expression of an agency's preemptive intent is not required, courts are not likely to find preemption where the agency has not indicated in any manner its intention to preempt state law. In the recent decision of the California Supreme Court in *Bronco Wine Co., et al., v. Jolly, et al.*, 2004 Cal. LEXIS 7082 (Aug. 5, 2004), discussed in greater detail below, the court held that a state statute was not impliedly preempted by a federal regulation. The court observed that regulatory agencies normally address problems in a detailed manner, and can make any preemptive intentions clear through a variety of means, including regulations, preambles, interpretive statements, and responses to comments. *Id.* at *105, *citing Jones v. Rath Packing Co. 430 U.S. 519, 525 (1977).* The court found no such expression of preemptive intent with respect to the federal regulations, and this finding contributed to its conclusion that the state statute was not preempted.

B. The Consumer Advisory Alone is Not Likely to be Held Preemptive

The advisory is addressed to women who are or might become pregnant, nursing mothers, and young children – the group that needs to be most careful about its mercury consumption. The advisory describes the health benefits and mercury-related risks of eating fish and shellfish and advises eating up to specified amounts each week of canned albacore or light tuna or other kinds of low-mercury fish. The 2004 joint advisory improves on advisories issued separately by the two agencies in 2001. The joint advisory emphasizes the positive benefits of eating fish and for the first time specifically addresses canned light tuna and canned albacore ("white") tuna.

It is unlikely that, standing alone, the Consumer Advisory would be deemed to preempt Proposition 65 warnings on tuna. The advisory is designed to inform consumers. It does not on its face mandate, prohibit or authorize any particular labeling for canned tuna, nor does it purport to interpret any statute or regulation. Further, it does not cite the FDA's power to regulate food labeling or an FDA/EPA conclusion or rationale against state labeling requirements. Arguably the advisory implies an FDA/EPA determination that the advisory and planned educational campaign are the "best" approach to informing consumers of the advisory's messages. This interpretation of the advisory is consistent with the fact that FDA has the statutory power to require warnings on food labeling but historically has opposed such warnings as a way to address food-safety concerns. Still, the advisory on its face does not rule out a potential inference that it was employed because of the relative difficulties (e.g., due to delay or opposition) of promulgating a labeling requirement, something FDA has done before in a few instances, as noted below. Nor does the advisory on its face rule out a potential inference that state governments are free to require their own mercury-warning labeling for tuna.

Accordingly, the Advisory of its own force does not preempt Proposition 65, because it lacks the force of law and does not set forth FDA's labeling authority, preemptive conclusion or complete rationale against mercury-warning labeling for fish. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67 (2002) ("although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an "authoritative" message of a federal policy against propeller guards.") (citation omitted); *see also Baltimore & Ohio R.R. v. Oberly,* 837 F.2d 108, 115 (3rd Cir. 1988) (EPA's statement merely that federal regulations on a subject were "unnecessary" did not preempt state law: "In this context, where the question is whether an administrative decision not to regulate should have the same preemptive effect as would a decision to regulate . . . we believe that it is essential that an agency declare, at a high level of specificity, its intention that its inaction preempt state law before we may assume such a desire and give it legal effect.") (relying on *Hillsborough Cty v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 718 (1985)); *Burlington N. and Santa Fe Ry. v. Doyle*, 186 F.3d 790, 802 (7th Cir. 1999) ("[W]hat the record does not show is that the FRA has considered the issue and *affirmatively decided* not to regulate.... Only this sort of affirmative decision preempts state requirements.") (citing *Ray*) (emphasis added); *Favel v. American Renovation & Const. Co.*, 59 P.3d 412, 425 (Mont. 2002) ("[R]egulatory preemption will not be implied absent some declaration of an intent to preempt."), *cert. denied*, 538 U.S. 1000 (2003).

C. An Authoritative and Carefully-Drafted Letter from FDA is Likely to Persuade a Court to Find Preemption

An authoritative letter from FDA asserting its intention to preempt Proposition 65 mercury warnings on tuna and setting forth with particularity its rationale for preemption would likely be held sufficient to establish preemption. Such a letter would emphasize the reasoning and intent behind the Consumer Advisory, and the rationale for taking that approach rather than any other. In order to be persuasive, such a letter should contain the following elements, derived from the case law described above and discussed later in this memorandum:

- Congress has delegated to FDA the authority to implement the labeling (misbranding) and food safety (adulteration) provisions of the FDCA;

- FDA has a thorough understanding of these provisions, as well as its Consumer Advisory and the objectives behind it, and is "uniquely qualified" to comprehend the likely impact of a Proposition 65 warning on tuna;

- the subject matter is technical, and FDA has substantial expertise in analyzing the scientific issues involved, as well as the consumer education aspects of the matter;

- the relevant history and background are complex and extensive. FDA has been examining this issue for many years and have compiled substantial data concerning mercury in fish;

- Under the circumstances, a Proposition 65 warning on canned tuna would be inaccurate and misleading;

- FDA has explained its food safety objectives and the interference that warnings pose thereto, consistently over time; and

- FDA intends to preempt Proposition 65 warnings concerning mercury in tuna, because such warnings would render the tuna misbranded, FDA has considered the issue and determined that such warnings would frustrate the carefully considered federal approach to advising consumers of the risk of mercury in seafood, as embodied in the Consumer Advisory.

III. Misbranding

The FDCA authorizes FDA to take action against misbranded food, as defined in sections 403(a)(1) and 201(n). Section 403(a)(1) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular, and section 201(n) explains that in determining whether a food is misbranded because its labeling is misleading, FDA will consider, among other things, whether the labeling fails to reveal facts material with respect to consequences which may result from the use of the article of food. FDA's regulations similarly provide, in relevant part, that the labeling of a food shall be deemed to be misleading if it fails to reveal facts that are material in light of other representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the article under the customary or usual conditions of use of the article. 21 C.F.R. § 1.21(a).

A Proposition 65 warning[5] such as "this product contains methylmercury which is known to the State of California to cause cancer, birth defects or other reproductive harm" is

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[5] The California Attorney General seeks to impose this warning through point-of-sale signs, rather than on product labels. Such signs meet the definition of "labeling" in section 201(m) of (continued...)

misleading because it overstates the risk of eating canned tuna fish and omits altogether to state the health benefits. Further, as discussed below, FDA's scheme of food regulation prohibits the marketing of unsafe food. Accordingly, warning labeling that suggests that lawfully marketed food poses a risk are misleading and would therefore render the food misbranded.

It is of no moment that a Proposition 65 warning such as the one described above might be technically true. This issue was recently addressed by the California Supreme Court in the context of Proposition 65 labeling on an FDA-regulated product in *Dowhal v. Smithkline Beecham Consumer Healthcare et al.*, 88 P.3d 1 (Cal. 2004). In that case, the court concluded that a Proposition 65-compliant warning on over-the-counter (OTC) smoking cessation drugs was preempted by the FDA-mandated pregnancy warning, where FDA advised the drug manufacturers by letter that using the Proposition 65 warning would render the products misbranded even though the agency was aware that nicotine in the products could cause reproductive harm.[6]

As expressed in the Consumer Advisory, FDA recognizes that consumption of methylmercury can cause reproductive harm. However, such a statement by itself is misleading and fails to accurately characterize the risk of consuming canned tuna. The *Dowhal* court observed that "even though it is probably true that the nicotine in defendants' products can cause reproductive harm, the FDA has authority to prohibit truthful statements on a product label if they are 'misleading' . . . or if they are not stated in 'such manner and form as are necessary for the protection of users.'" 88 P.3d at 12 (citations omitted). The court was citing to section 201(n) and the drug misbranding provisions, but three of the cases it cites as authority for this proposition are food cases. *See United States v. Ninety-Five Barrels of Vinegar*, 265 U.S. 438, 444 (1924) (Supreme Court found vinegar to be misbranded where label said vinegar was made from apples but was in fact made from dehydrated apples and was therefore different from that made from fresh apples, observing that deception "may result from the use of statements not technically false or which may be literally true"); *United States v. An Article of Food, Etc.*, 377 F. Supp. 746 (E.D.N.Y. 1974) (finding the label of Manischewitz's Diet-Thin matzos misleading because they contained the same number of calories as Manischewitz's plain matzos, for "[e]ven a technically accurate description of a food or drug's content may violate 21 U.S.C. § 343 if the description is misleading in other respects."; *United States v. An Article of Food*, 482 F.2d 581 (8th Cir. 1973) (holding that even thought the Nuclomin label was technically accurate, it was

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the FDCA, which provides that "labeling" means "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." The misbranding analysis therefore applies to point-of-sale signs as well as to product labels. *See also Dowhal v. Smithkline Beecham Consumer Healthcare et al.*, 88 P.3d 1, 11 (Cal. 2004) (finding point of sale signs bearing Proposition 65 warnings preempted by federal labeling requirements because warnings on the signs frustrated the purpose of the federal policy).

[6] *Dowhal* involved the labeling of OTC drugs, which must be approved by FDA as part of the drug approval process. As explained above, however, the FDA also has authority to determine that foods are misbranded.

misleading and subject to seizure because some of the ingredients are not needed in human nutrition or are included in such insignificant amounts as to be valueless).

The Consumer Advisory states that while some fish and shellfish contain higher levels of mercury that may harm an unborn baby, "[t]he risks from mercury in fish and shellfish depend on the amount of fish and shellfish eaten and the levels of mercury in the fish and shellfish." It states further that by following the recommendations in the advisory, "women and young children will receive the benefits of eating fish and shellfish and be confident that they have reduced their exposure to the harmful effects of mercury." The benefits of eating fish are emphasized, for the Advisory states that "[a] well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development. So, women and young children in particular *should include* fish or shellfish in their diets due to the many nutritional benefits." (Emphasis added.) The recommendations relating to canned tuna advise consumers to eat up to 12 ounces (2 average meals) a week of a variety of fish lower in mercury, including canned light tuna, and up to 6 ounces (one average meal) per week of albacore ("white") tuna, which has more mercury than canned light tuna.

In developing the recommendations set forth in the advisory, FDA tested over 3400 cans of tuna since July 2002, which results were added to the agency's previous sampling results. "Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish" (Backgrounder).[7] Lester Crawford, Acting Commissioner of the FDA, emphasized the scientific support for the Advisory in a statement released along with the new Advisory:

> Americans can be confident in the safety of the food supply because of the scientific expertise and diligence of the FDA and EPA working to promote the public health. FDA and EPA scientists are world leaders in the scientific investigation, toxicology and health impact of chemical contaminants in the food supply and in the environment, and our two agencies routinely assess and take steps to ensure that the foods Americans consume are nutritious, wholesome, and safe. This includes working together to provide uniform and consistent advice to consumers on the benefits of eating fish, and advice to consumers on how to select fish to maximize its benefits.

"Fish is an Important Part of a Balanced Diet," Lester M. Crawford, DVM, PhD, March 2004 (Crawford Statement).[8] "Because of the FDA's scientific expertise and long administrative experience, these views are entitled to judicial deference." *Dowhal*, 88 P.3d at 11 (deferring to FDA's views on the effect of nicotine on the fetus) (citation omitted).

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[7] Available at http://www.fda.gov/oc/opacom/hottopics/mercury/backgrounder.html.

[8] Available at http://www.fda.gov/oc/opacom/hottopics/mercury/mercuryop-ed.html.

Dr. Crawford also explained that prevailing consumer confusion regarding the benefits and risks of fish consumption played a role in prompting the agency to issue its revised Consumer Advisory:

> Recently, consumers have been bombarded by such confusing messages surrounding the consumption of fish. Given the focused media attention on some contaminants in fish and their potential health implications, consumers may be wondering about consuming fish as part of their diets. In light of this confusing barrage of information, it is important to set the record straight and to let all Americans know that fish continues to represent an important part of a balanced diet.

Crawford Statement.

A Proposition 65-compliant warning on canned tuna would add to the confusion the Consumer Advisory intended to obviate and would be misleading because it would imply that consuming tuna at levels at or below those recommended by FDA would cause reproductive harm, and because it would fail to acknowledge the benefits to women and children of consuming fish. Accordingly, FDA should assert that a Proposition 65 mercury warning would render canned tuna misbranded, and that the agency will take regulatory action against any products so labeled. This would render it impossible for manufacturers of canned tuna to comply with both federal and California law.[9]

It is well-settled that, when it is impossible to comply with both a state law and valid federal law, the state law is preempted. *E.g., Dowhal*, 88 P.3d at 10 (Proposition 65 warning held preempted where only a the FDA pregnancy warning would avert misbranding under an FDA letter); *Grocery Mfrs. of America, Inc. v. Gerace*, 755 F.2d 993, 1001 (2d Cir. 1985) ("[T]he New York labeling scheme is in direct conflict with its federal counterpart. Including the term imitation on the label of a nutritionally superior alternative cheese in order to comply with New York law, would render the product misbranded under federal law. Compliance with both the state and federal requirements is impossible. To th[at] extent . . . the New York law is preempted."), *aff'd without op.*, 474 U.S. 801 (1985); *McDermott v. State of Wis.*, 228 U.S. 115, 134 (1913) (state law prohibiting sale of food with any but state-required label was preempted by federal law that contemplated inspection for misbranding based on federally-required label); *see generally AT&T v. Central Office Tel. Co.*, 524 U.S. 214, 227-28 (1998) (federal telecommunications law pre-empts conflicting obligations imposed by state contract and tort law).

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[9] It could be argued that until FDA has actually taken regulatory action against manufacturers of canned tuna bearing a Proposition 65 mercury warning, it is possible to comply with both federal and state law. However, the court in *Dowhal* found it sufficient that FDA had asserted in a letter the agency's conclusion that a Proposition 65-warning would misbrand the product.

Based on the foregoing analysis, FDA should send a letter to California officials stating that a Proposition 65 mercury warning on canned tuna would misbrand the product, and that the agency will take regulatory action against any cans of tuna so labeled.

IV. Frustration of Federal Objectives

The California Supreme Court in *Dowhal, supra*, found that implied preemption was not precluded under section 751 of the FDCA mandating national uniformity for OTC drugs, where that provision contained an express preemption provision and a savings clause for Proposition 65. With respect to food product warnings, as noted, Congress explicitly has stated that implied preemption analysis remains fully viable.

The *Dowhal* court found preemption based upon frustration of federal purposes. It determined that the pregnancy warning mandated by FDA for nicotine-containing smoking cessation OTC drug products represented the agency's careful consideration of the risk of reproductive harm from nicotine and the effects of any warning language on consumer behavior. The Chairman of FDA's Nonprescription Drugs Advisory Committee emphasized that these are products that he would like lots of people to use but that consumers were underusing. The language of the pregnancy warning was therefore carefully crafted to alert pregnant women to the potential harm the products might cause to the developing fetus while not scaring such women away from these products and consequently continuing to smoke. *Dowhal*, 88 P.3d at 4-5. The court deferred to FDA's expertise, and concluded that in a letter asserting that a Proposition 65 warning would render the products misbranded, the agency had established a federal policy prohibiting the manufacturers from giving consumers any warning other than the one approved by FDA in that letter, and that the use of a Proposition 65 warning would conflict with that policy. *Id.* at 11.

More recently, the California Supreme Court held in *Bronco Wine, supra,* 2004 Cal. LEXIS 7082, that a state law regarding wine labeling did not frustrate the purposes of a federal regulation with a grandfather clause that would have allowed what the state statute prohibits, and therefore the state law was not impliedly preempted. The court's analysis reveals the contours of frustration of purpose preemption, and highlights the factors needed for a finding of this type of preemption.

In holding that the state law was not preempted, the court in *Bronco Wine* found that both the federal statutory and regulatory history expressly contemplated that states would enforce their own labeling requirements that may be stricter than federal regulations. *Id.* at *107-8. Additionally, as discussed above, the court observed that the regulatory agency charged with implementing the federal statute did not express any intention to preempt state law. *Id.* at *105. Further, the court found no federal purpose with which the state law interfered, for both state and federal requirements served the same purpose – to ensure to ensure that the purchaser of wine should get what he thought he was getting, and that the representations on the labels and in advertising should be truthful and straightforward. *Id.* at *106. Finally, the court determined that the federal government did not intend to preclude states from adopting more stringent requirements necessary to address local concerns, such as protecting the integrity of the California wine industry. *Id.* at *118.

Dowhal and *Bronco Wine* together indicate that a court will likely find frustration of purpose preemption where an agency draws upon its expertise to carefully balance competing considerations of risk and benefit, where a state requirement would in fact conflict with the purposes of the federal policy, where the agency makes clear its intention to preempt state requirements concerning the matter at issue, and where no local concerns justify more stringent state requirements. If FDA emphasizes its policy and preemptive intent concerning mercury in tuna warnings in a letter to California officials, these factors will be satisfied and a court would likely find that a Proposition 65-compliant warning on canned tuna would frustrate federal purposes and is therefore preempted by federal law.

The Backgrounder that accompanied the release of the Consumer Advisory describes the evolution of the joint advisory and the policy considerations and science behind it. The Backgrounder states that the purpose of the Advisory "is to inform women who may become pregnant, pregnant women, nursing mothers and the parents of young children on how to get the positive health benefits from eating fish and shellfish, while minimizing their mercury exposure." It explains that the criteria for the Advisory were "that it be based on sound science; is easy to understand and apply; and protects the public health." The Backgrounder notes that FDA and EPA consolidated their previous separate advisories and revised them according to recommendations received from FDA's Foods Advisory Committee in July 2002. Since that time, FDA tested over 3400 cans of tuna, and these results were added to the agency's previous sampling results, for FDA has been monitoring mercury in fish since at least 1990.

Consumer research plays an important part in FDA's determinations as to whether food label warnings are necessary and how the warnings should be worded. In the preamble to FDA's final rule on the unpasteurized juice warning, the agency discussed the comprehensive focus group testing it performed on the proposed label statements, in order to identify a statement that could inform consumers about a previously unrecognized hazard without being overly alarming. 63 Fed. Reg. 37030, 37035 (July 8, 1998). Similarly, in formulating the Consumer Advisory regarding mercury in seafood, FDA and EPA conducted 16 focus groups around the country to improve the advisory's readability. Based upon the agencies' scientific and consumer research,

> FDA and EPA designed an advisory that if followed should keep an individual's mercury consumption below levels that have been shown to cause harm. By following the advisory parents can be confident of reducing their unborn or young child's exposure to the harmful effects of mercury, while at the same time maintaining a healthy diet that includes the nutritional benefits of fish and shellfish.

Backgrounder, *supra*.

FDA meticulously balanced the need for alerting vulnerable populations to the potential harm from mercury in fish with its goal of encouraging consumption of fish. This is particularly the case because fish are a concentrated source of beneficial omega-3 fatty acids, which are not found in many other foods, and because fish often displaces less healthy sources of protein in the diet, such as meat higher in saturated fat. Additional policy considerations are

implicated with respect to canned tuna, which is the most affordable of the more popular commercial seafood items in the United States. As FDA acknowledged in a stakeholder meeting leading up to the issuance of the Consumer Advisory, canned tuna is an important source of omega-3 fatty acids and other nutrients for people on fixed and low income budgets.

Moreover, FDA and EPA crafted the Advisory to address dietary patterns of seafood consumption, rather than drafting separate messages for different species of fish. This deliberate choice was made to give a complete picture of the benefits and risks of seafood consumption, and to ensure that in making dietary choices, vulnerable consumers will not inadvertently choose less healthful options. A warning on canned tuna might lead pregnant women to consume instead a species of fish that is substantially higher in mercury, such as swordfish.

FDA should assert that a Proposition 65 warning on canned tuna would frustrate the federal policy embodied in its Consumer Advisory. The language of the Advisory expressly encourages consumption of healthful amounts of canned tuna and other beneficial fish so that the target population will receive the benefits of fish consumption while minimizing any risk. This delicate balance would be undermined by a Proposition 65 warning, which would discourage consumption of a food FDA expressly aims to promote, and would do so without an adequate scientific basis. The situation is comparable to that in *Dowhal*, where the court observed that

> in most cases FDA warnings and Proposition 65 warnings would serve the same purpose -- informing the consumer of the risks involved in use of the product -- and differences in wording would not call for federal preemption. Here, however, the FDA warning serves a nuanced goal -- to inform pregnant women of the risks of [smoking cessation] products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking. This creates a conflict with the state's more single-minded goal of informing the consumer of the risks. That policy conflict justifies federal preemption here.

Dowhal, 88 P.3d at 15.

For the reasons discussed above, FDA should state in a letter to California officials that the wording of the Consumer Advisory was carefully crafted by FDA and EPA, and is intended to convey the benefits and risks of seafood consumption in a manner that relates to patterns of dietary consumption. The language of the Advisory was tested through substantial consumer research to ensure that it accurately and meaningfully conveys the federal policy, and a Proposition 65 warning on canned tuna would frustrate this policy. Given the California Supreme Court's ruling in *Dowhal*, it is likely that a court would find persuasive an FDA assertion along the lines set forth above.

V. Negative Preemption

A. Principles of Negative Preemption

As noted in section I of this memorandum, a Congressional determination not to regulate a subject matter may provide grounds for a kind of "negative" preemption. *See Arkansas Elec. Co-op., supra*, 461 U.S. at 384; *Bonito Boats, supra*, 489 U.S. at 151. Similarly, courts have held that a federal agency's decision not to regulate can preempt state law. Specifically, the U.S. Supreme Court has held that "where failure of federal officials affirmatively to exercise their full authority takes on the character of a ruling that no such regulation is appropriate or approved pursuant to the policy of the statute, States are not permitted to use their police power to enact such a regulation." *Ray v. Atlantic Richfield*, 435 U.S. 151, 178 (1978) (internal ellipses and quotation marks omitted) (state's vessel-weight cap preempted on alternative grounds, including ground that Coast Guard could have, but did not, promulgate federal vessel-weight cap; state tug-escort requirement not preempted even though Coast Guard had not promulgated federal tug-escort requirement, because Coast Guard had issued notice of proposed rulemaking to adopt tug-escort requirement) (citing *NLRB v. Nash-Finch Co.*, 404 U.S. 138, 144 (1971); *Napier v. Atlantic Coast Line R. Co.*, 272 U.S. 605 (1926)); *United States v. Locke*, 529 U.S. 89, 110 (2000) (reaffirming *Ray*); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (stating that negative preemption by federal administrative agency is a "viable preemption theor[y]" but rejecting its application in that case based upon the facts); *see also Freightliner v. Myrick*, 514 U.S. 280, 286-87 (1995) (*Ray*'s negative-preemption reasoning inapplicable where "the lack of federal regulation did not result from an affirmative decision of agency officials to refrain from regulating air brakes...[but] from the decision of a federal court that the agency had not compiled sufficient evidence to justify its regulations.").

Significantly, even an agency determination that lacks the force of law might be sufficient to preempt conflicting state mandates under the doctrine of negative preemption. In *Sprietsma, supra*, 537 U.S. 51 (2002), the Supreme Court held that a Coast Guard decision against requiring propeller guards on motorboats did not preempt state tort claims against the boats' manufacturers based on the boats' lack of propeller guards. Several lower courts had concluded from the federal administrative history that the Coast Guard intended, by not regulating propeller guards, to preempt state tort law propeller-guard requirements; other lower courts concluded the opposite.

The Court rejected negative preemption in *Sprietsma* because it determined that the agency inaction was not intended to preclude the states from enacting propeller guard requirements. The Court explained:

> It is quite wrong to view [the Coast Guard's] decision as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation. The decision in 1990 to accept the . . . recommendation to "take no regulatory action" . . . left the law applicable to propeller guards exactly the same as it had been . . . .

537 U.S. at 65.

In analyzing the administrative history of the Coast Guard's determination, however, the Court's opinion provides guidance as to what kind of statement of agency policy against regulation might be sufficient to preempt state requirements on the subject at issue. The Court concluded that:

> nothing in [the Coast Guard's] official explanation [of its non-regulation decision] would be inconsistent with a tort verdict premised on a jury's finding that some type of propeller guard should have been installed on this particular kind of boat equipped with respondent's particular type of motor. Thus, although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, *it does not convey an "authoritative" message of a federal policy against propeller guards*. And nothing in the Coast Guard's recent regulatory activities alters this conclusion.

Id. at 67 (*citing Arkansas Elec. Co-op. Co.*, 461 U.S. at 384) (emphasis added).

Sprietsma is therefore best read as standing for the proposition that a federal agency's decision not to regulate will be accorded preemptive effect when it "convey[s] an 'authoritative' message of a federal policy against [the relevant kind of state regulation]." *Id.*; *Mejia v. White GMC Trucks, Inc.*, 784 N.E.2d 345, 352 (Ill. App. Ct. 1st Dist. 2002) ("[I]n *Sprietsma* . . . the Supreme Court held that the Coast Guard's decision not to regulate propeller guards did not preempt the plaintiff's common law action, *inter alia*, because 'it does not convey an "authoritative" message of a federal policy against propeller guards.'"), *app. denied*, 788 N.E.2d 729 (Ill. 2003).

Sprietsma's quotation of the word "authoritative" in the phrase "does not convey an 'authoritative' message of federal policy" is from *Arkansas Elec. Co-op. Co.*, 461 U.S. at 384, and in its original context the word cannot mean to require a positive enactment carrying the force of law. The original context states that "a federal decision to forgo regulation in a given area may *imply* an authoritative federal determination that the area is best left unregulated, and in that event would have as much pre-emptive force as a decision to regulate." *Id.* (emphasis added; and other emphases deleted from original as being irrelevant here). Accordingly, *Sprietsma*'s emphasis on the word "authoritative" should not be understood as requiring an agency statement carrying the force of law. Moreover, given that the four-judge minority in *Geier* two years earlier would have required an agency to publish its preemptive position in the Federal Register and subject it to notice-and-comment rulemaking, it is instructive that the unanimous decision in *Sprietsma* does not mention requiring such a formal assertion of preemption. Finally, as a practical matter, a decision *not* to regulate is rarely set forth in a regulation.

Further, lower court cases addressing negative preemption suggest that preemption could be found where a federal agency articulates the basis for its determination that no regulation is appropriate and states its intention to preempt states from enacting such regulation. *See, e.g., Burlington Northern R. Co. v. Minnesota*, 882 F.2d 1349, 1353 (8th Cir.

1989) (where FRA stated in "background report" apparently lacking any force of law, issued as part of a final rule published in the Federal Register, that "the FRA does not consider the lack of a caboose to be a safety issue per se," the "FRA's failure to enact a mandatory caboose requirement in the rule has 'taken on the character of a ruling that no such regulation is appropriate,' and is therefore the kind of inaction that has preemptive effect.") (quoting *Ray*, 435 U.S. at 178); *Pearson v. Columbus & Greenville Ry.*, 737 So.2d 390, 401 (Mo. Ct. App. 1999) ("[W]hen the [federal] agency molds inclinations and evidence into a determination that safety would not be enhanced [then] states become barred from regulating the subject.").

B. FDA Has Determined Authoritatively that Mercury Warnings on Canned Tuna Are Not Appropriate

FDA's authority to require warnings on food is grounded in the misbranding provisions of the FDCA set forth in sections 403(a)(1) and 201(n). In addition, FDA is empowered to promulgate labeling rules to achieve the implicit purposes of the FDCA, as well as its express provisions. *American Frozen Food Inst. v. Matthews*, 413 F. Supp. 548 (D.D.C. 1976), *aff'd*, 555 F.2d 1059 (D.C. Cir. 1977). Accordingly, FDA is authorized to require label warnings to ensure the safe consumption of food.

Despite this authority, FDA consistently has taken the position over many years that warnings should be used on FDA-regulated products judiciously, and only in cases that represent a significant risk. FDA has made clear that the FDCA "authorizes warnings and affirmative disclosures only with respect to serious hazards." 42 Fed. Reg. 22018 (April 29, 1977) (warning for fluorocarbons).

Agency decisions about whether to require the provision of particular warnings about a product are not made in isolation from fundamental decisions about whether the product is sufficiently safe to be marketed at all. FDA generally controls risk in food by prohibiting the marketing of a food or a food substance that may pose a risk to health, or by limiting the amount of a potentially dangerous substance in food by setting a tolerance level. As FDA explained in 1977, in response to a suggestion that warnings should be required on foods containing low levels of carcinogenic substances:

> The Commissioner advises that tolerances and action levels will be established at levels intended to ensure that food marketed is not hazardous to health. The suggested warnings would therefore be unnecessary and inappropriate. If any food is found to be hazardous to health, FDA will not permit it to be distributed in interstate commerce.

42 Fed. Reg. 52814 (Sept. 30, 1977).

To assure their efficacy, FDA has made sparing use of food product warnings. 42 Fed. Reg. 22018 (April 29, 1977) (warning for fluorocarbons). Indeed, current FDA regulations

contain only two mandatory food label warnings, relating to protein products (21 C.F.R. § 101.17(d)) and unpasteurized juice (21 C.F.R. § 101.17(g)).[10] FDA has repeatedly expressed its strong concern about proliferation of warnings on foods:

> A requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decision-making, and would not advance the public health.

44 Fed. Reg. 59509, 59513 (Oct. 16, 1979). More recently, FDA agreed that "too many warning labels on foods could result in loss of consumer credibility and effectiveness." 63 Fed. Reg. 37030, 37035 (July 8, 1998) (unpasteurized juice warning).

FDA has even expressed its label warning policy to California officials with respect to Proposition 65. In 1987, then FDA Commissioner Frank Young submitted the following statement to the California Scientific Advisory Panel:

> It is my strong belief that FDA regulated products that are lawfully sold in accordance with federal law do not pose a significant risk to human health. It is my further view that warnings on products that do not pose such a risk are unnecessary, are likely to be confusing and may be very costly to industry and consumers.

Statement of FDA Commissioner Frank E. Young to the California Scientific Advisory Panel (Dec. 11, 1987).

FDA is plainly authorized to mandate a warning for mercury in tuna, targeted to the susceptible population of women who are or may become pregnant, nursing mothers, and children. However, the agency has deliberately chosen not to do so. The Backgrounder emphasizes that "FDA and EPA want to ensure that women and young children continue to eat fish and shellfish because of the nutritional benefits and encourage them to follow the advisory so they can be confident in reducing their mercury exposure as well." Backgrounder, *supra*. As discussed, the Advisory was carefully crafted to express the dual message of encouraging consumption of seafood, including canned tuna, while advising certain consumers how to minimize their risk of harm from mercury. FDA and EPA plan to launch a comprehensive educational campaign promoting the Advisory's messages later this year.

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[10] Section 21 C.F.R. 101.17 contains certain other mandatory label requirements concerning safe handling or use of products, but these function essentially as directions for use, rather than as warnings about a substance in the food.

The Consumer Advisory, Backgrounder and related materials issued by FDA do not state that the agency considered and rejected the imposition of a label statement conveying a message regarding risks of mercury in tuna. It appears from these materials, however, that FDA and EPA deliberately chose a different vehicle for their message – the Advisory and the educational campaign. A letter from FDA to California officials should make clear that the agency considered and rejected requiring a label statement on tuna and other fish, or that FDA has since considered such a requirement and determined that it is inappropriate and contrary to the agency's approach to this issue.

Given FDA's statutory authority over food safety and labeling, including food warnings, the agency's scientific expertise in this area, its longstanding policy disfavoring warnings on food, and the approach to the mercury in seafood issue taken in the Consumer Advisory, an FDA "authoritative statement" expressed in a letter to California officials could preempt Proposition 65 mercury warnings on canned tuna under the doctrine of negative preemption, where the letter specifically articulates FDA's authority over the matter, its determination not to require such warnings, and its intention that states be preempted from mandating mercury warnings on tuna.

VI. Conclusion

A court would likely find Proposition 65 warnings on canned tuna to be preempted if FDA sent a letter to California officials articulating with specificity its statutory grant of authority over food labeling and food safety, its determination that a Proposition 65 warning regarding mercury in canned tuna would be misleading and would therefore misbrand the food, its conclusion that such warnings would frustrate the federal policy toward advising certain populations about the benefits and potential risks of seafood consumption, and its carefully-considered determination not to mandate mercury warnings on tuna.

October 8, 2004

MEMORANDUM

Re: Effect of FDA Action Level for Mercury in Fish on Federal Preemption of Proposition 65 Warnings for Canned Tuna

This supplements our August 12, 2004 memorandum regarding federal preemption of Proposition 65 warnings for canned tuna and considers the preemptive effect of the FDA action level for mercury in fish. As explained in our August 12, 2004 memorandum, Proposition 65-compliant warnings for canned tuna would be preempted by federal law, provided that FDA issues a letter to California officials clearly expressing the agency's preemptive intent. Proposition 65 warnings would be preempted on three grounds. Such warnings: (1) would be misleading in light of the recently revised joint FDA/EPA consumer advisory: "What You Need to Know About Mercury in Fish and Shellfish" (Consumer Advisory); (2) would frustrate the federal objective, reflected in the Consumer Advisory, of encouraging consumption of fish; and (3) would conflict with FDA's deliberate decision to address mercury in fish through means other than warnings. The FDA action level for mercury in fish provides further evidence of the agency's deliberate choice of pursuing a regulatory approach that excludes warnings.

In 1974, FDA published a proposal to establish by regulation an action level for mercury in fish and shellfish of 0.5 ppm.[1] The notice noted that methylmercury poses a greater potential for harm to pregnant women and women of childbearing age because methylmercury readily crosses the placenta and can potentially cause fetal brain damage.

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[1] 39 Fed. Reg. 42738 (December 6, 1974).

The 0.5 ppm action level was challenged in *United States v. Anderson Seafoods, Inc.*,[2] where the court concluded that, based upon the scientific data, an action level of 1.0 ppm was sufficient to protect the public health. FDA examined the data and agreed that a 1.0 ppm regulatory level would provide adequate protection to consumers, and in 1979 issued a Withdrawal of Proposed Rulemaking and Termination of Rulemaking Proceeding, setting the action level at 1.0 ppm rather than issuing a formal regulation.[3]

In setting the methylmercury action level, FDA did not explicitly state an intention to preempt state efforts to regulate mercury in fish. In contrast to the Consumer Advisory, which expressly promotes the health benefits of consuming fish, the action level addresses only the risks of consumption of methylmercury in seafood. FDA stated that it was proceeding by action level rather than a formal tolerance because the agency expected to continue to receive new information bearing on the appropriate limit for mercury in fish. FDA also announced that it would continue to monitor mercury levels in fish and related information, and would revise the action level accordingly if necessary. As recently as 2001, FDA stated that the agency is reevaluating the 1.0 ppm action level in light of significant new data on the health effects of methylmercury from consumption of fish, which data have become available since the action

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[2] 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980).

[3] 44. Fed. Reg. 3990 (January 19, 1979).

level was developed.[4] While FDA officials have stated that the agency may need to consider revising the action level,[5] no more recent assessment of the action level has been published.

The fact that FDA has established an action level for methylmercury in seafood supports the conclusion that Proposition 65 warnings for canned tuna are negatively preempted. FDA has clear authority to require a label warning but deliberately chose not to do so. Rather, the agency has pursued an alternative path – setting an action level, maintaining a monitoring program, and issuing the Consumer Advisory.

As discussed in our August 12 memorandum, FDA generally controls risk in food by prohibiting the marketing of a food or food substance that may pose a risk to health or by limiting the amount of a potentially dangerous substance in food by setting a tolerance or action level, rather than through label warnings. FDA's mercury action level and ongoing monitoring program, together with the agency's Consumer Advisory, represents FDA's carefully considered and multifaceted approach to regulating mercury in tuna, which excludes label warnings. In its recent responses to petitions for health claims for omega-3 fatty acids, FDA confirmed that it has broad discretion in choosing the means to pursue public policy, has determined that the Consumer Advisory is the preferable method to educate the target population about mercury in

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[4] *See* FDA/CFSAN, "Fish and Fisheries Products Hazards and Controls Guidance," Third Edition, June 2001, Chapter 10 (Methyl Mercury), available at http://www.cfsan.fda.gov/~comm/haccp4j.html.

[5] *See* Statement by Michael Friedman, M.D., Deputy Commissioner for Operations, FDA, before the Subcommittee on Livestock, Dairy, and Poultry Committee on Agriculture, U.S. House of Representatives, May 22, 1996, available at http://www.fda.gov/ola/1996/cfood.html.

fish and that label statements regarding mercury would have adverse public health consequences.[6]

While the Consumer Advisory is the principal basis for FDA preemption of Proposition 65 warnings for mercury in canned tuna, the FDA action level for mercury in fish provides significant additional evidence of FDA's carefully considered policy of addressing mercury in fish through means other than warnings. As explained in our August 12, 2004 memorandum, it is essential that FDA set forth the basis for preemption in a letter from the Acting Commissioner to appropriate California officials in order to prevent the nullification of FDA's carefully balanced regulatory scheme that limits mercury levels in fish, provides consumers with appropriate information about mercury risks and encourages consumption of healthful amounts of fish.

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[6] September 8, 2004 Letter Responding to Health Claim Petition (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease, p. 24.