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ORDER

PEOPLE OF THE STATE OF CALIFORNIA VS. TRI-UNION SEAFOODS, LLC.,

001C01447323

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO

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

Plaintiff,

vs.

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

Defendants.

Consolidated Case Nos. CGC-01-402975 and CGC-04-432394

Complaint Filed: June 21, 2004

FINDINGS OF FACT AND CONCLUSIONS OF LAW RE: PREEMPTION, MADL, and NATURALLY OCCURRING

Date: April 17, 2006
Time: 9:00 a.m.
Dept.: 206
Judge: Hon. Robert L. Dondero

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The State of California filed this action to challenge the Tuna Canners' refusal to comply with California's Proposition 65 warning requirements according to Health & Safety Code section 25249.5 et seq. The State argues that the Tuna Canners are required to place a Proposition 65 compliant health warning on defendants' tuna cans because of the potential health risks of methylmercury in canned tuna. This Decision is structured in four parts: (1) Issues Presented; (2) Findings of Fact; (3) Conclusions of Law; and (4) Court Order.

I.

ISSUES PRESENTED

This case contains three central issues: (1) Federal Preemption; (2) Maximum Allowable Dosage Level ("MADL") for methylmercury in canned tuna according to Proposition 65; and (3) Naturally Occurring Exception to Proposition 65 under 22 CCR §12501. This Court finds in favor of the Tuna Canners on all of the three central issues.

PREEMPTION

This Court is asked to decide whether federal law preempts Proposition 65 consumer warning requirements for canned tuna products. This Court concludes that federal law and the policy promulgated by the Food and Drug Administration ("FDA") preempts Proposition 65 warnings for canned tuna products.

MADL

This Court is asked to decide whether the Tuna Canners have met their burden of proving that the Maximum Allowable Dose Level ("MADL") for methylmercury under Health & Safety Code section 25249.5 et seq. ("Proposition 65") is 0.3 micrograms per day. This Court is also asked to determine whether the Tuna Canners have met their burden of

proving that the exposure of methylmercury in the Tuna Canners' food products is below the MADL, therefore exempting the defendants from Proposition 65's warning requirements.

After hearing extensive expert testimony from both sides and evaluating the persuasiveness and credibility of several peer-reviewed scientific studies, this Court finds that the Tuna Canners have met their burden of proving that the appropriate MADL for methylmercury under Proposition 65 is 0.3 micrograms per day based on the 1980 Bornhausen study involving methylmercury in rats. Furthermore, this Court finds that the Tuna Canners' exposure model shows that the level of methylmercury exposure in the Tuna Canners' food products is between 0.26-0.28 micrograms of methylmercury per day, which is below the approved MADL. Therefore, the Tuna Canners' products are exempt from Proposition 65's warning requirements.

NATURALLY OCCURRING

Lastly, this Court is asked to determine whether methylmercury in tuna is "naturally occurring" within the meaning of 22 CCR §12501. This Court is persuaded on balance that virtually all of the methylmercury in tuna originates from natural sources, while a small amount may be attributable to human activity. After undergoing traditional statutory construction analysis, this Court concludes that methylmercury in tuna fits within the "naturally occurring" exception to Proposition 65, in large part because the Tuna Canners have no way to control the level of methylmercury in their canned tuna products.

II.

FINDINGS OF FACT

PREEMPTION

I. FDA'S AUTHORITY AND ACTIONS CONCERNING WARNINGS FOR METHYLMERCURY IN CANNED TUNA

1. The United States Food and Drug Administration ("FDA") is an agency within the United States Department of Health and Human Services ("HHS"). Sullivan, Volume 14 Transcript ("14 Tr.") 1689:12-13, 19-21. FDA is entrusted to protect the safety of food, including seafood, in the United States through the administration of the Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. §§ 301 *et seq.*). Trial Exhibit ("TX 727"), p. 1-2. The FDCA prohibits the transmission in interstate commerce of food, including seafood, which is adulterated or misbranded. *Id.*; 21 U.S.C. §§ 343(a)(1) and 321(n). FDA also has broad statutory authority under the FDCA to regulate food labeling. TX 727, p. 2 (21 U.S.C. §§ 343 *et seq.*)

A. FDA Established a Methylmercury Action Level to Protect Against Adulterated Seafood

2. FDA generally controls food safety risks by prohibiting the marketing of foods that may pose health risks or by limiting the amount of potentially dangerous substances in foods by developing tolerance and action levels. *See, e.g.*, 42 Fed. Reg. 52814 (Sept. 30, 1977) (rejecting a suggestion that warnings should be required on foods containing low levels of carcinogenic substances as "unnecessary and inappropriate" because "tolerances and action levels will be established at levels intended to ensure that food marketed is not hazardous to health"). FDA's enforcement of "action levels" regarding the existence of contaminants in seafood guides the determination of "adulteration" under the FDCA. In 1979, FDA determined that a methylmercury action level of 1.0 part per million

is safe for seafood. 44 Fed. Reg. 3990, 3992 (January 19, 1979). Since then, FDA has maintained a rigorous monitoring and evaluation program but has found no need to adjust the methylmercury action levels in seafood. *See id.*

B. Tuna Is a Healthy Product that the Federal Government Encourages Americans to Eat

3. The Court heard the testimony of Dr. Louis Sullivan, the former Secretary of Health and Human Services ("HHS") from 1989 to 1993, regarding FDA's food labeling policy. Sullivan, 14 Tr. 1689:12-16; TX 836, p. 2. Dr. Sullivan has practiced medicine since 1958, held numerous teaching and academic positions, and is the founding dean of the Morehouse College School of Medicine. Sullivan, 14 Tr. 1693:28-1694:13; TX 836, pp. 1-2.

4. According to Dr. Sullivan, it is generally accepted in the medical community that fish consumption benefits health and that Americans would be better off eating more fish. Sullivan, 14 Tr. 1720:19-21; 14 Tr. 1721:4-7. For example, fish, including tuna, is a low-calorie source of protein and omega-3 fatty acids. Sullivan, 14 Tr. 1720:22-1721:3; Beard, 17 Tr. 2073:19-22; 17 Tr. 2073:25-2074:1; 17 Tr. 2074:11-24. Omega-3 fatty acids are important in enhancing the growth and development of infants prior to birth, and aid in the development the brain, nerves and eyes. Beard, 17 Tr. 2072:13-19; TX 501.

5. The Court also heard testimony about the health benefits of tuna from Dr. Lillian Beard, an expert witness proffered by the Tuna Canners who is a practicing physician with over thirty years of experience. TX 500, p. 1. Dr. Beard's practice specialty is pediatrics and adolescent medicine. Beard, 17 Tr. 2059:5-8. Dr. Beard is a Board-certified pediatric specialist and Diplomate for the National Board of Medical Examiners. Beard, 17 Tr. 2060:4-21; TX 500, p. 1. She is a spokesperson for the American Academy of Pediatrics and is an advocate for children. Beard, 17 Tr. 2067:26-2068:20; 17 Tr. 2070:18-21; TX 500, p. 5. Dr. Beard has been honored for her work improving the health of infants. Beard, 17 Tr. 2061:2-11; TX 500, p. 2.

6. Dr. Sullivan explained that pregnant women who consume less fish have a higher incidence of low birth weight preterm babies and babies born with complications.

Sullivan, 14 Tr. 1723:1-1724:1; TX 705. Interestingly, preterm birth is considered a developmental harm, which is the harm Proposition 65 warnings are supposed to communicate. Sullivan, 14 Tr. 1724:12-18; TX 2, p. 196 (22 CCR § 12601). Moreover, consumption of canned tuna, which is a low-cost, low-calorie food, is vital to American health because there is such a high incidence of obesity, especially among the poor. Sullivan, 14 Tr. 1696:4-27; Beard, 17 Tr. 2074:20-24; 17 Tr. 2075:7-21.

7. It is Dr. Beard's expert testimony that if people stop eating canned tuna, they will substitute other low-cost foods that are higher in fat, calories and cholesterol, such as processed meat or cheese. Beard, 17 Tr. 2077:17-2078:13; TX 501. For many people, substituting other fish for canned tuna is not practical because of the higher cost and increased difficulty in preparing the meal. Beard, 17 Tr. 2129:12-19.

8. The United States Food and Drug Administration ("FDA") and Environmental Protection Agency ("EPA") recommend in their 2004 Advisory ("FDA/EPA Advisory") that women who may become pregnant, pregnant women, nursing mothers, and young children eat up to 12 ounces (2 average meals) a week of fish and shellfish that are lower in mercury, including canned light tuna. TX 706. The FDA and EPA advise the same group that they may eat up to 6 ounces (one average meal) of albacore tuna per week. TX 706. According to FDA and EPA, fish and shellfish can contribute to heart health and children's proper growth and development. TX 706.

C. FDA Is Uniquely Qualified to Determine How to Convey Information to Consumers About Food and Health Issues

9. Dr. Sullivan is a well-known food-labeling expert who has advised and monitored the administration of food labeling in the United States for many years. TX 837, p. 2; Sullivan, 14 Tr. 1707:16-1710:24. During his tenure as HHS Secretary, Dr. Sullivan was responsible for overseeing the fourth largest budget in the world. Sullivan, 14 Tr. 1706:16-20. As HHS Secretary, Dr. Sullivan provided leadership and oversight of several agencies, including the Public Health Service, Social Security Administration and FDA. Sullivan, 14 Tr. 1705:16-1706:2.

10. Dr. Sullivan directed the amendment of FDA's food labeling regulations to make food labels more useful and understandable to consumers. Sullivan, 14 Tr. 1707:16-1708:6; TX 837, p. 2. Dr. Sullivan testified that he led this effort because of the concern that the information that was then on food labels was not in a form that was readily understood or usable by consumers. Sullivan, 14 Tr. 1708:7-18. The revised labels translate nutritional information, such as serving sizes, into a frame of reference that people use. Sullivan, 14 Tr. 1712:1-4; TX 838 (labels showing that one 2-ounce serving of canned tuna contains one percent of the daily value of total fat and twenty-three percent of the daily value of protein).

11. According to Dr. Sullivan, the process to amend FDA's food labeling regulations took more than two years to complete and involved a multi-disciplinary approach including consultation with scientists, consumer signage experts, survey experts, and other professionals and experts. Sullivan, 14 Tr. 1710:8-24; 14 Tr. 1781:5-14.

12. Consistent with its mission and practice, FDA has studied carefully the issue of methylmercury in fish for more than twenty-five years and has developed substantial expertise in analyzing both the scientific and consumer education aspects of the issue. TX 727, p. 2; 42 Fed. Reg. 52814. Accordingly, FDA is uniquely qualified to determine how to advise consumers on the issue of methylmercury in fish. *Id.*

D. Targeted Consumer Advisory Notices are the Preferred Method of Communicating Health Information Respecting Methylmercury in Fish

1. FDA's Consistent Policy Against Warnings on Food

13. FDA's policy on warning labels on food has been to implement a nuanced approach, where ingredient and nutrition information is disclosed, and warnings are required only under exceptional circumstances,[1] such as when food has been adulterated or

[1] *See, e.g.*, the regulations governing: aspartame (TX 839 (21 C.F.R. 172.804)); high protein products used for weight loss (TX 840 (21 C.F.R. 101.17(d))); and unpasteurized juice (TX 840 (21 C.F.R. 101.17(g))).

misbranded. Sullivan, 14 Tr. 1713:23-1714:1; 14 Tr. 1714:15-1715:6; 14 Tr. 1719:13-15; TX 727, p. 2; TX 837, p. 34; TX 839; TX 840. It is FDA's position that warning overexposure could lead consumers to ignore all warnings, which could create an even greater public health problem. *Id.*

14. FDA's policy against warnings concerning mercury is likewise reflected in a formal response to a 2003 petition requesting an extension of the Omega-3 fatty acids and coronary heart disease qualified health claims. TX 727, p. 4-5. FDA considered the petitioner's argument that the presence of mercury in seafood needed to be addressed in the health claim because Omega-3 fatty acids are contained primarily in oily fish. *Id.* FDA rejected this argument after extensive scientific review and deliberation, stating that:

> FDA has been addressing the issue of reducing the exposure to the harmful effects of mercury by communicating with this target population (pregnant women, women who might become pregnant, nursing mothers, and parents of young children) through the use of consumer advisories.

TX 727, p. 5. FDA concluded that the 2004 FDA/EPA Advisory provides the required information and ruled that "it is preferable not to use a label statement about mercury." TX 727, pp. 4-6.

2. FDA's Mandate for a Targeted, Balanced Message and Development of the Advisories

15. FDA's concern with warnings is the risk of overexposing consumers. Sullivan, 14 Tr. 1714:26-1715:6; 14 Tr. 1780:4-11. FDA also expresses this concern in its letter to Attorney General Lockyer describing why Proposition 65 is preempted as it applies to canned tuna. TX 727.[2]

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[2] FDA recently reiterated that state warnings on medications can frustrate FDA policy by: (1) overwarning, which causes consumers to ignore important warnings; (2) discouraging consumption of healthy products; and (3) threatening FDA's role as the expert agency responsible for evaluating and balancing benefits and risks. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3921, 3922, 3925 (January 24, 2006).

16. Dr. Sullivan testified that there is a negative relationship between warnings about fish and fish consumption. Sullivan, 14 Tr. 1722:6-15; 14 Tr. 1725:8-10. This opinion is supported by a study that found there was a decrease in fish consumption among pregnant women caused by negative press reports of chemicals in fish. TX 704; Sullivan, 14 Tr. 1722:5-15. This decrease in fish consumption could have adverse health consequences. *Id.* Dr. Sullivan stressed that, prior to imposing warnings, it is necessary to ensure that more harm is not caused by changing people's dietary habits inappropriately so that their diets are actually less healthy as a result. Sullivan, 14 Tr. 1734:13-21.

17. Following FDA's careful and long-term consideration of the issue, FDA concluded that a consumer advisory is the best method to educate the target population about mercury in fish for several reasons. TX 727, pp. 2-3. First, consumer advisories are communicated to the target audience directly. *Id.* Second, a consumer advisory approach is more effective than a label statement in communicating the complex messages about mercury in seafood. *Id.* Third, a label statement that reaches the general public can have unintended adverse public health consequences, such as reduced consumption. *Id.* FDA's policy approach in the FDA/EPA Advisory specifically avoids warning all consumers in favor of a more comprehensive and targeted approach. TX 727, pp. 1-2, 6.

18. FDA has issued fish advisories since the mid-1990s. TX 727, p. 3. In March 2001, FDA revised and changed the emphasis of its advisory to balance the relative benefits and possible risks of eating seafood. TX 727, p. 3; TX 507. In the March 2004 advisory, FDA presented the benefits of fish consumption first, followed by the risks of methylmercury exposure. TX 507, p. 1.

19. The FDA/EPA Advisory released in 2004 is the latest advisory in the evolution of FDA's nuanced and balanced approach to communicating the benefits and risks of fish consumption. TX 706. As FDA explained in its *Backgrounder for the 2004 FDA/EPA Consumer Advisory*, the FDA/EPA Advisory emphasizes the positive benefits of eating fish and addresses issues about mercury in fish. TX 762, p. 2; TX 727. The FDA/EPA Advisory was developed over the course of two years, and is based on several

recommendations made by the FDA Food Advisory Committee extensive scientific data and consumer testing through eight focus groups around the country. TX 762, pp. 2-3; TX 109, p. 1; TX 727, p. 3.

20. The objective of the 2004 FDA/EPA Advisory is to inform the target population of women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their exposure to methylmercury. TX 727, pp. 3-4; TX 706, p. 1; TX 762, p. 1. Although the FDA/EPA Advisory may reach people outside these populations, the advisory is targeted to these groups, is very specific that the consumption limitations are just for the target group, and reduces the risk of frightening people who are not at risk. TX 727, p. 1; Beard, 17 Tr. 2112:13-18; 17 Tr. 2115:3-12; Sullivan, 14 Tr. 1777:3-1780:11.

21. The current FDA/EPA Advisory, in contrast to previous advisories, also contains a section that provides a question and answer section about mercury in fish. TX 762, p. 2. The American Academy of Pediatrics concurs with the current FDA/EPA Advisory. Beard, 17 Tr. 2083:4-8.

22. FDA is opposed to warnings that reach the public at large because such warnings can "have unintended adverse public health consequences." TX 727, p. 3; *see,* Sullivan, 14 Tr. 1777:3-6.

23. Dr. Sullivan and Dr. Beard agree with FDA that it is important to communicate the balanced message of the benefits of consuming tuna along with the risks, just as the FDA/EPA Advisory now does. Sullivan, 14 Tr. 1746:13-16; Beard, 17 Tr. 2112:19-25.

24. Dr. Sullivan confirmed that, based on his experience overseeing FDA's food labeling amendment process, and his familiarity with current federal food labeling policy, FDA's approach to fish warnings is consistent with the agency's approach to food labels in general. Sullivan, 14 Tr. 1722:16-21; 14 Tr. 1734:11-25.

25. As a practicing physician that specializes in pediatrics and adolescent medicine, Dr. Beard uses the 2004 FDA/EPA Advisory in her practice when working with

patients. Beard, 17 Tr. 2059:8; 17 Tr. 2081. Dr. Beard verified that she receives hundreds of copies of the FDA/EPA Advisory from the FDA. Beard, 17 Tr. 2082:1-9. Dr. Beard places the Question and Answer Section of the Advisory in the waiting room of her office for patients to pick up and read about the benefits and risks of consuming tuna. Beard, 17 Tr. 2082:26-2083:3. When patients do see Dr. Beard, she finds the Question and Answer section of the Advisory as an excellent opportunity to have a dialogue with the patient families about fish and mercury. Beard, 17 Tr. 2082:13-2083:3. Dr. Beard's experiences evidence the FDA's targeted approach.

3. FDA's Information Campaign

26. FDA has undertaken several efforts to inform its targeted audience about fish and shellfish consumption and methylmercury in seafood through a comprehensive education campaign, which includes the publication of a consumer oriented magazine, the development of videos, and the dissemination of information through FDA's Offices of Consumer Affairs and Public Affairs ("CFSAN"). TX 727, p. 4; TX 762, p. 3.

27. FDA has developed and is implementing a comprehensive information plan that includes working with state, local, and tribal health departments to get information out to communities. TX 727, p. 4; TX 762, p. 3. FDA also sends information to physicians, other health professionals and health care associations to distribute through their offices. *Id.*; Beard, 17 Tr. 2082:1-9. CFSAN also operates a toll-free "Seafood Hotline" designed for consumers who have questions about labeling and other related matters. TX 706, pp. 2-3.

28. Dr. Beard testified that she disseminates and uses the FDA/EPA Advisory in her medical practice. Beard, 17 Tr. 2081:3-7. She testified that she receives hundreds of copies of the FDA/EPA Advisory from FDA and EPA for use in her practice in working with patients. Beard, 17 Tr. 2081:3-7. Dr. Beard uses the FDA/EPA Advisory to talk to her patients about their diet, fish consumption, and to have a dialogue about what is not clear concerning mercury in fish. Beard, 17 Tr. 2081:7-9; 17 Tr. 2082:15-2083:3.

29. Dr. Beard believes that it is important as a practicing pediatrician to decipher and distill the information on the FDA/EPA Advisory to her patients. Beard, 17 Tr. 2083:9-16. Dr. Beard opines that it is her role as a physician to explain the benefits of fish consumption and to help her patients understand the risks. Beard, 17 Tr. 2084:2-5.

30. Dr. Beard concurs with FDA's approach in distributing the FDA/EPA Advisory to physicians and healthcare providers to use with patients, and to include the question and answer section. Beard, 17 Tr. 2084:6-17. In her practice, Dr. Beard sees patients who, even after reading the FDA/EPA Advisory, still are confused about the FDA/EPA Advisory, and need to discuss it with her. Beard, 17 Tr. 2085:4-20. Therefore, the FDA/EPA Advisory provides Dr. Beard an opportunity to talk about the importance of fish consumption, and to discuss and explain the import of the advisory. Beard, 17 Tr. 2085:12-20; 17 Tr. 2111:28-2112:2.

E. FDA's Position that Product Label Statements Concerning Methylmercury Intake Are Preempted

31. In its letter to Attorney General Lockyer dated August 12, 2005 ("Preemption Letter")(Attachment A of this opinion), FDA makes clear that Proposition 65 warnings on tuna products are preempted for three reasons: (1) Proposition 65 warnings frustrate FDA's carefully considered and nuanced approach to advising the public concerning the benefits and risks of consuming canned tuna; (2) point of purchase warnings conflict with FDA's longstanding opposition to warning signs in connection with the sale of food; and (3) by singling out a healthy product that the federal government encourages Americans to eat, Proposition 65 warnings on canned tuna would be misleading under section 343 of the FDCA. TX 727, p. 6.

32. The views FDA expressed in its Preemption Letter are consistent with FDA's longstanding policy concerning food labeling and its work over the years concerning mercury and fish. Sullivan, 14 Tr. 1734:1-25.

II. THE STATE'S ATTEMPT TO RECONCILE FEDERAL LAW AND PROPOSITION 65

A. Proposition 65's Core and Mandatory Language

33. 22 CCR Section 12601(a) requires that, for a warning to be clear and reasonable, "the message must clearly communicate that the chemical in question is known to the state to cause birth defects or other reproductive harm." TX 2, p. 196. This is the language the defendant Tuna Canners assert is the core and mandatory language of any Proposition 65 warning sign. Plaintiffs argue that the core and mandatory language is just one way to adhere to Proposition 65's warning requirement. However, no Court ruling in favor of Proposition 65 enforcement has mandated anything other than the core and mandatory language of Proposition 65 codified in 22 CCR §12601.

34. One of the "safe harbor" warnings eliciting this core and mandatory language reads: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." §12601(b)(4)(B).

35. The Final Statement of Reasons for Section 12601 ("FSOR") explains that there are two parts to any Proposition 65 compliant warning: the manner in which the warning is presented and the message that is communicated. *See* FSOR, p. 2. The FSOR states that the term "clear" "appears to have been intended to refer to the message which the warning must convey." *Id.*, p. 2.

36. The FSOR also states that "the reference to the 'State of California' [in a warning] is intended to lend authority to the warning message and is an important part of it." *Id.*, p. 25.

37. Businesses are allowed to provide additional language to the warning. TX 2, p. 196 (22 CCR § 12601(a)). Section 12601(a) states that nothing in the section "shall be construed to preclude a person from providing warnings other than those specified in subsections (b), (c), and (d) which satisfy the requirements of this subsection, or to require that warnings be provided separately to each exposed individual." TX 2, p. 196.

B. The State Abandoned Proposition 65's Core and Mandatory Language in Order to Avoid Preemption

38. The State acknowledges that the safe-harbor language would be inappropriate in light of the FDA's approach to methylmercury in tuna and its own concern with violating the federal preemption doctrine. The Attorney General responded to the FDA's Preemption Letter on August 30, 2005 ("Lockyer Letter"). TX 728. In the Lockyer Letter, the Attorney General acknowledges that the safe-harbor language "would not be appropriate in these circumstances." *Id.*, p. 1. Rather, the State claimed that its proposed warning (which the Attorney General did not describe) would be consistent with the FDA/EPA Advisory, but be "more concise." *Id.*, p. 2.

III. THE STATE'S PROPOSED WARNINGS

A. Griffin Shelf Sign

39. The State's proposed shelf sign introduced at trial was designed by Dr. Dale Griffin ("Griffin Shelf Sign"). TX 365A. Dr. Griffin is a marketing professor at the University of British Columbia's Sauder School of Business. TX 105, p. 1.

40. Prior to this case, Dr. Griffin had never prepared a warning sign or label and had never prepared a point-of-purchase sign of any kind for any product. Griffin, 5 Tr. 570:28-3; 6 Tr. 673:4-11. Moreover, Dr. Griffin has no expertise concerning shoppers' in-store behaviors. Griffin, 6 Tr. 692:20-22.

41. Prior to developing the Griffin Shelf Sign, the Attorney General's Office did not ask Dr. Griffin to look at either the statute or the regulations. Griffin, 6 Tr. 634:19-22. Dr. Griffin did not look at the regulations until after he completed his signs, and he never read the statute. Griffin, 6 Tr. 634:23-27; 6 Tr. 673:15-20.

42. When Dr. Griffin was developing his sign and label, he happened to review the "safe harbor" Proposition 65 warning language from a "Fish Alert" that Dr. Jerry Wind, one of the Tuna Canners' experts, tested for purposes of settlement (Fiering, 14 Tr. 1672:27-1673:6, 9-13). Griffin, 6 Tr. 716:1-13. When Dr. Griffin asked the Attorney General's

Office whether he should include this language, the Attorney General instructed him not to include it or even work off it as a model. Griffin, 6 Tr. 678:25-679:10; 6 Tr. 682:2-686:28. Dr. Griffin further testified that "I think my instructions were don't think about legal issues, make it clear and reasonable." Griffin, 6 Tr. 634:13-14.

43. Instead, the Attorney General instructed Dr. Griffin to work off the FDA/EPA Advisory to develop his sign. Griffin, 6 Tr. 606:27-607:3; 6 Tr. 677:28-678:7; 6 Tr. 678:25-679:3. Accordingly, Dr. Griffin captured what he thought were the key messages from the FDA/EPA Advisory to put into his sign. Griffin, 6 Tr. 615:28-617:8. The Griffin Shelf Sign is Dr. Griffin's "concise way of telescoping what was important on the FDA site" and to "translate [the FDA/EPA Advisory] into a simpler, clearer sign." Griffin, 5 Tr. 581:4-6; 6 Tr. 617:9-12. According to Dr. Griffin, "clear" means, "it's easy to process and it's easy to find if you're searching for it." Griffin, 6 Tr. 612:18-19.

44. With no experience in developing warning signs, and with no consideration of the requirements of Proposition 65, Dr. Griffin developed his warning sign (and a can label) in just eighteen days, revising and cutting down the message that a team of FDA experts took at least four years to develop. Griffin, 6 Tr. 698:27-699:27; TX 106; TX 108.

45. Dr. Griffin followed the State's directive that he create a condensed version of the FDA/EPA Advisory and changed the FDA/EPA Advisory in several ways. Dr. Griffin's Shelf Sign does not begin with, and indeed excludes, the first paragraph of the FDA/EPA Advisory, which announces, "Fish and shellfish are an important part of a healthy diet." Griffin, 6 Tr. 699:11-27; TX 706; TX 365A. By excluding the lead-off benefits paragraph, Dr. Griffin does not include several of the detailed benefits from eating fish, including its being low in saturated fat and containing Omega-3 fatty acids. Griffin, 6 Tr. 699:14-17; TX 706; TX 365A.

46. Dr. Griffin's Shelf Sign starts with Recommended Limits (rather than benefits), but leaves off the identification of fish that pregnant women should not eat: Shark, Swordfish, King Mackerel and Tilefish. Griffin, 6 Tr. 696:4-9; TX 365A. The Griffin Shelf Sign suggests that women and children in the target groups can safely eat up to twelve

ounces of these fish per week, because no qualification is placed upon the recommended limits other than for canned tuna. TX 365A.

47. Dr. Griffin changes the FDA's recommendation that the target group eat a certain amount of fish and shellfish, including canned light and albacore tuna, to a limiting statement. TX 706; TX 365A.

48. Dr. Griffin changes the FDA/EPA Advisory's language from "Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system" to "Mercury can build up in the body and harm the developing nervous system of an unborn baby or young child." TX 706, p. 1; TX 365A.

49. Dr. Griffin also omits the Frequently Asked Questions contained in the FDA/EPA Advisory. Griffin, 6 Tr. 701:4-7; TX 706, p. 2; TX 365A.

50. Dr. Griffin testified that consumers often stop reading after the first or second point in a message and never get to the third point. Griffin, 6 Tr. 693:5-14. However, Dr. Griffin placed his purported warning language ("Risks") in the third paragraph of the sign, so consumers would be unlikely ever to read the warning part of his point of purchase sign. Griffin, 6 Tr. 609:9-15; 6 Tr. 693:10-27. Because this language is not easy to find, it is not "clear" according to Dr. Griffin's standards. Griffin, 6 Tr. 612:18-19.

51. Additionally, the Griffin Shelf Sign does not contain the core and mandatory language of Proposition 65. *See* 22 CCR § 12601(a). The Griffin Shelf Sign does not include the word "Warning", it does not mention the State of California, and it does not say that methylmercury is known to cause birth defects or reproductive harm. TX 365A.

52. Dr. Griffin targeted nursing mothers and young children in the sign. Griffin, 6 Tr. 688:4-15; TX 365A. However, because methylmercury is listed as a developmental toxicant, and only prenatal exposure is to be considered, the only target audience for any methylmercury warning under Proposition 65 is women of childbearing age. Rice, 2 Tr. 82:6-14; 4 Tr. 353:11-13. Also, the Griffin Shelf Sign refers to fish and shellfish, which would lead not only to a reduction in the consumption of tuna, but also of all seafood. Cohen, 7 Tr. 808:1-809:24; TX 365A.

53. The Griffin Shelf Sign is designed as a point-of-purchase sign to be placed on the shelf where canned tuna is sold. Griffin, 5 Tr. 574:23-27; TX 365A. According to the State's expert Dr. Cohen, any point-of-purchase sign or package label could affect the purchase decisions of all consumers, not just those in the target population. Cohen, 7 Tr. 801:7-19. In fact, the State's penalties theory is based on the premise that a point-of-purchase warning sign would reduce tuna consumption by all consumers by at least eleven percent. Cohen, 7 Tr. 778:2-12. Dr. Cohen used eleven percent as a conservative estimate. Cohen, 7 Tr. 779:1.

B. Griffin Can Label

54. The other warning Dr. Griffin produced, the Griffin Can Label, starts with the word "Warning," which Dr. Griffin testified is a fear-provoking word. Griffin, 6 Tr. 686:8-17; TX 365B. Also, the label contains neither a reference to the State of California nor language about birth defects or reproductive harm. TX 365B.

C. Dr. Griffin's Internet Experiment

55. Dr. Griffin testified that, in his opinion, the shelf sign and can label are "clear and reasonable" warnings about methylmercury in canned tuna. Griffin, 5 Tr. 579:23-580:12. However, Dr. Griffin did not testify what, if any message, was clearly and reasonably conveyed. There is limited support for Dr. Griffin's conclusion in any event. Dr. Griffin's opinion is based on an Internet experiment he conducted where he tested the effect of the Griffin Shelf Sign, Griffin Can Label and Wind Shelf Sign. Griffin, 6 Tr. 635:20-27. Dr. Griffin admitted that the experiment is not generalizable to the California population, was not conducted in an in-store environment, and was conducted without a control group. Griffin, 6 Tr. 638:24-26; 6 Tr. 708:21-26; 6 Tr. 711:21-712:18.

56. Dr. Yoram (Jerry) Wind testified about additional deficiencies in Dr. Griffin's experiment. His background and significant experience is detailed in this Statement of Decision at paragraph 66.

57. Dr. Wind criticized Dr. Griffin for not taking measures to ensure that the experiment's participants were not professional respondents who are paid and want to

answer questions. Wind, 17 Tr. 2170:21-2171:21. Another issue is that Dr. Griffin did not verify his results. Wind, 17 Tr. 2186:25-2187:3; 17 Tr. 2189:10-12. The questions Dr. Griffin asked in his experiment also encouraged respondents to guess if they did not know an answer. Wind, 17 Tr. 2189:19-20. According to Dr. Wind, encouraging such speculation is against industry practice and affects the reliability of the data. Wind, 17 Tr. 2189:23-2190:9.

58. Dr. Griffin's experiment does show that exposure to the Griffin Shelf Sign may lead to decreased tuna consumption. Griffin, 6 Tr. 663:7-20; TX 110, p. 15.

D. PMC Campaign

59. A second plaintiff in the case, Public Media Center ("PMC"), proposed a nebulous education campaign. TX 368. Herb Gunther of PMC testified that this unformed "concept" might include point-of-purchase signage, but had not yet developed the message to be communicated. Gunther, 7 Tr. 748:16-23; 7 Tr. 751:4-12; 7 Tr. 751:21-25. Mr. Gunther did not know if the Attorney General's Office approved of this concept. Gunther, 7 Tr. 748:24-749:5.

MADL

I. THE WITNESSES

60. **F. Jay Murray, Ph.D.**, received his Ph.D. in toxicology from the University of Cincinnati College of Medicine, Institute of Environmental Health in 1974. Murray, Volume 10 Transcript ("10 Tr.") 1143:1-3; 10 Tr. 1147:21-23; Trial Exhibit ("TX") 657, p. 1. Dr. Murray was certified as a toxicologist by the American Board of Toxicology in 1980, and has been recertified every five years thereafter. Murray, 10 Tr. 1148:14-28; TX 657, p. 2. He is a member of the following toxicology associations: American Board of Toxicology, Society of Toxicology, Society of Risk Analysis and Academy of Kettering Fellows. TX 657, p. 2. Dr. Murray has thirty-one years of experience as a toxicologist. TX 657, p. 1. Since 1992, he has been a consulting toxicologist for business, trade and

government agencies, including the United States Environmental Protection Agency and the California Environmental Protection Agency ("California EPA"). Murray, 10 Tr. 1144:21-26; 10 Tr. 1146:1-3; TX 657, p. 2.

61. Dr. Murray has significant credentials as a Proposition 65 toxicologist. He was appointed by the governor of California and served nearly three years as a member of the Proposition 65 Scientific Advisory Panel from 1987-1989. Murray, 10 Tr. 1136:28-1137:1-6; 10 Tr. 1141:1-3; TX 657, p. 2. As a member of the Scientific Advisory Panel he participated in reviewing the State's risk assessments, including MADLs, under Proposition 65 and the regulations. Murray, 10 Tr. 1137:14-17; 10 Tr. 1138:12-15. From 1987-1989, he served on the Reproductive Toxicity Subcommittee for Proposition 65. Murray, 10 Tr. 1137:12-14. Several years later, he was invited to rejoin the successor to the Scientific Advisory Panel, the Developmental and Reproductive Toxicity Committee, but declined for personal and professional reasons. Murray, 10 Tr. 1141:6-9, 11-13. Recently, Dr. Murray was asked to serve as a peer reviewer on the California EPA's internal report evaluating the quality and role of the science in the California EPA. Murray, 10 Tr. 1141:28-1142:13; TX 817.

62. **Dr. Deborah Rice** is a Toxicologist at the Environmental Health Unit, Maine Bureau of Health. She is not Board Certified. Rice, 2 Tr. 70:26-71:5; TX 7, p. 1. Before this case, Dr. Rice had no experience performing a quantitative risk assessment under Proposition 65 and had never calculated an MADL. Rice, 2 Tr. 81:20-82:1; TX 7. The State presented Dr. Rice's testimony both to criticize Dr. Murray and in support of the alternative MADL the State proposes for methylmercury. The Office of Environmental Health Hazard Assessments ("OEHHA"), a division of the California EPA, has never submitted Dr. Rice's MADL for internal review and public comment in accordance with OEHHA's procedures for developing a proposed MADL. Zeise, 16 Tr. 2027:23-2028:12; Rice, 4 Tr. 320:24-27. The State instructed Dr. Rice not to consult with OEHHA in developing her MADL. Rice, 3 Tr. 241:24-242:1. Dr. Rice never asked OEHHA (1) how the agency calculated its MADLs; (2) whether, and under what circumstances, OEHHA had ever used human studies as the

basis for its MADLs; (3) why OEHHA chose the Bornhausen study as the basis for its draft MADL; and (4) whether OEHHA had ever used a benchmark dose ("BMD") analysis as the basis for an MADL. Rice, 3 Tr. 240:27-241:16.

63. **Dr. Mari Golub** is a part-time staff scientist at the Reproductive and Cancer Hazard Assessment Branch of OEHHA. Golub, 4 Tr. 377:21-23. This branch works primarily on Proposition 65 issues, with the bulk of its work devoted to hazard identification and MADL development. Golub, 4 Tr. 378:3-11. Dr. Golub worked on the draft MADL for methylmercury that OEHHA prepared and published beginning in 1993. Golub, 4 Tr. 452:16-18; TX 77.

64. **Dr. Lauren Zeise** has been the Chief of the Reproductive and Cancer Hazard Assessment Branch of OEHHA since 1991. Zeise, 16 Tr. 1960:11-13, 18-21. She has worked for OEHHA on Proposition 65 MADLs since 1988. Zeise, 16 Tr. 1961:10-14. Dr. Zeise was on a team that recommended the final draft MADL for methylmercury in 1993. Zeise, 16 Tr. 1962:11-13.

65. **Dr. Robert Brodberg** is a senior toxicologist at the Pesticide Environmental and Toxicology Branch ("PETS") of OEHHA. Brodberg, 16 Tr. 1929:18-25; 16 Tr. 1930:20-26. Dr. Brodberg has a Ph.D. in biology with an emphasis in genetic toxicology. Brodberg, 16 Tr. 1929:15-17. As part of his job at PETS, Dr. Brodberg issues advisories that are included in fishing regulations published by the California Department of Fish & Game. Brodberg, 16 Tr. 1930:13-16. Dr. Brodberg testified about OEHHA's calculation of permissible methylmercury exposure through fish consumption.

66. **Dr. Yoram (Jerry) Wind** is a tenured professor of marketing at the Wharton School of Business with a Ph.D. in Marketing from Stanford. Wind, 17 Tr. 2137:24-2138:1; 17 Tr. 2138:4-9; TX 734, p. 1. Dr. Wind is a forty-year veteran in the field of market research who has designed and conducted hundreds of surveys of consumer behavior and preference for trials, consulting engagements, and in his lectures at Wharton. Wind, 17 Tr. 2156:4-12. Dr. Wind is a recipient of the four most prestigious awards in marketing: the Charles Coolidge Parlin Award, the Irwin Award, the Paul D. Converse Award, and the

Elsevier Science Distinguished Scholar Award. Wind, 17 Tr. 2150:27-2151:21; TX 734, p. 1. He is a member of the Attitude Research Hall of Fame, and in 2001 was selected as one of the ten *Grand Auteurs* in Marketing. Wind, 17 Tr. 2151:22-25; TX 734, p. 1. Dr. Wind has consulted to the United States and Canadian governments, and to the Israeli Defense Ministry. He is currently consulting an agency of the Treasury Department on methods of identifying terrorist financing. Wind, 18 Tr. 2213:15-2214:6; TX 734, p. 33. Dr. Wind has been a member of the editorial boards of a number of leading marketing journals. Wind, 17 Tr. 2159:17-28; TX 734, pp. 40-41. Among Dr. Wind's publications (21 books and more than 250 papers, articles and monographs), Dr. Wind authored "Statistics in Marketing" in the Encyclopedia of the Statistical Sciences. Wind, 17 Tr. 2151:27-2152:12; TX 734 passim and p. 19. Dr. Wind testified about the survey he prepared and conducted in order to determine the average frequency of consumption of canned tuna by women of childbearing age in California.

67. **Dr. Dale Griffin** is a professor at the Sauder School of Business at the University of British Columbia. Griffin, 19 Tr. 2370:14-17. The State offered Dr. Griffin's testimony on the meaning of the word "average."

68. **Dr. Sander Greenland** is a professor of epidemiology and professor of statistics at the University of California Los Angeles. Greenland, 20 Tr. 2606:9-11. He received a Bachelor's and Master's in mathematics from the University of California at Berkeley in the early 1970s. Greenland, 20 Tr. 2606:24-27. The State offered Dr. Greenland's testimony on the meaning of the word "average."

II. TUNA CANNERS' IDENTIFICATION OF THE APPROPRIATE MADL UNDER SECTION 12803

69. Under Proposition 65, "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause ... reproductive toxicity without first giving clear and reasonable warning to such individual...." TX 1 p. 1. The Regulations provide that if a person can show that the

exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, a warning is not required. This exposure is termed the maximum allowable dose level, or MADL. TX 2, § 12801, pp. 200.4-200.5; Murray, 10 Tr. 1147:6-7.

70. Regulations governing Proposition 65 outline the procedures for identifying the level at which a chemical has no observable effect (the "NOEL") and calculating whether the level of exposure to the chemical is at or below the NOEL. TX 2, pp. 200.5-200.6.[3] A risk assessor calculating a MADL under section 12803 is required to select the study producing the lowest NOEL from the most sensitive study deemed to be of sufficient quality. Murray, 10 Tr. 1172:25-1173:12; TX 2, p. 200.5.

A. Dr. Murray's Reliance on the Bornhausen Study as the Most Appropriate Study Under Section 12803

71. To prepare his risk assessment under section 12803, Dr. Murray reviewed more than thirty epidemiological and animal studies to determine the most appropriate study upon which to base a Proposition 65 MADL for methylmercury. Murray, 10 Tr. 1183:6-9.

72. Dr. Murray concluded that the Bornhausen study represented the best quality study that yielded the lowest NOEL – 0.005 milligrams per kilogram – out of all the studies he evaluated. Murray, 10 Tr. 1181:2-4; 10 Tr. 1183:21-24; 10 Tr. 1184:4-6.[4] The Bornhausen study was performed by a team of doctors in the Department of Radiation Biology, Department of Toxicology, Gesellscheft fur Strahlen-und Umweltfaschung, in Germany. TX 82. The senior author, Dr. Helmut Greim, is a well-known and renowned

[3] Section 12801(a) outlines the general framework for establishing the level at which methylmercury has no observable effects under Proposition 65, and mandates that the NOEL shall be divided by one thousand (1,000) to arrive at a maximum allowable dose level. TX 2, p. 200.4.

[4] The Burbacher study yielded the same NOEL. Murray, 10 Tr. 1197:7-10.

toxicologist, and the recipient of one of the highest awards in the field of toxicology. Murray, 10 Tr. 1182:10-16; TX 82, p. 305. In 1980, the Bornhausen study was published in a prominent peer-reviewed scientific journal, *Toxicology and Applied Pharmacology*, which at the time was the official journal of the Society of Toxicology. Murray, 10 Tr. 1182:17-20; TX 82, p. 305.

73. The Bornhausen study tested the potential effects of prenatal exposure to methylmercury using rats. Murray, 10 Tr. 1183:2-3. Rats have been sufficiently well studied to enable researchers to conclude that the half-life of methylmercury in a rat is fourteen days, and that the normal gestation period is twenty-two days. Murray, 10 Tr. 1183:2-3; 10 Tr. 1186:6-9. A total of sixteen pregnant rats were dosed with varying levels of methylmercury (control, 0.005, 0.01, and 0.05 mg/kg) on the sixth, seventh, eighth, and ninth days of gestation. Murray, 10 Tr. 1186:2-5; TX 82, p. 305. The methylmercury was delivered to the pregnant rats' stomachs directly through a tube inserted into the mouth ("by gavage"). Murray, 10 Tr. 1184:8-23; 10 Tr. 1185:12-15; TX 82, p. 306(2). Because the rats were dosed by gavage, the researchers could control the exposure dose. Murray, 10 Tr. 1184:26-28. Given the fourteen-day half-life of methylmercury and the twenty-two-day gestation period, dosing the pregnant rats through the ninth day guaranteed that the exposure to methylmercury in the fetal rats continued through the period of brain development until birth. Murray, 10 Tr. 1186:1-27. By cross-fostering the rat pups after birth, the Bornhausen study researchers ensured that the pups were not postnatally exposed to methylmercury. Murray, 10 Tr. 1186:28-1187:17.

74. After the pups reached full physical and mental maturity, the researchers examined their growth, survival, and sex ratio. Murray, 10 Tr. 1188:4-6, 21-28. The researchers also administered the Differential Reinforcement of High Rates ("DRH") test to assess the potential effects of prenatal methylmercury exposure on the pups' learning and motor skills. Murray, 10 Tr. 1189:2-4. Initially, each rat was trained to press a lever at a high rate and was rewarded with a food pellet. Murray, 10 Tr. 1189:7-8. The rat was then required to learn that when a light came on, it had to press a lever during a five-minute

period to get a food pellet. Murray, 10 Tr. 1189:7-14. The pattern changed from two bar presses per second, to four bar presses in two seconds, to eight bar presses in four seconds. Murray, 10 Tr. 1189:14-21; TX 82, p. 306. The test was designed specifically to evaluate neurodevelopmental learning deficits. Murray, 10 Tr. 1190:2-10.

75. A total of eighty rats were tested in four dose groups. Murray, 12 Tr. 1458:4-6; TX 82, p. 306. Among the four groups, effects of methylmercury exposure were seen in the pups at 0.05 and 0.01 mg/kg/day but not at 0.005 mg/kg/day. TX 82, p. 308; TX 659, p. 3. Based on these figures, the Bornhausen study concluded that the NOEL for methylmercury in rats is 0.005 mg/kg. Murray, 10 Tr. 1250:25-26; TX 659, p. 3.

B. OEHHA Also Relied on the Bornhausen Study to Prepare the Draft MADL in 1993

76. In 1993, Drs. Mari Golub and Lauren Zeise, together with other scientists at OEHHA, also determined that the Bornhausen study represented the best quality study that yielded the lowest NOEL under section 12803. Golub, 4 Tr. 452:9-18; TX 77, p. 1. OEHHA considered epidemiological data from the Minamata and Iraq poisoning episodes, and a New Zealand human epidemiological study, but concluded that the Bornhausen study was the most sensitive and most scientifically appropriate study on which to base the MADL for methylmercury. Golub, 5 Tr. 493:11-494:4; TX 77, pp. 54-68.

77. From 1993 and continuing throughout the trial, OEHHA published the draft MADL for methylmercury of 0.3 micrograms (ug)/day in OEHHA's Status Report available on the OEHHA Proposition 65 website.[5] Golub, 4 Tr. 465:8-11; TX 548, p. 16; TX 549, p. 16.

[5] Dr. Zeise testified that, based on discussions with the Attorney General's Office and no scientific evidence, shortly before trial, OEHHA noted in an obscure portion of its website that the draft MADL for methylmercury was "obsolete." Zeise, 16 Tr. 1979:21-2009:11.

78. Although OEHHA used the Bornhausen study as the basis for the draft MADL for methylmercury, at trial Dr. Golub questioned whether the rats were exposed to methylmercury during the critical periods of brain development. Golub, 4 Tr. 423:5-23. Because of the fourteen-day half-life of methylmercury, the dosing assured that exposure continued through the period of brain development to birth. Murray, 10 Tr. 1183:2-3, 1186:6-9.

79. Dr. Golub also questioned whether the pups in the Bornhausen study may have been exposed to methylmercury during the postnatal period through their food. Golub, 4 Tr. 421:3-6. Dr. Golub conceded that only Purina formula 5001 and AIN-93G rat chow have been found to have detectable levels of methylmercury. Golub, 5 Tr. 524:14-15. The rats in the Bornhausen study were fed the Altramin standard diet, and no study has ever suggested that this diet was contaminated with methylmercury. Murray, 10 Tr. 1193:16-23. If the rat chow used in the Bornhausen study had contained methylmercury, the NOEL would have been higher because the rats would have actually ingested more methylmercury than accounted for by the study. Murray, 10 Tr. 1194:9-19, 10 Tr. 1195:8-11. The resulting MADL would have been higher, not lower. Murray, 10 Tr. 1195:8-11.

C. Both Dr. Murray and OEHHA Selected Animal Studies Rather Than Human Studies to Calculate an MADL for Methylmercury Under Proposition 65

80. Both Dr. Murray and OEHHA agree that, unlike animal studies, human studies such as the Faroe Islands, Seychelles, and New Zealand studies fail to provide the necessary "reliable ascertainment of exposure" that Proposition 65 requires. Murray, 10 Tr. 1202:18-28; TX 2, p. 200.5; TX 77, p. 2. In his expert report, Dr. Murray stated that "there is no scientifically sound way to derive a LOEL or a NOEL from [the] human epidemiologic studies" conducted in the Faroe Islands, the Seychelles, or New Zealand. TX 659, p. 8.[6]

[6] Section 12803(a)(7) provides that where data in the most sensitive study deemed to be of sufficient quality do not allow for the determination of a NOEL, a NOEL may be derived by dividing the lowest observable effect level ("LOEL") by a factor of 10. TX 2, p. 200.5.

Further, none of these studies distinguished between effects due to pre- rather than postnatal exposure. TX 659, p. 10. Due to the difficulty of controlling all aspects of humans' lives, epidemiological studies are often confounded by exposure to chemicals other than methylmercury, like PCBs, which are known to cause neurodevelopmental harm. Murray, 10 Tr. 1203:1-9; 10 Tr. 1239:16-29; TX 659, pp. 11-12. In contrast, all aspects of the animal's life can be controlled in an animal study, including exposing the animals to the same drinking water, climate, and living conditions. Murray, 10 Tr. 1203:2-5.

81. Dr. Chernoff, an OEHHA scientist who authored a memo explaining OEHHA's reliance on the Bornhausen study for the draft MADL in 1993, mirrored Dr. Murray's concern with using human studies as a basis for calculating an MADL, noting that the human data "was limited in terms of sample size, range of exposure, time of exposure, and actual intake levels of MeHg (methylmercury). Since these variables were well defined in the rat study, the animal NOEL was considered the most appropriate for deriving a Proposition 65 MADL." TX 77, p. 3. Dr. Chernoff declined to rely on the human data from the Iraq poisoning episode[7] because it would produce a MADL of 0.004 ug/day, a number so low that it would be "scientifically difficult to defend." Murray, 11 Tr. 1357:18-27; TX 77, p. 3.

82. Dr. Golub testified that, "all final MADLs that have ever been formulated by OEHHA have been based on animal studies" and "animal studies will always be permitted if they represent the most sensitive study of sufficient quality." Golub, 4 Tr. 385:5-8; 4 Tr. 387:12-25. Consistent with this, OEHHA's Final Statement of Reasons for Proposition 65 (the "Statement of Reasons") recognizes "[t]he difficulty in identifying a NOEL from

[7] In Iraq, individuals consumed bread over a period of several months that was made with grain treated with a fungicide containing methylmercury, resulting in severe mercury poisoning. Rice, 2 Tr. 124:1-20.

reproductive toxicants when the effects of concern are based upon human experience rather than animal bioassays" because "there is often no precise data predicting what levels will produce no observable effect." TX 3A, p. 78.

83. The only chemicals for which OEHHA has used and calculated a MADL based on human studies are lead and ethylene oxide. Murray, 11 Tr. 1344; Zeise, 16 Tr. 1975:8-27. For each of these chemicals, OEHHA relied on the federal Occupational Safety & Health Administration ("OSHA") Permissible Exposure Levels (a "PEL") as surrogates for the NOEL. Murray, 12 Tr. 1456-1457. OSHA PELs pinpoint the level of exposure to a particular chemical that will not cause reproductive harm based on "experience derived from the occupational exposures..." TX 3, p. 78.

D. Currently Available Epidemiological Data on Methylmercury Is Not Suitable for Use Under Proposition 65

84. Dr. Murray properly concluded that the Faroe Islands, Seychelles and New Zealand studies were unsuitable as a basis for a quantitative risk assessment under § 12803(a)(2) of the California Code of Regulations. TX 2, p. 200.5; Murray, 10 Tr. 1202:18-28.

1. Faroe Islands

85. The Faroe Islands study is a human epidemiologic study involving 900 children in the Faroe Islands beginning in 1986 (the "Faroe Islands study"). Rice, 2 Tr. 126:5-127:5; TX 34, p. 1. A team of researchers from the Harvard School of Public Health and a team of government-employed scientists in the Faroe Islands conducted the Faroe Islands study. TX 38, p. 1. The Faroe Islands study researchers sought to analyze the effects of prenatal exposure to methylmercury. The Faroese's primary exposure to methylmercury comes from eating pilot whale. Murray, 10 Tr. 1214:19-22; TX 34, p. 418. To measure exposure to methylmercury, researchers examined maternal hair and umbilical cord blood

and tissue.[8] Rice, 2 Tr. 126:17-21. Levels of mercury detected in the hair and cord blood were then correlated with a variety of endpoints, including motor skills, sensory, hearing, vision, balance, and neuropsychological development tests. Golub, 4 Tr. 402:20-25.

86. The Faroe Islands study does not meet the requirements of § 12803(a)(2) because it fails to have both an exposed and a reference group, fails to have reliable ascertainment of exposure, has incomplete follow-up, and fails to identify or quantify all biases and confounding factors.[9] Murray, 10 Tr. 1164:14-23; TX 2, 200.5. Additionally, the exposure in the Faroe Islands population was not limited to the prenatal period. Murray, 11 Tr. 1376:81-14.

2. New Zealand

87. The New Zealand study was designed as a case control study.[10] Rice, 2 Tr. 129:3. The principal exposure to mercury in New Zealand is through the popular meal of fish and chips, which is made from shark meat. Rice, 3 Tr. 267:1-268:13; TX 91, 1691. After delivering a baby, women were surveyed about their pregnancy diet, specifically how many fish meals they ate per week during their pregnancy. TX 4A, p. 134.

88. Dr. Murray testified he did not believe that the New Zealand study was appropriate to use in developing a Proposition 65 MADL because the size of the study was very small. Murray, 10 Tr. 1242:4-9. The analysis was based on approximately 38 mother-child pairs found to have high mercury levels. Murray, 10 Tr. 1242:9-11. OEHHA also

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[8] Cord blood levels will show mercury ingestion during the last trimester of pregnancy. Rice, 3 Tr. 258:21-24. Maternal hair will show mercury ingestion only during the second trimester of pregnancy. Murray, 10 Tr. 1212:16-1213:6.

[9] A confounding factor is "a factor that is associated both with the chemical that is being studied and the endpoint that is being studied ... it's something that can explain the results of the study other than the chemical that was originally being studied." Murray, 10 Tr. 1171:8-13.

[10] A potential strength of the New Zealand study was that it grouped the data according to hair mercury levels and frequency of fish consumption. Rice, 2 Tr. 129:3-8; TX 77, p. 59. However, the size of the study was too small to be meaningful. TX 77, p. 60.

rejected the New Zealand study because it was too small, making it impossible to predict a threshold dose or the probability of a response at a given dose. TX 77, pp. 2-4; TX 77, p. 60; Zeise, 16 Tr. 1972:9-1973:3.[11]

89. Furthermore, the New Zealand data was not published in the peer-reviewed literature. Murray, 10 Tr. 1242:13-15. The New Zealand study documents in evidence are copies of reports issued by the Swedish government. TX 45 & 46; Rice, 2 Tr. 100:12-15. These reports are not peer-reviewed and no copies of subsequent analysis of the study in a peer-reviewed journal were placed in evidence. TX 45; TX 46.

3. The Seychelles Study

90. The Seychelles study is a large epidemiologic study examining the effects of methylmercury on more than 700 children. Rice, 2 Tr. 130:11-13. Unlike the Faroe Islands, the Seychelles is an island nation where the primary source of methylmercury is from ocean fish, which are consumed on average twelve times per week. Murray, 10 Tr. 1243:1-10; TX 91, p. 1. Methylmercury exposure in the Seychelles was measured in maternal hair. TX 91, p. 1. Although the maternal hair mercury levels in the Seychelles were actually higher than those recorded in the Faroe Islands, no adverse effects from methylmercury exposure to the neurological performance of children have been noted in the Seychelles study. Rice, 2 Tr. 130:16-17; Murray, 10 Tr. 1249:14-15; TX 91, p. 1. Notably, the ocean fish consumed in the Seychelles have undetectable levels of PCBs. Murray, 10 Tr. 1244:1-28; TX 33, p. 703.

E. Dr. Murray's MADL Calculation Is Based on the Bornhausen Study

91. Health and Safety Code section 25249.10(c) provides that businesses are exempt from the Proposition 65 warning requirements if an exposure "will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and

[11] Dr. Rice stated that the New Zealand authors did not address whether the exposure was limited exclusively to prenatal exposure. Rice, 3 Tr. 192:9-12.

standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8." TX 1, p. 4.

92. Dr. Murray calculated his MADL by multiplying the NOEL from the Bornhausen study by 58 kg, the statutorily defined weight of the average woman, and dividing this number by 1,000 to reach a Proposition 65 MADL of 0.00029 mg/day, which he rounded to 0.3 micrograms (ug)/day. Murray, 10 Tr. 1250:18-1251:2; TX 659, p. 3. Dr. Murray's method for deriving the MADL was identical to the calculation OEHHA used in 1993 to develop the draft MADL for methylmercury. Murray, 10 Tr. 1251:4-6; TX 77, pp. 1-2.

93. Dr. Rice contended that a methylmercury MADL of 0.3 ug/day is inappropriate because "actual clinical effects" have been seen at levels less than 300 ug, which is 1,000 times the Tuna Canners' MADL. Rice, 2 Tr. 157:17-23. Dr. Rice claimed that the Iraq study noted clinical effects at exposures of 200 and at 50 micrograms/day. Rice, 2 Tr. 157:17-23; TX 786, p. 2. Dr. Rice claimed that the World Health Organization ("WHO") had "observed" paresthesia in persons poisoned in the Iraqi grain episode at a daily dose of 50 and 200 micrograms.[12] She was specifically asked, and testified under penalty of perjury that the paresthesias were "observed not modeled." Rice, 25 Tr. 3152:10-15. When, however, Dr. Rice reviewed the WHO Report, she admitted that the 50-ug/day "impairment" and the "impairment" of 200 ug/day and below were modeled "extrapolations beyond the observed data." Rice, 25 Tr. 3154:10-3156:11.

94. Dr. Murray compared the MADL derived from the Bornhausen study with a study evaluating spatial vision in monkeys exposed prenatally to methylmercury (the "Burbacher study"). Murray, 10 Tr. 1196:14-16; TX 48. As with the Bornhausen study, the Burbacher study's experimental design included a control group and three dosed groups.

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[12] Dr. Rice wrote that an intake of 50 ug/day would result in a 0.3 percent risk of paresthesia, while an intake of 200 ug/day would involve a paresthesia risk of approximately 6-8 percent. TX 786, p. 2. Parethesia is not a developmental effect. Murray, 11 Tr. 1371:6-7; 1372:7-8.

Murray, 10 Tr. 1197:4-5; TX 48, p. 2. The Burbacher study identified a LOEL of 50ug/kg/day and a NOEL for methylmercury of 5ug/kg/day. Murray, 10 Tr. 1198:18. The NOEL calculated from the Burbacher study is identical to the NOEL identified in the Bornhausen study. Murray, 10 Tr. 1197:7-10. To calculate an MADL from the Burbacher study, Dr. Murray multiplied the NOEL by 58 kilograms and divided by 1,000 to reach an MADL of .3ug/day, as required by §§ 12801(b)(1), 12803(b). TX 820; Murray, 10 Tr. 1198:9-1199:7; TX 2, pp. 200.4-200.5. [13]

95. The State's expert, Dr. Rice, endorsed the Burbacher study as an appropriate study from which to derive the MADL, but performed an additional calculation designed to adjust the monkey NOEL to a human NOEL to account for pharmacokinetics. TX 786, p. 1; Murray, 10 Tr. 1199:22-28. Section 12803 does not require adjustments to NOELs derived from animal studies, nor are there any regulations that dictate how to adjust an animal NOEL to a human NOEL.[14] Murray, 10 Tr. 1200:5-16; Golub, 5 Tr. 491:11-15; Murray, 12 Tr. 1464-1465; TX 2, p. 200.5. Significantly, as discussed above, OEHHA has used animal studies for every published MADL except for lead and ethylene oxide, and has never adjusted an animal LOEL or NOEL to a human NOEL. Murray, 12 Tr. 1464:15-20; 11 Tr. 1464:25-1465:1; Golub, 5 Tr. 491:9-10. It mystifies this Court why Dr. Rice felt compelled to go against traditional scientific norms and adjust the NOEL derived from animal studies

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[13] Dr. Murray testified that he initially rejected the Burbacher study because the only information that was available about the study when he prepared his report was a 1999 abstract. Murray, 10 Tr. 1197:13-14. The abstract did not eliminate the possibility that the baby monkeys were postnatally exposed to methylmercury through their mothers' milk. Murray, 10 Tr. 1201:17-20. The full article published in 2005, however, does not state that the animals were cross-fostered. TX 48. Dr. Rice, one of the authors of the Burbacher study, testified that the baby monkeys were isolated from their mothers and raised in a primate nursery, where they were bottle fed, thus alleviating Dr. Murray's only concern regarding the Burbacher study. TX 48; Rice, 25 Tr. 3172:20-3173:5; 3073:16-23.

[14] Dr. Murray testified that while section 12803(a)(6) does not allow the mathematical conversion proposed by the State, it does permit a scientist to use certain factors like pharmacokinetics in their reasoning as to whether or not a study is appropriate for use under section 12803. Murray, 11 Tr. 1385:22-1388:5. The statement of reasons for 12803(a)(6) and OEHHA's practice support Dr. Murray's interpretation of the regulations. TX 3A, p. 76; TX 77, pp. 1-2.

when the statute does not call for any such adjustment nor do historical practices of OEHAA make such corrections.

III. THE STATE'S PROPOSED MADL

96. In this case, the State proposes that the Court accept the MADL that its expert, Dr. Deborah Rice, calculated. As noted above, OEHHA has not adopted or proposed Dr. Rice's MADL, and Dr. Rice did nothing to ensure that her MADL was calculated consistently with MADLs that OEHHA has adopted. Rice, 3 Tr. 240:27-241:16.

97. Dr. Rice based her MADL on the Faroe Islands study. Rice 2 Tr. 126:5-127:5. The principal neuropsychological development test in the Faroe Islands study that showed an effect upon the children was the Boston Naming Test, which is a test of both language processing and expressive language. Rice, 2 Tr. 149:24-150:1. The children's performance on the Boston Naming Test at age seven was correlated to the mercury level in cord blood drawn at the time of birth. TX 4A, p. 300.

A. Deficiencies of the Faroe Islands Study

98. An epidemiological study may form the basis of a risk assessment under section 12803(a)(2) if the study has features such as: selection of the exposed and reference group, reliable ascertainment of exposure, completeness of follow-up, and both identification and quantification of biases and confounding factors. Murray, 10 Tr. 1164:14-23; TX 2, p. 200.5. Further narrowing the range of appropriate Proposition 65 studies is the requirement that a study evaluate pre-, rather than postnatal, exposures.[15] Murray, 10 Tr. 1376:8-14.

[15] The parties agreed that because Proposition 65 evaluates chemicals that cause reproductive toxicity, a study that forms the basis for a risk assessment under section 12803 must evaluate prenatal exposure to methylmercury. Murray, 11 Tr. 1376:8-14; Rice, 2 Tr. 95:28-96:8; TX 659, p. 10.

99. Few human epidemiologic studies can meet the strict requirements Proposition 65 imposes.[16] As discussed above, OEHHA has never authored a published MADL based on human epidemiologic data. Murray, 10 Tr. 1164:5-10. Ignoring the heightened requirements Proposition 65 imposes, Dr. Rice mistakenly assumed that suitable epidemiological studies under section 12803 are the same as for any other type of risk assessment. Rice, 2 Tr. 96:9-14. Contrary to Dr. Rice's assumptions, the Faroe Islands study is not of sufficient "quality and suitability" under section 12803(a)(2) to derive a NOEL under Proposition 65.

1. The Faroe Islands Study Has No Exposed or Reference Groups

100. Appropriate Proposition 65 epidemiological studies will have grouped data including an exposed group and a reference or control group. Murray, 10 Tr. 1164:14-20; 10 Tr. 1165:1-8; TX 2, p. 200.5. The Faroe Islands study had no groups because all islanders were exposed to an unknown amount of methylmercury primarily through eating pilot whale. Murray, 10 Tr. 1209:21-22, 1214:19-22; Golub, 4 Tr. 441:11-15; TX 34, p. 418. According to the Faroe Islands study investigators; the average Faroese adult eats 12 grams of pilot whale muscle and 7 grams of pilot whale blubber per day. Pilot whale contains an average mercury concentration of 3.3 ug/g. TX 80, p. 141. Whale blubber contains large amounts of DDT – about 20 ug/g. TX 80, p. 145. Additionally, the blubber contains substantial amounts of PCB's, which acted as a significant confounding factor to the epidemiological study. See discussion, *infra,* at III (A)(4). Without a control group, investigators were unable to compare the effects on exposed groups to non-exposed groups. Murray, 10 Tr. 1165:6-28, 1223:15-27.

[16] OEHHA proposed that human epidemiological data form the basis for the MADL for arsenic, but a public comment critical of the study sent the proposed arsenic MADL back to the drafters. Murray, 12 Tr. 1454:13-1455:6.

2. The Faroe Islands Study Lacks a Reliable Ascertainment of Exposure

101. Proposition 65 also requires epidemiological studies to have a reasonable ascertainment of exposure. Murray, 10 Tr. 1166:1-8; TX 2, p. 200.5. For all published final MADLs, OEHHA has known the amount of exposure to the chemical. Golub, 5 Tr. 496:27-497:5. One way that investigators can reliably ascertain exposure to methylmercury (or another chemical) in an epidemiological study would be to require participants to maintain a food diary. Murray, 10 Tr. 1166:1-10. The Faroe Islands investigators, however, did not have the mothers keep a food diary and do not know how much mercury was ingested by any of the women in the study. Golub, 5 Tr. 489:15-24; Murray, 10 Tr. 1211:8-10.

102. Cord blood is not a reliable indicator of the actual dose of methylmercury ingested during pregnancy because cord blood primarily reflects mercury exposure during the third trimester only, which "might not correspond to the periods of greatest fetal sensitivity to MeHg neurotoxicity." TX 4A, p. 137. Dr. Golub narrowed the period of exposure even further, testifying that cord blood reflects exposure only during a two to three week time period late in the pregnancy. Golub, 4 Tr. 454:7-11.

103. Reliable ascertainments of exposure also cannot be pinpointed through the use of a benchmark dose analysis ("BMD"), which uses mathematical modeling to predict the likely exposure to a chemical over time based on the known chemical level in the blood (a biomarker) on a particular day. Murray, 10 Tr. 1267:1-10; 10 Tr. 1207:1-8. OEHHA's Status Reports have never included a final or draft MADL based on a BMD analysis, nor has OEHHA issued a draft or a final MADL in which a BMD was used as a surrogate for a LOEL. Golub, 4 Tr. 438:21-27-439:1. For all previous MADLs the actual dose of the chemical exposure was known. Golub, 4 Tr. 441:7-10.

3. The Faroe Islands Study Suffers from Incomplete Follow-Up

104. Proposition 65 mandates that an appropriate epidemiologic study have complete follow-up of the subjects enrolled in the study. Murray, 10 Tr. 1167:16-18; TX 2,

p. 200.5. The Faroe Islands study suffered from incomplete follow-up by: (1) failing to collect prenatal PCBs and DDT from umbilical cord blood, (2) failing to test for postnatal exposure to methylmercury, PCBs, and DDT, and (3) failing to publish neuropsychological data from the 14-year-old cohort. Murray, 10 Tr. 1167:16-1168:15; 10 Tr. 1228:22-28; 10 Tr. 1239:24-1231:1.

105. The average daily exposure to PCBs among Faroese women exceeds the United States reference dose ("RfD") for PCBs by 172 times, and the average daily exposure to methylmercury exceeds the RfD for methylmercury by four times. Murray, 10 Tr. 1216:21-1218:27; 10 Tr. 1221:1-11; TX 821. Despite these higher exposure levels, the Faroe Islands researchers never measured the prenatal PCB exposure for approximately half of the children. Murray, 10 Tr. 1228:22-25; TX 796, p. 3. The Faroe investigators also failed to document and analyze the amount of methylmercury, PCBs, and DDT that the children were exposed to postnatally by either their mother's milk or by eating whale after they were weaned. Murray, 10 Tr. 1169:18-1170:2; 10 Tr. 1223:20-23; 10 Tr. 1241:15-25. If a child is exposed prenatally to both methylmercury and PCBs, and proper exposure measurements are not made of both chemicals, it is impossible to determine what chemical caused the poor results on the Boston Naming Test. Murray, 10 Tr. 1228:2-10; TX 796, p. 3.

4. The Faroe Islands Study Does Not Adequately Identify or Quantify Biases and Confounding Factors

106. An appropriate epidemiologic study for use under Proposition 65 must identify and quantify all biases and confounding factors. Murray, 10 Tr. 1168:16-1169:3; TX 2, p. 200.5. A bias is any factor that consistently changes the results in one direction of the study. Murray, 10 Tr. 1170:4-7. A confounding factor is "a factor that is associated both with the chemical that is being studied and the endpoint that is being studied ... it's something that can explain the results of the study other than the chemical that was originally being studied." Murray, 10 Tr. 1171:8-13. The Faroe investigators failed to identify and quantify the bias and confounding factors that could overestimate the effects of methylmercury mercury in their data.

107. PCBs are a confounding factor in the Faroe Islands study. Murray, 10 Tr. 1233:19-1234:5. Like methylmercury, PCBs are an established neurotoxicant. Murray, 10 Tr. 1228:2-10; TX 796, p. 3. Prenatal exposure to PCBs was documented to be a confounding factor on the children's performance on the Boston Naming Test in the seven-year-old cohort for whom PCB exposure was measured. Murray, 10 Tr. 1223:26-28; Golub, 4 Tr. 408:1-9; TX 34, p. 425; TX 98. Although the initial report from the Faroe Islands study found a correlation between neuropsychological developmental defects and methylmercury exposure as measured by the Boston Naming Test, when the investigators controlled for concurrent PCB exposure, they found that the *correlation* between methylmercury exposure and performance deficits on the Boston Naming Test was not significant. Golub, 4 Tr. 408:1-9; Tx 34, p. 425; Tx 98. In other words, the Faroe Study investigators raised doubts about the statistical significance of the methylmercury exposure in the Boston Naming Test because of the PCB confounding factor. Golub, 4 Tr. 408:1-23; Tx. 34, p. 425; Tx 98. Dr. Rice ignored the confounding effects of PCBs, and did not quantify the effects that PCBs had on the Boston Naming test in her proposed MADL. Rice, 3 Tr. 213:9-13; TX 8.

108. The incomplete PCB data introduced bias, which was not adequately quantified into the results of the Faroe Islands study. Murray, 10 Tr. 1235:2-10; TX 796, p. 1. In the Faroe Islands study the PCB measurements were collected from cord tissue rather than cord blood, the way PCBs are usually measured. Golub, 5 Tr. 529:6-9; TX 34, p. 420. The authors theorized that about half of the PCBs were recovered from the cord tissue and made estimations of exposure based on this assumption. Golub, 5 Tr. 528:16-25; TX 363, p. 307. In a recent attempt to quantify the influence PCBs had on the study endpoints, the Faroe investigators acknowledge that if the error in measurement of the PCBs exceeds 46%, the effects seen in the Faroe Islands are not due to methylmercury at all. Murray, 10 Tr. 1226:28-1227:11; TX 796, p. 16. The investigators' failure to quantify error can cause an overestimate of the mercury effect in the Faroe Islands. Golub, 5 Tr. 515:24-27; Murray, 10 Tr. 1227:2-11; TX 796, p. 16. The authors admit that they assumed an error

rate of zero, even though the error rate for the measurement of PCBs is definitely greater than zero. Murray, 10 Tr. 1227:22-1228:1; TX 796, p. 16.

109. Another confounding factor in the Faroe Islands study was the fact that rural and urban populations had different availability of food. Whale meat was not available in Tvan, a city on the Faroe Islands where some of the mothers in the study lived while they were pregnant. Murray, 10 Tr. 1229:6-23; TX 796, p. 3. Although the authors noted that the city children had higher scores on the Boston Naming Test than their rural counterparts (where whale meat was available), they did not consider whether the difference was attributable to the lower levels of PCBs and DDT in the city mothers' diets compared to the rural dwelling mothers, a possible explanation for the difference. Murray, 10 Tr. 1229:6-1231:5; TX 796, p. 3.

5. The Faroe Islands Study Does Not Adequately Separate Prenatal from Postnatal Effects

110. The Faroe Islands investigators recognized that one of the "shortcomings" of the study was its failure to separate the effects caused by pre- versus postnatal methylmercury exposure. Murray, 10 Tr. 1209:23-25; TX 38, p. AGO 01712. This is a unique requirement under Proposition 65 because most agencies do not separately regulate prenatal and postnatal exposure. Rice, 2 Tr. 96:4-8.

111. Children were exposed to methylmercury, PCBs, and DDT prenatally during gestation and postnatally through breast milk and subsequently through their own diet. Murray, 10 Tr. 1169:18-1170:2; 10 Tr. 1222:12-24; 10 Tr. 1223:20-23; 10 Tr. 1241:15-25. The authors made no attempt to quantify the level of mercury in the breast milk and to determine what, if any, effect the postnatal methylmercury exposure had on the children. Murray, 10 Tr. 1222:14-20; TX 34, p. 420. The authors also did not measure postnatal exposure to PCBs through breast milk, even though the authors noted in an earlier paper that an "infant's total intake of PCBs during the nursing period may average up to five percent of the total lifetime exposure and increased susceptibility may augment the risk." Murray,

10 Tr. 1222:25-1223:8; TX 80, p. 145. The authors also did not measure pre- or postnatal exposure to DDT. Murray, 10 Tr. 1223:20-23.

112. In a paper published after the NRC report,[17] the Faroe investigators examined maternal serum, breast milk, and cord blood for 28 individual PCB congeners[18] and 18 types of pesticide and pesticide metabolites.[19] Murray, 10 Tr. 1221:21-1222:7; TX 791, p. 13. In a cohort established solely to study the effect of PCB exposure, the Faroe Islands investigators noted that the milk of the Faroese mothers has some of the highest concentrations of PCBs found in the world. TX 823, pp. 1-2. The nursing children in the Faroe Islands are therefore exposed to high levels of PCBs, a known neurotoxicant, during an important time of human brain development and in the postnatal period. Murray, 10 Tr. 1239:16-27. Failure to identify and quantify PCB exposure through breast milk disqualifies the Faroe Islands study for use under Proposition 65 because there is no way to separate out prenatal versus postnatal exposures to neurotoxicants. Murray, 10 Tr. 1241:12-14; TX 659, p. 10.

6. The NRC Report, Which Endorsed Reliance on the Faroe Islands Study, Was Published in 2000, Before a Series of Articles Focused on PCBs in the Faroes

113. The State relies heavily on the 2000 NRC Report, which concludes that the Boston Naming Test results of the Faroe Islands study are an appropriate basis for a reference dose ("RfD"). TX 4A, p. 317. The NRC failed to cite a critical paper in which the Faroe Islands authors state that a new cohort was being formed in the Faroe Islands to study the role of PCBs. Murray, 11 Tr. 1269:20-1270:11; TX 4A; TX 80.[20] Following the

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[17] Toxicological Effects of Methylmercuy, National Research Council (2000).

[18] Cogener is defined as (1) a member of the same taxonomic genus as another plant or animal; (2) a chemical substance related to another. Merriam-Webster's Medical Dictionary (2002).

[19] Metabolite is defined as a substance essential to the metabolism of a particular organism or to a particular metabolic process. Merriam-Webster's Medical Dictionary (2002).

[20] In 1998 the health authority in the Faroe Islands issued the following advisory – "The best way to protect fetuses against the harmful effects of PCBs is if girls do not eat blubber until after they have given birth to their children" but the NRC failed to mention this in their report. Murray, 10 Tr. 1237:23-1238:3; TX 822, p. 899.

publication of the NRC report, four papers have been published discussing the high levels of PCBs in the Faroe Islands. Murray, 11 Tr. 1270:12-1272:10; TX 796; TX 822; TX 791; TX 823. [21]

B. The Boston Naming Test Has No Statistically Significant Relationship to Methylmercury Exposure

114. Dr. Rice based her MADL on a single endpoint, the Boston Naming Test, which tests language-processing skills. Rice, 2 Tr. 149:20-150:1. The initial report from the Faroe Islands study correlated neuropsychological developmental defects and methylmercury exposure reflected in the Boston Naming Test results. TX 34, p. 1. When investigators controlled for concurrent PCB exposure, there was no statistically significant correlation between methylmercury exposure and performance deficits on the Boston Naming Test. Golub, 4 Tr. 408:1-9; TX 791, p. 12. The authors of the Faroe Islands study recognized the impact of PCBs rather than methylmercury on the results of the Boston Naming Test, noting that "especially for the Boston Naming Test, the PCB concentration appeared to be an important predictor" of the children's performance. TX 34, p. 425. Consequently, the EPA peer review of the methylmercury Reference Dose advised against relying on the Boston Naming Test without an adjustment for PCB exposure. TX 362, p. 5. Dr. Rice herself listed PCB exposure as causing deficits on the Boston Naming Test. TX 791, p. 18.

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[21] While the NRC (National Research Council) is a part of the National Academy of Sciences and a respected professional group, this Court has on at least one prior instance dealt with a series of reports by the NRC that created controversy. In 1992, the NRC published *DNA Technology in Forensic Science.* The report addressed DNA evidence in the courtroom, and suggested serious controls on its use. A number of groups, led by the FBI Laboratory, challenged the 1992 NRC Report. The tumult triggered a new, more embracing assessment of forensic DNA. That new report was *The Evaluation of Forensic DNA Evidence,* published in 1996 by the NRC. This 1996 rejected certain findings in the 1992 Report.

C. Benchmark Dose Has Never Been Used by OEHHA and Is Not a Reliable Method for Determining the MADL

115. Dr. Rice used a benchmark dose ("BMD") analysis to derive her MADL. Using data generated from the Boston Naming Test in the Faroe Islands study, Dr. Rice chose a number that she describes as the benchmark dose level ("BMDL") corresponding to a 5% likelihood of an effect due to methylmercury on the Boston Naming Test as the starting point for her MADL calculation. Rice, 3 Tr. 184:21-185:21; TX 360X. There are sixteen different models that can be used to produce a BMD analysis, and each would yield a different result. Murray, 10 Tr. 1207:9-14.

116. A BMD is not the same as a NOEL or LOEL. Murray, 10 Tr. 1205:21-24; Rice, 3 Tr. 245:25-246:3; TX 95, p. 110. Section 12803(a)(1) of the regulation requires that the risk assessor arrive at a NOEL in order to calculate a Proposition 65 MADL. TX 2, p. 200.5. In a 2003 article, Dr. Rice recognized that values derived from a BMD analysis do not represent a threshold, nor are they comparable to a NOAEL or LOEAL as typically derived from animal studies. TX 95, p. 110.[22] The NRC cautioned that "cord blood is not a reliable indicator of the actual dose of methylmercury ingested." TX 4A, p. 137. Nevertheless, to calculate her MADL, Dr. Rice used a BMD as a substitute for a LOEL. Rice, 3 Tr. 244:5-12.

117. OEHHA has never used a BMD analysis to calculate a MADL. Golub, 4 Tr. 438:21-26. Dr. Golub testified that OEHHA has never used a BMD analysis for a final MADL and none of the final or draft MADLs that have been published in the status report are based on BMD analysis. Golub, 4 Tr. 438:21-26. OEHHA has never issued a draft or a final MADL in which a BMD analysis was used as a surrogate for a LOEL. Golub, 4 Tr. 438:27-439:1. For all previous MADLs, the actual dose of the chemical exposure was known. Golub, 5 Tr. 496:27-497:5.

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[22] Dr. Rice testified that a NOAEL and a LOAEL are virtually indistinguishable from a NOEL and a LOEL. Rice, 3 Tr. 243:27-244:4.

118. Using her BMD analysis, Dr. Rice calculated virtually the same MADL from the Faroe Islands study and from the Seychelles study, which showed no adverse effects of methylmercury. Murray, 10 Tr. 1243:1-5; Rice, 3 Tr. 288:2-25; TX 91, p. 1; 360T. According to Dr. Golub, because no adverse effect was seen in the Seychelles, this study cannot be used to derive a LOEL or a MADL. Golub, 4 Tr. 451:16-452:1. Dr. Rice testified that she based her methodology on the NRC report; however, the NRC committee did not say that the BMDL analysis was analogous to a LOEL, nor did it endorse using it to find a NOEL. Rice, 2 Tr. 168:2-9; TX 4A: 272-273.

119. Dr. Rice testified that to create her MADL, she took the BMD and called it a LOEL. Rice, 3 Tr. 244:5-16. The BMDL in the NRC Report is 58. TX 4A, p. 327. If that is a LOEL, under the Regulations, one would divide it by 10, multiply by 58 and divide by 1,000. TX 2, p. 200.5. This would give a MADL of 0.3. Instead, Rice derived a much lower MADL by transforming the BMDL to a much lower number, 0.8, based on an article entitled "A Revised Probabilistic Estimate of the Maternal Methyl Mercury Intake Dose Corresponding to a Measured Cord Blood Mercury Concentration," authored by Dr. Alan H. Stern. TX 42. Among other things, Dr. Stern postulated that the maternal to fetal blood ratio for methylmercury is 1.0:1.7, meaning that the fetus has a 70% higher concentration of methylmercury circulating in its blood than the mother. Rice, 3 Tr. 222:22-24; TX 42. Dr. Stern's 1.0:1.7 ratio has not been factored into the risk assessment performed by the EPA/FDA Advisory authors or by OEHHA's fish advisory group. Rice, 4 Tr. 345:11-13; Murray, 11 Tr. 1277:24-27; Brodberg, 16 Tr. 1939:24-1940:2; TX 514, p. 7. According to Dr. Murray, there is no scientific consensus that the ratio is 1.0:1.7, or that it is anything other than 1:1; therefore, it is not appropriate to incorporate this calculation into a Proposition 65 risk assessment. Murray, 11 Tr. 1277:12-27; TX 360E; TX 825.

D. Problems with Dr. Rice's Credibility

120. Dr. Rice neglected to quantify the effect of PCBs on the Boston Naming Test for her MADL calculation even though in 2003 she published a paper entitled "Effects of PCB Exposure on Neuropsychological Function in Children," which concluded that PCBs

caused the performance deficiencies measured by the Boston Naming Test. TX 791, p. 18. Dr. Rice's paper reports that a number of endpoints in the Faroe Islands study, including the Boston Naming Test, were negatively associated with methylmercury until the authors controlled for the effects of PCBs. TX 791, p. 12. After the researchers controlled for PCBs, there was no statistically significant correlation between methylmercury and the Boston Naming test or any neuropsychological endpoint other than the continuous performance test. *Id.* A more detailed analysis of the data "confirmed a relationship between umbilical cord PCB concentrations and poorer performance on the Boston Naming Test." TX 791, p. 13. When asked about this article, Dr. Rice initially denied that she had ever written a paper stating that PCB exposure caused deficits on the Boston Naming Test. Rice, 3 Tr. 275:27-276:10. Then, when she was shown her article stating this precise conclusion (TX 791, p. 18), she first tried to distance herself from its authorship, but then admitted to reviewing and approving it, and that the article was published under her name. Rice, 3 Tr. 279:5-13.

121. Dr. Rice provided misleading testimony that a single exposure to methylmercury of the kind at issue in this case can cause adverse effects in humans. Rice, 2 Tr. 115:14-117:1; TX 360E; TX 360F; TX360G. Dr. Rice produced a series of abstracts where animals were exposed to a single dose of methylmercury at levels that likely exceeded the levels of the Minamata poisoning.[23] TX 423; Rice, 25 Tr. 3141:9-3146:28. This level of exposure exceeded the Tuna Canners' proposed MADL by more than a million-fold.[24] Rice, 25 Tr. 3142:22-23; TX 423. Contrary to Dr. Rice's testimony, these studies do not conclude

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[23] The Tuna Canners' counsel confirmed with Dr. Rice at trial that Minamata was a "massive exposure to methylmercury" and then asked whether there is any reason to believe that anyone in Minamata was exposed to 232,000 micrograms of methylmercury. Dr. Rice responded "I would doubt it." Rice, 25 Tr. 3141:1-8. In the Iraq poisoning, people died when exposed to more than 200,000 micrograms of methylmercury. TX 865, p. 54.

[24] Dr. Rice was unable to compare the mercury levels involved in the poisoning episode in Minamata Bay to the levels of mercury consumed in fish in the New Zealand, Seychelles, or the Faroe Islands studies. Rice, 3 Tr. 269:10-11. Dr. Rice was not even sure if the levels of exposure differed by a factor of ten. Rice, 3 Tr. 269:11-12. Data from Iraq demonstrated that the exposure levels in a poisoning episode can exceed a body burden of 200 milligrams (mg) or 200,000 micrograms (ug). TX 865, p. 54. The proposed MADLs in this case are fractions of a microgram. TX 659; TX 8.

that a single serving of canned tuna could contain enough methylmercury to harm the fetal brain. Rice, 2 Tr. 115:14-117:1; Rice, 24 Tr. 3093:3-14; 25 Tr. 3140:26-3146:28.

122. To buttress her misleading testimony that a single exposure to methylmercury at the levels at issue in this case can have harmful effects, Dr. Rice misstated the WHO's analysis of the Iraq poisoning, and testified that the WHO "observed" paresthesia from a single day's exposure to methylmercury at 50 and 200 ug/day. Only when confronted with the WHO report did Dr. Rice acknowledge that the 50 and 200 ug/day levels were modeled, not observed, and were for cumulative exposures over a long period of time, and not single exposures. Rice, 25 Tr. 3154:10-3156:11; 25 Tr. 3149:23-3152:15.

123. The Court finds that Dr. Rice's testimony was unreliable. It was also biased. Under Dr. Rice's MADL, products with methylmercury levels below the level of detection would be required to carry a Proposition 65 warning. Murray, 11 Tr. 1296:23-1297:17. As a result, all servings of fish and shellfish larger than literally a grain of rice would require a warning under Proposition 65. Murray, 11 Tr. 1296:23-25; 11 Tr. 1298:18-1299:5; TX 828. Dr. Rice disagrees with the fish consumption advisories issued by the FDA/EPA, and the advisories put forth by state agencies (including her home state of Maine) regarding safe fish consumption for pregnant women and women of childbearing age. Rice, 4 Tr. 361:15-368:27; TX 706; TX 347; TX 348; TX 349; TX 350; TX 351; TX 764. Specifically, Dr. Rice does not believe that women and young children should eat up to 12 ounces of canned light tuna per week and 6 ounces of canned albacore per week. Rice, 3 Tr. 237:15-238:3.[25]

E. Dr. Golub's Cursory Review and Endorsement of the Rice MADL

124. The State also presented testimony from OEHHA scientist Dr. Mari Golub to endorse the appropriateness of Dr. Rice's MADL under Proposition 65. Although Dr. Golub

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[25] Dr. Rice did not include a section in her report on the application of the MADL in terms of exposure. TX 8. Dr. Rice was not sure how many grams or ounces of canned tuna her MADL would allow a person to eat without issuing the warning. Rice, 3 Tr. 300:3-7. Dr. Rice did not compare her MADL to other commercial seafood. Rice, 3 Tr. 301:8-11.

reviewed Dr. Rice's report and endorsed her MADL, she did not conduct an independent analysis of the reliability of the studies that Dr. Rice relied on to evaluate, for example, whether in the Faroes Islands study, confounding factors had been adequately identified and quantified.[26] Golub, 4 Tr. 450:10-451:7; TX 74. Dr. Golub's unfamiliarity with the Faroe Islands study is reflected in her mistaken belief that PCBs were a main focus of the Faroe Islands study and the analysis performed by the NRC. Golub, 4 Tr. 404:22-26.

IV. CALCULATING LEVEL OF EXPOSURE TO METHYLMERCURY IN TUNA CANNERS' PRODUCTS

125. California Code of Regulations section 12821 outlines the exposure guidelines for determining whether the level of exposure to methylmercury in canned tuna exceeds the MADL for methylmercury.

A. Dr. Murray's Formula for Calculating Exposure to Methylmercury

126. Dr. Murray testified that the level of exposure to methylmercury in canned tuna is below the MADL for methylmercury. Murray, 11 Tr. 1289:6-1293:21; TX 659, p. 18; TX 827 A-C. He used the following formula to calculate the average daily intake of methylmercury from canned tuna: S x F x C, where "S" is the serving size of canned tuna, "F" is the frequency of consumption of canned tuna among women of childbearing age in California, and "C" is the average concentration of methylmercury in canned tuna. Murray, 10 Tr. 1254:15-19; TX 659, pp. 15-16. Dr. Murray testified that this formula was consistent with section 12821 exposure guidelines. Murray, 10 Tr. 1253:15-18; TX 2, p. 200.6.

127. The parties stipulated that the average serving size of canned tuna ("S") is 2.3 ounces (64.4 grams). Murray, 10 Tr. 1254:20-1255:25; TX 824.

1. Average Concentration of Methylmercury in Canned Tuna

128. To determine the average concentration of methylmercury in a can of tuna

[26] Neither Dr. Golub nor Dr. Rice noticed that Dr. Rice had made a serious mathematical error of an order of magnitude (a factor of ten) on the first four drafts of her report. Rice, 2 Tr. 101:10-19; TX 74.

("C"), and the frequency with which women of childbearing age in California consume canned tuna ("F"), Dr. Murray relied on survey data collected by Dr. Wind (the "Frequency of Consumption Survey" or the "Frequency Survey"). Murray, 10 Tr. 1256:9-11. The Frequency Survey targeted women in California between the ages of fifteen and forty-four who were asked to identify the last two times they ate canned tuna.[27] Wind, 17 Tr. 2165:18-2167:22; 17 Tr. 2191:6-2192:17. The time difference between the two eating occasions was calculated arithmetically by subtracting the number of days since the most recent canned tuna consumption from the number of days since the prior canned tuna consumption. Wind, 17 Tr. 2201:18-2203:20; TX 732A. To validate the study, respondents were also asked if this was a typical amount of time between canned tuna consumptions. Wind, 17 Tr. 2197:1-26. Seventy percent (70%) of respondents verified that the reported frequency was typical for their consumption of canned tuna. Wind, 17 Tr. 2197:22-26; TX 732A. Respondents were also asked to identify the percentage of canned light tuna versus canned albacore tuna that they consumed. Wind, 17 Tr. 2198:28-2200:5.

129. Dr. Wind personally designed every aspect of the Frequency Survey, including the targeted population, the research design, the questions, and the data collection method. Wind, 18 Tr. 2269:20-2270:24; TX 732A. Drawing on his forty years of experience in market research, Dr. Wind framed the Frequency Survey questionnaire as a perception study in a clear, open-ended, leading, and unbiased manner that was designed to trigger the respondent's memory of her canned tuna eating habits. Wind, 17 Tr. 2156:4-12; 17 Tr. 2192:15-2194:25. The Frequency Survey was "double blind," meaning that neither

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[27] Dr. Wind obtained the database of telephone numbers from Survey Sampling, Inc. and Data Development Worldwide, which conducted the Frequency Survey. TX 732A; Wind, 17 Tr. 2168:9-13; 17 Tr. 2176:13-16. Telephone surveys are generally preferable to other survey techniques because they ensure that all persons in the population have an equal chance of being included. Wind, 17 Tr. 2163:1-2165:16. To obtain a representative sample of California women of childbearing age from the database of telephone numbers, Dr. Wind used the random digit dialing technique, which generates random telephone numbers from every county in the state. Wind, 17 Tr. 2168:14-2169:13; TX 732A.

the interviewer nor the respondent knew the name of the sponsor of the survey. Wind, 17 Tr. 2176:24-2177:6.

130. The State's expert witness, Dr. Griffin, offered statistical theoretical critiques of the methods and results of the Frequency Survey, but did not proffer any independent survey data to undermine the Frequency Survey results. Griffin, 19 Tr. 2383:8-2395:25.

131. The Frequency Survey data represents the responses of 401 non-pregnant women of childbearing age and 115 pregnant women in California. Wind, 17 Tr. 2167:20-22. The data establishes that the average non-pregnant woman of childbearing age in California eats canned tuna once every 61.5 days, and the average pregnant woman eats canned tuna once every 60 days. Wind, 18 Tr. 2223:1-3; TX 732A. Among non-pregnant women of childbearing age in California, 59.7% eat canned albacore tuna and 40.3% eat canned light tuna. Wind, 18 Tr. 2245:9-11; TX 732A. For pregnant women in California, 51.6% eat canned albacore tuna and 48.4% eat canned light tuna. Wind, 18 Tr. 2245:11-12; TX 732A. Taken together, the Frequency Survey data reflects that among women of childbearing age in California, 51.6-59.7% eat canned albacore tuna and 40.3-48.4% eat canned light tuna. Murray, 10 Tr. 1257:20-25; TX 659, p. 17.

132. The FDA has determined that the average concentration of methylmercury in canned light tuna is 0.12 ppm, and the average concentration for canned albacore is 0.35 ppm. Murray, 10 Tr. 1256:15-1257:3; TX 53.[28]

133. Assuming that 51.6 to 59.7% of women of childbearing age eat canned albacore, that 40.3 to 48.4% of women of childbearing age eat canned light tuna, and that the

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[28] The FDA's "Mercury Levels in Commercial Fish and Shellfish" provides the mean, median, and minimum and maximum levels of methylmercury in canned light tuna and canned albacore. TX 53, pp. 3-5. Dr. Murray relied on the average, or mean, methylmercury level to calculate the average exposure to methylmercury. Murray, 12 Tr. 1471:6-20. The State challenged Dr. Murray's reliance on the mean, rather than the maximum, levels of mercury. Murray, 11 Tr. 1312:6-1314:5. Dr. Murray explained that the regulations required that he use the average. Murray, 12 Tr. 1471:6-7. Dr. Murray did not use the median or the lowest levels of detection, which would have yielded lower levels of exposure because he did not believe that the regulations allowed him to consider anything other than the average, or mean, concentration. Murray, 12 Tr. 1471:1-20.

FDA's average methylmercury concentration for canned light tuna is 0.12 ppm and 0.35 ppm for canned albacore, Dr. Murray derived a weighted average of methylmercury concentration in canned tuna, both light and albacore, that is between 0.239 and 0.257 ppm. Murray, 10 Tr. 1257:25-28; TX 659, p. 17.

2. Averaging Frequency of Consumption Over Two Months Is Appropriate

134. Section 12821(b) requires that "the reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to reproductive effects which provided the basis for the determination that the chemical is known to the state to cause reproductive toxicity." Golub, 4 Tr. 394:1-12; TX 2, p. 200.6. A "short duration" of exposure is the appropriate frame of reference through which to evaluate the potential harm caused by a reproductive toxicant. Murray, 11 Tr. 1279:16-1280:3; TX 2, p. 200.6.

135. The parties disputed whether exposure to methylmercury could be averaged over a period of time, rather than on a single day. Proposition 65 does not prohibit averaging exposure to a reproductive toxicant. Zeise, 16 Tr. 2036:16-24; TX 2, p. 200.6. According to Dr. Zeise, OEHHA has never taken a formal position on whether methylmercury exposure ought to be analyzed over a long term or during a single day only. Zeise, 16 Tr. 2036:16-24; 2043:7-9. OEHHA does not have a general rule for averaging any reproductive toxicant. Zeise, 16 Tr. 2036:16-24; 16 Tr. 2043:3-9.

a. Evidence Supporting Averaging Exposure to Methylmercury Over a Time Period Greater Than One Day

136. OEHHA's Statement of Reasons for section 12821(c)(2) dictates that exposure to reproductive toxins should be assessed on a "short-term" basis. Golub, 4 Tr. 397:3-23; TX 3A, p. 85. The Statement of Reasons does not define short-term, and according to Dr. Golub, there is no scientific consensus on the definition of short-term exposure in risk assessment. Golub, 4 Tr. 455:3-456:12.

137. Dr. Murray testified that in his opinion, two months is the proper "short duration" over which to average exposure to methylmercury under section 12821(b). Murray, 11 Tr. 1280:9-15. He justified this opinion based on two factors: (1) the period over which the developmental effects of a chemical occur, and (2) that the half-life of methylmercury in humans is approximately two months. Murray, 10 Tr. 1258:23-1259:5.

138. Dr. Murray recognized that it is not always appropriate to average developmental toxins. Murray, 10 Tr. 1258:21-22; 10 Tr. 1259:15-17. For example, some chemicals like thalidomide have a short half-life of a few hours and cause harm only during a few isolated, specific days of development. Murray, 10 Tr. 1259:15-23. As a result, averaging exposure to thalidomide over a period of two months would be inappropriate. Murray, 10 Tr. 1259:15-23; 11 Tr. 1283:8-25. Dr. Murray testified that where, as here, methylmercury has a two-month half-life, and where developmental harm has never been isolated to a specific day or period during development, averaging exposure to methylmercury over a two-month period is appropriate. Murray, 10 Tr. 1259:24-27; 10 Tr. 1260:15-18; 11 Tr. 1274:27-1275:10; 11 Tr. 1283:26-28.

139. Consistent with Dr. Murray, state and federal agencies that advise consumers of the risks associated with exposure to methylmercury through fish consumption average exposure to methylmercury over time. Murray, 11 Tr. 1284:12-17; 11 Tr. 1287:13-19. For example, the 2004 FDA/EPA Consumer Advisory (the "FDA Advisory") states that a pregnant woman can safely eat up to twelve ounces of low mercury fish, including canned light tuna, per week. TX 706. By not prohibiting women from eating all twelve ounces in one meal, or advising them to eat seven small fish meals per week, the FDA Advisory is implicitly averaging exposure over a one-week period at a minimum. Murray, 11 Tr. 1285:5-1287:12; TX 706. Likewise, the FDA Advisory's advice that women who consume more than the recommended amount of fish in one week should reduce their intake for the following week suggests that the FDA is averaging exposure over a period of at least three weeks. Murray, 11 Tr. 1288:4-20; 11 Tr. 1397:19-28; TX 706, p. 2. Further evidence of the FDA's averaging period is the FDA Advisory's recommendation that women can safely eat

six ounces of albacore per week. Murray, 11 Tr. 1306:10-21; TX 706. If the averaging period was limited to one week, the FDA would not advise women to consume six ounces of albacore in one week because the amount of methylmercury consumed during that period would exceed the EPA Reference Dose. Murray, 11 Tr. 1306:10-21.

140. Dr. Robert Brodberg testified that OEHHA averages exposure to methylmercury over a one-month period because it is not biologically appropriate to consider a daily intake of methylmercury. Brodberg, 16 Tr. 1938:26-1939:16; TX 514, p. 5. In reaching this decision, OEHHA reasoned "methylmercury is metabolized quite slowly in the body and has a half-life of more than two months. This means that short-term fluctuations (on a daily or weekly basis) in dietary intake affect blood mercury slowly." Brodberg, 16 Tr. 1938:26-1939:4; TX 514, p. 5.

b. Calculating Exposure to Methylmercury Over a Single Day Is Inappropriate

141. The State presented testimony that for chemicals causing developmental toxicity only the daily exposure should be taken into account. Rice, 2 Tr. 105:20-26. Dr. Rice presented "dose effect curve" graphs reflecting the mercury concentration levels in maternal and fetal blood that she predicted would result from eating canned tuna once every sixty days if the exposure were not averaged. Rice, 2 Tr. 115:14-117:10; TX 360E; TX 360F; TX 360G. According to Dr. Rice, when exposure to methylmercury is not averaged over a period of sixty days, the mercury concentration could range between approximately 0.1 ug to approximately 0.5 ug of methylmercury per day. TX 360E, TX 360G. She contended that the difference between averaging exposures versus considering exposure at a single meal "may be very significant in terms of what that means for the fetal brain." Rice, 2 Tr. 116:27-117:1. According to Dr. Rice, even at these extremely low levels exposure to methylmercury can "[go] from no effect to a profound effect very, very quickly as the dose increases." Rice, 2 Tr. 115:14-116:26; TX 360 E; TX 360 F; TX 360 G. (emphasis added)

142. Contrary to her testimony, during her time at the EPA Dr. Rice wrote that there are no studies addressing whether the effects on the fetal brain differ when methylmercury is taken in episodically or on a more continuous basis. Rice, 4 Tr. 342:24-343:13; TX 362, p. 15. Faced with this evidence, Dr. Rice conceded that if sufficient information is available regarding the mechanisms of a chemical and its effects, and a single exposure would not be sufficient to produce adverse effects, averaging is appropriate. Rice, 3 Tr. 181:24-182:6.

143. Relying on the same figures Dr. Rice used in her "dose effect curve," Dr. Murray demonstrated that the levels of methylmercury at issue in this case are far below any levels ever associated with harm to the fetal brain, and are well below the EPA Reference Dose for methylmercury. Murray, 11 Tr. 1275:28-1278:28; TX 825. To demonstrate this, Dr. Murray presented a graph containing a line corresponding to the EPA Reference Dose of 0.1 ug/kg/day for methylmercury. Dr. Murray used the Proposition 65 required weight of 58 kg to produce the EPA Reference Dose line of 5.8 ug of methylmercury per day. TX 825. His graph illustrates that the levels at issue in this case are far below the EPA Reference Dose, which is a daily intake that "is designed to not produce deleterious effects over the course of a lifetime of [daily] exposure." Murray, 11 Tr. 1278:8-27; Rice, 2 Tr. 69:19-21; TX 825.

144. Dr. Rice presented the only evidence supporting the conclusion that a single exposure to methylmercury could cause harm during rebuttal. Rice, 24 Tr. 3093:3-14; TX 423. Dr. Rice produced a series of abstracts where animals were exposed in a single dose to mercury levels that likely exceeded the levels of the Minamata poisoning.[29] Rice, 25 Tr. 3141:4-8; TX 423. The methylmercury levels given to the animals in the abstracts also exceeded the Tuna Canners' proposed MADL by more than a million-fold. Rice, 25 Tr.

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[29] In the 1950's, a severe poisoning episode occurred in Japan, when a factory discharged large amounts of methylmercury into Minamata Bay. The high-dose exposure caused severe abnormalities. Rice, 2 Tr. 121:11-122:3.

3141:8-3142:23; 25 Tr. 3146:2-28; TX 423. These abstracts are unpersuasive because they do not support the idea that a single serving of tuna fish could contain enough methylmercury to harm the fetal brain.

145. For purposes of this case, the Court finds that averaging exposure to methylmercury over two months is the appropriate "short duration" under section 12821 of the California Code of Regulations.

B. Defining the Term "Average" Under the Statute

1. Evidence Construing Average to Be the Arithmetic Mean

146. Pursuant to section 12821(c)(2) , the "level of exposure [to methylmercury] shall be calculated using the reasonably anticipated rate of intake or exposure for *average users of the consumer product*" (emphasis added). The term "average" is not defined in the statute, the regulations, or in the Statement of Reasons. TX 1; TX 2, p. 200.6; TX 3A, pp. 84-85. The Tuna Canners presented evidence that the term "average" in section 12821(c)(2) means the arithmetic mean, and not, as the State argued, the median.[30]

147. As discussed above, the Frequency Survey data reflects that the average non-pregnant woman of childbearing age in California eats tuna once every 61.5 days and the average pregnant woman eats canned tuna once every 60 days. Wind, 18 Tr. 2223:1-3; TX 732A. These figures represent the average, or arithmetic mean, frequency with which women of childbearing age consume canned tuna in California. Murray, 12 Tr. 1436:1-12.

148. Dr. Murray testified the word "average" is not ambiguous in statistics, and that upon reading or hearing the word "average," he has never had to determine whether it meant median, mode, or central tendency instead of mean. Murray, 10 Tr. 1140:10-16; 12 Tr. 1461:12-1162:24. Dr. Murray testified that based on his extensive experience as a toxicologist and Proposition 65 consultant, it is appropriate to use the arithmetic mean to

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[30] The State urged the Court to conclude that women of childbearing age in California consume canned tuna once every 22.5 days, which represents the median frequency of canned tuna consumption from Dr. Wind's report. Murray, 12 Tr. 1435:12-15.

determine "average exposure" of women to methylmercury in tuna fish. Murray, 12 Tr. 1436:3-5; 12 Tr. 1436:8-12.

149. Dr. Wind also testified that in his experience, the professional and common meaning of the term "average" is the arithmetic mean, and not the median. Wind, 18 Tr. 2229:19-18. According to Dr. Wind, widely used statistics textbooks at leading universities define the term "average" as "the sum of entries divided by number of entries," which is the definition of the arithmetic mean. Wind, 18 Tr. 2231:7-11; TX 843, p. 76. Furthermore, an "average" cannot be the median because the median represents the fiftieth percentile, whereas the mean is another measure of distribution. Wind, 18 Tr. 2232:3-5. Dr. Wind testified that the *San Francisco Chronicle* uses the word "average" to signify "mean" when it discussed the average monthly rainfall, or the average points, rebounds, and assists of different basketball players. Wind, 18 Tr. 2235:22-27; TX 845, pp. 1-2. In contrast, when discussing the median, the term "median" is specifically stated, such as when the *Chronicle* reported on the median home prices for October. Wind, 18 Tr. 2235:2-7.

150. OEHHA scientists Dr. Robert Brodberg and Dr. Zeise testified that when they apply "daily average" and "average daily intake" of tuna fish, they equate the "average" to the arithmetic mean. Brodberg, 16 Tr. 1942:14-18; Zeise, 16 Tr. 2018:23-26. Even Dr. Griffin admitted that he uses "average" to mean "the arithmetic mean" in his work. Griffin, 6 Tr. 703:13-17.

2. The State's Evidence Proffered to Support Reliance on the Median Rather Than the Mean

151. The State claims the term "average" in section 12821(c)(2) means the "median," "typical," or some other measure of central tendency. Based on Dr. Wind's report, the median for tuna consumption among pregnant women in California is 22.5 days. Griffin, 19 Tr. 2405:2-6; TX 397; Murray 12 Tr. 1435:12-25; TX 561, p. 13.[31]

[31] Although the State contended that "average" could mean "typical," it conceded that "typical" is not used in the regulations. Griffin, 19 Tr. 2392:2-7; TX 2, p. 200.6. Dr. Wind (footnotes continued . . .)