

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

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

18 18. FDA has issued fish advisories since the mid-1990s. TX 727, p. 3. In March
19 2001, FDA revised and changed the emphasis of its advisory to balance the relative benefits
20 and possible risks of eating seafood. TX 727, p. 3; TX 507. In the March 2004 advisory,
21 FDA presented the benefits of fish consumption first, followed by the risks of
22 methylmercury exposure. TX 507, p. 1.

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