

**UNITED STATES DISTRICT COURT  
DISTRICT OF MAINE**

NATURAL RESOURCES DEFENSE )  
COUNSEL and MAINE PEOPLE'S )  
ALLIANCE, )  
 )  
Plaintiffs, )  
v. )  
 )  
HOLTRACHEM MANUFACTURING )  
COMPANY, LLC and MALLINCKRODT )  
US LLC, )  
 )  
Defendants. )

Civil No. 00-69-B-W

**MALLINCKRODT US LLC'S POST-TRIAL BRIEF**

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## **I. Introduction.**

As the Court stated on the first day of trial, “the focus of this hearing is, how bad is the problem? How bad is it likely to be in the future? And what do we do about it?” Tr. 9:13-15. While the lower Penobscot River contains mercury, evidence demonstrates that it is less contaminated than the Phase II Report suggests, and much less contaminated than other sediment sites around the country where active remediation has been undertaken. Mercury in the river is not posing an unacceptable risk to human health, nor is it causing significantly adverse effects on populations of organisms. Moreover, no one has identified a better way to clean up the lower Penobscot other than letting natural attenuation take its course. Plaintiffs themselves simply punt on the ultimate issue before the Court—What do we do about the problem?—urging it to empanel a new slate of experts to conduct an “open” Phase III study in hopes that a magic bullet might somehow be discovered. Pls. Br. 46. The Court should decline to go down that path.

Much has been learned from the almost nine-year, \$20 million study. Tr. 76:16-19; DX 886.<sup>1</sup> The evidence at trial demonstrates that mercury in the lower Penobscot does not pose an unacceptable risk to human health. Plaintiffs attempt to confuse that issue through misplaced reliance on threshold screening levels as bright lines to determine whether food is unsafe to eat, rather than as an indicator of whether a potential risk may exist. Here, that potential has been investigated, and no unacceptable risk to human health has been found. The evidence further establishes that mercury is not having significantly adverse effects on populations of fish or mammals in the Penobscot, and that only a few species of songbirds may be at risk. Even if unacceptable risks to human health or significantly adverse effects on populations of organisms

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<sup>1</sup> In this brief, JX refers to joint exhibits, PX refers to plaintiffs’ exhibits, DX refers to defendant’s exhibits, and Tr. refers to the trial transcript.

had been found, the evidence shows that the remedial options the Study Panel suggests would not work and might well be counterproductive.

Mallinckrodt agrees that further study of the potential risk to songbirds is warranted. But any such study should be focused on the few species that may be at risk. Because work remains to be done to determine the nature and extent of any harm that may need to be remedied, and the need for and reasonableness of potential remedies is inextricably intertwined with the extent of the harm to be remedied, it would be premature for the Court to find that active remediation is appropriate at this time or launch a massive new investigation of potential remedial schemes until the one outstanding harm question (about songbirds) has been answered.

Further, Mallinckrodt agrees that a targeted study of the mobile pool and the Orland River should be undertaken to obtain information necessary to make sound decisions regarding possible remediation (if any) related to the lower Penobscot and the Orland River. But given the extensive amount of information gathered to date by the Study Panel, enough is known that it makes no sense to further evaluate or consider large-scale remedies such as bank-to-bank dredging, bank-to-bank capping, sediment trenches, or activated carbon—remedies that would accomplish little or nothing, would be extremely expensive, and could easily end up doing more harm than good. The Court should therefore rule that these remedies are no longer under consideration, and order that Mallinckrodt proceed with targeted further study of the issues that remain to be addressed.

## **II. The State of the River.**

The Penobscot River has been contaminated with mercury, but has recovered significantly over the last 40 years (Tr. 128:6-8; 128:14-16; 394:20-22 (Rudd); Tr. 628:13-18 (Whipple); Tr. 1856:25-1857:5 (Phillips); Tr. 3232:3-4; 3273:10-21 (Connolly)), and is less

contaminated than the Study Panel suggests. Tr. 3244:7-10; 3247:19-22; 3258:18-22; 3264:23-3265:4 (Connolly). To put the levels of contamination in perspective, current levels of mercury in Penobscot sediments are equal to the post-remediation mercury targets at other mercury-contaminated sediment sites in the United States. Tr. 2190:14-2191:8 (Driscoll); Tr. 3271:6-3272:9 (Connolly). Compared to other mercury-contaminated sediment sites where active remediation is taking place, the Penobscot is much less contaminated (Tr. 2937:1-6 (Henry); Tr. 3146:13-21 (Glaza); Tr. 3269:23-3271:5 (Connolly)), and it continues to recover. Tr. 3232:3-4 (Connolly).

**A. The river is less contaminated than the Study Panel suggests.**

The Phase II Report states that mercury concentrations in surface sediments in the upper estuary are 10-to-20 times higher than background levels. (JX 6-23 at 23-2). But as Dr. Connolly testified, those figures misconstrue the Study Panel's own data, because (*inter alia*) they were calculated without using carbon-normalized data and were based upon a comparison to pristine water bodies with far less industry and population density than the lower Penobscot. Tr. 3247:23-3264:17. Carbon normalization means looking at the data as "nanograms of mercury per gram of organic carbon in the sediment." Tr. 3250:16-17. Dr. Connolly explained that when comparing river reaches or systems, it is important to carbon normalize the data so that it more accurately reflects what biota are actually exposed to in the environment. Tr. 3251:1-17.

The Study Panel's approach to site-to-site comparisons in the Phase I Report is consistent with Dr. Connolly's opinion. It explained that "although in the scientific literature concentrations of Hg in sediments are commonly presented on a dry weight basis, site-to-site comparisons using this metric are problematic." JX 4 at 52. To minimize variability from dry-weight calculations in the Phase I Report, the Study Panel "normalized mercury concentrations

to the organic carbon content of the sediments.” *Id.* Dr. Rudd testified that “you end up doing an apples and oranges comparison if you [compare locations] on the dry weight basis.” Tr. 51:25-52:14 (Rudd). Dr. Fisher testified that “one reason to normalize organic carbon in a sense is to ... take into consideration grain size differences that might exist from one river to another, which may account for differences that one observes in mercury concentrations in sediments between two rivers.” JX 107 at 11:11-19 (Fisher).

When comparing the lower Penobscot to background sites in the Phase II Report, however, the Study Panel examined the data on a dry weight basis and stated that the Penobscot was elevated 10-to-20 times above background concentrations. JX 6-23 at 23-2; Tr. 3257:18-3258:7 (Connolly). By using non-carbon-normalized data, the Study Panel failed to measure mercury in a way that is relevant to the Court’s questions about its effects on biota and human health, and exaggerates the extent to which mercury in the Penobscot is elevated over background and has the potential to cause harm. Tr. 3253:11-3254:23. Dr. Connolly evaluated the Study Panel data on a carbon-normalized basis and found that mercury concentrations in the upper estuary are actually 3-to-5 times higher than background levels, not 10-to-20 times higher. Tr. 3263:9-3264:17; 3264:23-3265:4.

Dr. Bodaly agreed with Dr. Connolly that if you examine the data on a carbon-normalized basis you get “somewhat less dramatic degrees of elevation.” Tr. 1025:25-1026:2. Dr. Bodaly calculated mercury concentrations on a carbon-normalized basis, using different background sites to compare the lower Penobscot, and found that the Penobscot was elevated 6.5-to-9 times background, not 10-to-20 times background as stated in the Phase II Report. Tr.

1025:10-24.<sup>2</sup> In short, using the proper type of data to compare river systems, the lower Penobscot is not as contaminated as the Study Panel suggests.

**B. The lower Penobscot is less contaminated than sites around the country subject to active remediation.**

The lower Penobscot is not a highly contaminated system compared to other sites around the country. Tr. 3269:23-3270:1 (Connolly). Dr. Bridges, an Army Corps of Engineers scientist hired by the Study Panel with experience working on contaminated sites across the country, characterized the Penobscot as “moderate[ly]” contaminated.<sup>3</sup> JX 33 at 178:6-17. Dr. Connolly explained that “the typical site that is being actively investigated and considered for active remediation around the country is much more contaminated than three to five times background.” Tr. 3270:2-3271:5. For example, many contaminated sediment sites involving PCBs are typically 10-to-100 times background. *Id.* In the Passaic River in New Jersey, dioxin levels are more than 100 times background. *Id.* In the South River in Virginia, mercury levels are 30 times background. *Id.* In the Carson River in Nevada, mercury concentrations are about 100 times background. *Id.*

The mercury concentration cleanup targets the Study Panel proposed are also low compared to other sites around the country. Tr. 3271:6-8 (Connolly). The Study Panel set a target for the main stem of the Penobscot River of about 450 nanograms-per-gram dry weight. JX 6 at ES-7; JX 6-21 at 21-2; Tr. 3271:19-3272:9 (Connolly). As of 2009, concentrations of mercury in the lower Penobscot averaged about 900 nanograms-per-gram dry weight. In

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<sup>2</sup> Dr. Driscoll attempted to calculate the data on a carbon normalized basis, but his calculation was erroneous and was not close to either Dr. Connolly’s calculation or Dr. Bodaly’s calculation Tr. 3265:5-3266:21 (Connolly); 2196:5-2204:25 (Driscoll); JX 49 at 4; 1024:7-1025:6 (Bodaly). At trial, Dr. Driscoll did not know which data set had used and could not explain why his estimate was so different from either Dr. Connolly’s or Dr. Bodaly’s. Tr. 2203:3-2204:25.

<sup>3</sup> Dr. Bridges has twenty years of experience working on sediment management and contaminated sediment sites. JX 33 at 5:18-6:14. The Study Panel consulted with him during its consideration of remedial alternatives. JX 33 at 49:9-52:13.

comparison, at mercury-contaminated Onondaga Lake in New York, the post-remediation target goal is 800 nanograms-per-gram dry weight, close to the actual mercury level in the Penobscot as of 2009. Tr. 3271:25-3272:9; Tr. 2189:23-2191:25 (Driscoll). At the Peconic River on Long Island, New York, the target was 1,000 nanograms-per-gram dry weight on the site and 700 nanograms-per-gram in the downstream portion of the river. *Id.* At the Sudbury River site in Massachusetts, active remediation targeted sediments with mercury concentrations greater than 10,000. *Id.*

**C. Background concentrations create a floor for remediation.**

For remediation purposes, the fact that the Penobscot River is 3-to-5 times background (Connolly) or 6.5-to-9 times background (Bodaly), as opposed to 10-to-20 times background, is important, because background represents “the level below which you cannot go,” as “what comes in from upstream and ... from the coast is contaminated at the background levels and will tend to keep the system contaminated at those levels.” Tr. 3266:22-3268:5 (Connolly). Even if one could remove all the mercury from the system, other ongoing sources (such as atmospheric deposition, mercury from above Veazie dam, mercury from tributaries, mercury from other smaller sources and mercury from the ocean) set a practical limit on the amount of reduction that can be achieved. *Id.*; 364:14-356:3 (Rudd) (discussing 157 possible sources of mercury); Tr. 1007:12-22 (Bodaly).

**D. The river is recovering faster than the Study Panel estimates.**

The Study Panel estimates that the lower Penobscot will recover with an average recovery half-time of 32 years. JX 6-1 at 1-14; 1-19; JX 6-18 at 18-2; Tr. 408:10-12 (Rudd). This estimate utilizes half-times calculated for cores taken in numerous locations of the Penobscot, even in locations where the sediment is disturbed (i.e. tracers used to date the

sediment layers are mixed, making data unreliable) and difficult to use in calculating recovery half-times. Several Study Panel scientists, including all of the scientists with expertise in dating sediment cores and calculating recovery half-times (Dr. Rudd, Dr. Harris, Dr. Santschi, and Dr. Yeager), testified that the sediment cores in Mendall Marsh are the best cores to use in evaluating recovery half-times for the system as a whole. JX 87; Tr. 406:1-4 (Rudd).<sup>4</sup> Tr. 1394:1-6 (Yeager); Tr. 1743:8-1744:16 (Santschi); JX 38 (Dep. Tr. Of Mr. Harris at 13:13-18). Dr. Santschi, the expert selected by the Study Panel to calculate recovery half-times, testified that the sediment cores in Mendall Marsh are the most reliable in the system. Tr. 1744:10-20. As Dr. Rudd explained, “[b]ecause Mendall Marsh is quiescent yet well connected to the main stem of the river, it is the best sedimentary environment in the ecosystem for the preservation of records of timing of mercury deposition to the Penobscot Estuary.” JX 87 at 3 (Rudd).

Dr. Santschi calculated a half-time for recovery in Mendall Marsh of 22 years. Tr. 1710:12-13. Dr. Connolly performed his own evaluation and estimated the half-time for recovery using the sediment cores from Mendall Marsh. Tr. 3273:1-3316. He examined each sediment core individually (as opposed to using the arbitrary 21-year cut off period Dr. Santschi used) and found that all of the interpretable Mendall Marsh cores showed recovery. *Id.*, Tr. 3315:18-3316:11. He concluded that the system is recovering with a half-time of approximately 15 years. *Id.* Based upon Dr. Connolly’s analysis, mercury concentrations in the sediment of the main stem of the lower Penobscot will reach the Study Panel’s target in about 15 years, as opposed to 32 years. Tr. 3334:4-25. Therefore, whether you use the Study Panel’s half-time for recovery in Mendall Marsh of 22 years or Dr. Connolly’s 15-year estimate, if Mendall Marsh

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<sup>4</sup> Dr. Rudd explained that the only reason the Study Panel did not use the half-time for Mendall Marsh for the entire system is because he and Dr. Kelly were outvoted by Whipple, Fisher, Bodaly and Kopec – none of whom have much experience calculating recovery half-times from sediment cores. Tr. 408:13-409:13.

cores are most representative of the system, then the system should recover within a half-time of between 15 and 22 years. Dr. Rudd agreed at trial that the 32-year recovery half-time number needs to be revisited. Tr. 409:21-25.

Dr. Driscoll presented sediment cores that have increasing mercury concentrations towards the surface, attempting to show the system is getting worse. Tr. 2139:22-2140:2; 2221:7-15 (Driscoll); Pls. Br. 36-37. But such cores tell little about system recovery where they are disturbed at the surface. Tr. 3435:14-3436:21 (Connolly). Dr. Driscoll admitted that several of these cores had a cesium peak at the surface indicating the core was disturbed (cesium peak is associated with 1963, and should not be at the surface). Tr. 2219:3-2220:11. Moreover, several of the sediment cores represented as increasing were in fact at or below the Study Panel's sediment-mercury target and did not indicate potential danger. Tr. 2222:15-2225:11 (Driscoll).<sup>5</sup> Cherry-picking individual sediment cores tells little about the system as a whole or particular areas, as mercury calculations in sediment cores are highly variable across the system. Tr. 1684:17-24.

Unable to attack his core opinions, Plaintiffs spend several pages (Pls. Br. 42-44) attacking Dr. Connolly for reporting USGS data and examining biota trends, even though he explained at trial that his conclusions were not based upon either USGS data or biota trends and that he looked at this information only as an additional line of evidence to support his conclusions.<sup>6</sup> Tr. 3442:7-22. Plaintiffs' attack is off base, but understandable, given that Dr.

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<sup>5</sup> Dr. Driscoll also presented several misleading charts that purported to show that the Penobscot was more contaminated than other areas, by altering other scientist's charts and presenting them without checking the date to make sure they were apples-to-apples comparisons. Tr. 2180:14-2188:22. He copied charts from the work of other scientists and presented them in his report, but omitted a statement helpful to Defendants regarding mercury discharges of pulp and paper mills. Tr. 2180:14-2188:22 (admitting among other things that his presentation of data (without presenting depths of mercury concentrations for comparison) could be misleading); JX 47 at 10, Table 1.

<sup>6</sup> As explained by Dr. Connolly, after examining each sediment core profile (as opposed to simply assuming an arbitrary 21-year recovery period as Dr. Santschi did), he observed increases in mercury more recently than 21

Connolly is a well-regarded sediment expert with experience at contaminated sites across the country. Dr. Connolly has had significant involvement at the site and made several important comments on the Study Panel's work plans that would have saved significant time and money had they been credited. Tr. 3222:20-3240:5.<sup>7</sup>

Dr. Connolly and several others also testified, consistent with the Study Panel findings, that the sediment-core data demonstrate that the highest mercury concentrations remain buried in deep sediments, and therefore are not causing any adverse effects to biota or human health. Tr. 3273:13-21 (Connolly); Tr. 578:7-12; 644:16-25 (Whipple), Tr. 277:14-278:9 (Rudd); Tr. 3097:19-3098:4 (Glaza).

### **III. The Questions Before the Court.**

Whatever the Court may conclude about mercury levels in the Penobscot River, the ultimate questions before it are whether that mercury is causing harm to human health and biota, and if so, what to do about it. Twelve years ago, this Court ruled that mercury in the river “may present an imminent and substantial endangerment to public health and the environment.” *Maine People's Alliance v. Mallinckrodt Inc.*, 211 F.Supp.2d 237, 251 (D. Me. 2002). The Court held that “[a] finding that an activity may present an imminent and substantial endangerment does not require a showing of actual harm.” *Id.* at 246. Rather, “injunctive relief is authorized when there may be a risk of harm, not just when there is a risk of harm.” *Id.* at 246 (emphasis in original).

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years. Tr. 3295:3-3298:15. Although not necessary for his analysis, he provided several potential explanations for this observation. Tr. 3304:23-3306:5. One explanation involved USGS data which showed relatively high mercury discharges from above Veazie Dam. While the methods USGS used prevent verification of the levels, the data nevertheless exists and Dr. Connolly reviewed it. This data has no bearing on his analysis or conclusions. After conducting his sediment core analysis and half-time calculations, Dr. Connolly reviewed biota trend data to see if the trends were consistent with system recovery. Such evaluation was unnecessary, but provides another line of evidence to support system recovery. Tr. 3335:18-3336:4.

<sup>7</sup> For example, the Study Panel failed to heed Dr. Connolly's advice that a multi-cell model had a “fairly low probability of success” and would be extremely challenging to develop given the complexity of the system, and ultimately abandoned the effort after two years of work. Tr. 3236:2-3239:24; DX 24; DX 878; DX 234. The effort was very costly. DX 886.

That was the standard at the liability phase to justify the study of the Penobscot River that Mallinckrodt has funded: not actual harm, but “a risk” of harm.

The standard for the remedy phase is different. In the remedy phase, the Court directed the Study Panel to determine “the extent of the existing harm resulting from mercury contamination to the Penobscot River/Bay system,” including whether mercury in the Penobscot is “posing an unacceptable risk to human health” or “having significantly adverse effects on populations of organisms.” Implementing Order for Penobscot River Study Pursuant to Memorandum of Decision and Order, July 29, 2002. JX 2 at 1-2. Or as framed by the First Circuit, the question at the remedy phase is “whether, in actuality, mercury contamination in the lower Penobscot adversely affects either human health or the environment.” *Maine People’s Alliance v. Mallinckrodt, Inc.*, 471 F.3d 277, 282 (1st Cir. 2006). That was the first issue Plaintiffs had to prove at trial.

If Plaintiffs are able to prove that mercury in the Penobscot is posing an unacceptable risk to human health or having significantly adverse effects on populations of organisms, the Court would then proceed to “consider the balance of relevant harms before granting injunctive relief.” *Id.* at 296. “The familiar four-part framework for injunctive relief is a suitable guide” in environmental cases like this one. *Id.* at 296. “Under that framework, the injunction-seeker must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law . . . are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the [parties], a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.” *Id.* at 296 (quotation marks omitted).

**IV. There is no Evidence That Mercury in the River is Posing an Unacceptable Risk to Human Health.**

The Court directed the Study Panel to determine whether “mercury in the Penobscot River/Bay system [is] posing an unacceptable risk to human health.” JX 2 at 2-3. Study Panel member Dr. Whipple testified at trial that the Study Panel “does not conclude that eel or lobster, [or] black duck . . . pose an unacceptable risk to human health,” and that the most that could be said was that these food items “may create an unacceptable exposure or health risk.” Tr. 623:25-624:7.

Levels of mercury found in edible species in the Penobscot are in the range of values found in widely consumed seafood in the United States. With respect to lobster in the study area, mercury levels are “very similar to and below levels that are found in fish that are normally consumed on an everyday basis around the country.” Tr. 2349:10-13 (Bolger). In particular, mercury concentrations in Penobscot lobster are within the range or below concentrations found in albacore tuna. Tr. 2457:14-2458:10 (Keenan). They are also within the range of average lobster concentrations reported in various federal publications and a recent peer reviewed paper collecting data on mercury in seafood. Tr. 2456:22-2457:9 (Keenan); DX 1087; DX 1225 at 4; DX 514 at App. 11. In fact, the U.S. Department of Agriculture’s Dietary Guidelines for Americans (DX 514) reports an acceptable mercury concentration for lobster of 0.310 ppm, just about the same as the average concentration the Study Panel found in Penobscot lobster in the (now closed) upper estuary area, and well above concentrations in the study area as a whole. Tr. 2458:11-23 (Keenan). Mercury levels in Penobscot eel and duck are at the “kinds of levels [found] in grouper, orange roughy, [and] other species that are consumed on a . . . daily basis.” Tr. 2349:14-21 (Bolger). Eating food items from the Penobscot River poses no greater risk than the consumption of seafood items found in supermarkets throughout Maine and the United

States. Tr. 2459:4-12 (Keenan). Unless one were to conclude that there is an unacceptable human health risk from consumption of all seafood items with similar mercury levels, we cannot conclude that there is unacceptable risk associated with food items from the Penobscot.

**A. The U.S. EPA's reference dose and the Maine Fish Tissue Action Level are conservative screening thresholds, exceedance of which does not prove an unacceptable risk.**

If mercury in the Penobscot seafood does not present any greater risk to human health than mercury in seafood found at supermarkets throughout Maine, how do Plaintiffs purport to demonstrate the existence of an unacceptable risk to human health? Their argument goes like this:

The average mercury concentrations in these species at many locations substantially exceed the state safety standard (. . . the Maine Fish Tissue Action Level) . . . . Consumption of these foods would also cause consumers to exceed the U.S. [EPA] reference dose, the safe ingestion rate set by the federal government. Mercury levels in Penobscot foods therefore pose an unacceptable risk to human health.

Pls. Br. at 13. The logic of Plaintiffs' position is that if consumption of a food item causes consumers to exceed the U.S. EPA's reference dose or Maine's Fish Tissue Action Level, that food item must therefore pose an unacceptable risk to human health. The argument is simple, but wrong, as it rests on a fundamental misunderstanding of the nature and purpose of the screening thresholds.

The EPA reference dose is the product of a safety assessment that builds in a tenfold safety factor. Tr. 2332:1-18 (Bolger). An exceedance of this threshold value does not signal an increase in the probability of adverse effects (Tr. 2303:16-25 (Bolger)) or that any particular consequences may be expected to occur. DX 1226 at 19, n.4; Tr. 2304:11-16; 2305:3-5 (Bolger). People with blood levels in excess of the reference dose retain a substantial margin of safety (up-

to-tenfold-higher where no effects have been observed), and are not subject to an unacceptable risk of harm. DX 1024; Tr. 2335:22-2337:3; 2337:5-2339:8 (Bolger).

The blood level that corresponds to the reference dose is 5.8 ppb (Tr. 2319:22-25 (Bolger)), which is tenfold below 58 ppb – and 58 ppb is “the most conservative estimate of an increase of 5 percent risk in a population of a small decrement in IQ.” Tr. 2437:17-23 (Bolger). An exceedance of the reference dose should not be misunderstood as reflective of any demonstrable human health risk.

The reference dose is “the lowest and most conservative value” developed by any public health agency anywhere in the world. DX 1070; Tr. 2332:19-2334:11 (Bolger); 899:12-15 (Grandjean). For example, the screening value set by the U.S. Centers for Disease Control is threefold greater than the reference dose. Tr. 2467:13-22 (Keenan). In fact, all screening levels established by public health bodies subsequent to the reference dose have been higher. DX 1070.

The reference dose is “intended to serve as a level of exposure without expectation of adverse effects when that exposure is encountered on a daily basis for a lifetime.” PX 122 at xiii. But Plaintiffs offer no evidence that anyone is being exposed to mercury-contaminated Penobscot food items on a daily basis (or any duration). Instead, their expert, Dr. Grandjean, misuses the reference dose to form the basis for his unsupported opinion that a single, one-time exposure to Penobscot lobster, eel, or black duck creates a substantial risk to human health. Tr. 871:23-872:19 (Grandjean). Dr. Grandjean’s single-exposure theory of harm is unsupported at levels found in the Penobscot and at odds with the purpose for which the reference dose was designed, which was as a screening threshold. Tr. 2304:-2305:12 (Bolger); 2491:17-2495:12 (Keenan). Indeed, the U.S. FDA disagrees with Dr. Grandjean’s opinion and has concluded that

there is no evidence that a single serving of mercury-contaminated fish can pose a reasonable possibility of injury, even in the case of a pregnant woman. DX 515 at 14-15.

Nor is the Maine Fish Tissue Action Level a useful tool for assessing whether Penobscot food items pose an unacceptable risk to human health. The Maine Fish Tissue Action Level is a screening level which is derived from the EPA reference dose (Tr. 2420:18-2421:3 (Bolger)); thus the foregoing critique of the reference dose applies with equal force to the Fish Tissue Action Level. The Court should not use screening values designed to flag a potential risk as a basis for ruling that mercury in the Penobscot has in fact created an actual and unacceptable risk to human health.

Like the EPA's reference dose, the Maine Fish Tissue Action Level does not represent a concentration of mercury above which there is an unacceptable risk of harm; it is a level below which there is a negligible risk of harm. JX 85 at 1. This distinction is critical in risk assessment. The action level is merely the threshold at which advisories are considered. JX 85 at 1. The State's 0.2 ppm action level is "exceeded throughout the State of Maine." Tr. 2452:2-14 (Keenan), Tr. 2420:18-20 (Bolger). The 0.2 ppm action level is also about the same as the average concentration reported in lobster nationally in a peer reviewed study of which Dr. Fisher is a co-author. Tr. 2455:20-2456:1; 2457:5-13 (Keenan). Indeed, the State has issued consumption advisories for exceedances of the Fish Tissue Action Level for all freshwater bodies in Maine, including the Penobscot River below Lincoln, well above the aquatic influence of discharges from the HoltraChem facility. Tr. 2452:15-2453:10 (Keenan); DX 512; DX. 576. More broadly, 70,000 square kilometers of lakes and over 2 million kilometers of rivers are

under fish consumption advisories for mercury in the United States. Tr. 1508:19-22 (Wiener).<sup>8</sup> Essentially all rivers and lakes in Maine (to say nothing of other water bodies across the United States) would require remediation if 0.2 ppm in fish tissue were the standard for making remediation determinations.

The Fish Tissue Action Level is not calibrated to actual human exposure to Penobscot species. Tr. 2462:11-16 (Keenan). It is based on a rate of fish consumption derived from surveys measuring how much fish recreational freshwater anglers might eat. Tr. 2462:17-18 (Keenan). Lobster and crab are saltwater shellfish that are fished commercially, and information specific to shellfish consumption could have (but has not) been used by the Study Panel or Plaintiffs to assess exposure to those species. As for eel and duck, few people eat eel or duck from the Penobscot. Tr. 601:5-8 (Whipple), Tr. 606:1-4, 8-13 (Whipple). Plaintiffs' human health expert failed to obtain any information about the rate of actual human consumption of Penobscot lobster, eel, or black duck. Tr. 889:8-891:12 (Grandjean). Such evidence is required for Plaintiffs to meet their burden to prove that "in actuality, mercury contamination in the lower Penobscot adversely affects . . . human health . . ." *Maine People's Alliance*, 471 F.3d at 282. Plaintiffs have failed to muster that proof.

As the Plaintiffs point out, Maine agencies have acted in accordance with their action levels by issuing a duck consumption advisory and closing an area to lobster trapping "as a precautionary measure." Pls. Br. at 15; PX 84. These decisions are the product of "policy call[s]," as opposed to scientific evaluation of human health risk. Tr. 2374:20-23; 2436:2-22 (Bolger). Maine's regulatory decisions on fish and waterfowl consumption advisories and fishery closures are driven by a range of factors that may not be tied to a scientific evaluation of

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<sup>8</sup> Advisories are issued by the states, and the level at which advisories are issued varies among the states, with some states setting advisory thresholds as high as 1 ppm in fish. Tr. 1509:7-18 (Wiener).

human health risk. Tr. 2343:1-15 (Bolger). That much is clear from the State's acknowledgment, when it announced the closure of a small section of the lower Penobscot River to lobster and crab fishing, that:

It is important to understand that lobsters from within the closed area are still safe to eat, but the State Toxicologist would advise that sensitive populations limit their consumption of lobsters from this area.

DX 575. If the regulatory agency charged with overseeing Maine's fisheries has deemed lobsters from within the closed area still safe to eat, the implementation of the closure cannot be enough to prove (or even constitute evidence that) the lobsters in question pose an unacceptable risk to human health.

**B. FDA's net benefits assessment establishes that eating Penobscot seafood in the quantities the parties have assumed has no net adverse health effects.**

Plaintiffs' unacceptable-risk-of-harm argument is at odds with the comprehensive analysis of the health effects of mercury in seafood published earlier this year by the FDA. DX 1226. The FDA concludes that eating seafood confers substantial health benefits, even when seafood contains the levels of mercury found in the Penobscot and even when consumed in quantities far higher than either Dr. Keenan or Dr. Grandjean assume. Tr. 2311:2-11 (Bolger).

The FDA's quantitative assessment of the net benefits of fish consumption (published in June 2014) is the "best available consideration of the totality of the science . . . on the net effect of fish consumption and on health." Tr. 2297:24-2298:1 (Bolger); DX 1226. FDA examined the effect of eating different species of fish having varying mercury levels. It found that consumption of albacore tuna—which has an average mercury level of 0.35 ppm, higher than the Study Panel found in the average upper estuary lobster and much higher than lobster in the entire study area—is on balance beneficial up to 67 ounces (over four pounds) per week; only then does albacore tuna consumption begin to have net adverse health effects. DX 1226 at 104. FDA

even found net benefits to eating shark (0.98 ppm) and swordfish (1.00 ppm). Tr. 2348:19-22 (Bolger); DX 1266 at 104. To experience net adverse health effects from eating these species—which have average mercury levels over three times higher than Penobscot lobster—a person would have to eat 24 ounces (1.5 pounds) per week. DX 1226 at 104. Again, this is a much larger weekly intake than either Dr. Keenan or Dr. Grandjean posited, and of fish much higher in mercury.

Plaintiffs' position that eating a small fraction of those amounts could cause adverse effects, or an unacceptable risk thereof, cannot be correct.<sup>9</sup> Dr. Grandjean's position that a single six-ounce meal of Penobscot lobster could cause harm is also at odds with the position of the U.S. Department of Agriculture and Department of Health and Human Services that pregnant women can eat six ounces per week of white tuna, even though it has mercury levels above those found in Penobscot lobster (Tr. 843:18-844:24 (Grandjean)), and with the State of Maine's advice that eating tuna in limited quantities is safe for pregnant women. Tr. 853:19-854:1 (Grandjean).

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<sup>9</sup> Plaintiffs take the position that lobster and tuna cannot be compared in this fashion because tuna contains higher quantities of omega-3. But the FDA ran its analysis twice—first treating all fish as identical packets of nutrients that are the source of beneficial effects, then again treating omega-3 as the sole source of beneficial effects. DX 1226 at 104, 107. Either way, the findings as to how much tuna or lobster could be eaten in a week without net adverse effects were the same. Moreover, although tuna does provide more omega-3 than lobster, eating 67 ounces of tuna in a week still entails exposure to levels of mercury far higher than the levels Dr. Grandjean claims are harmful, and the FDA's inescapable conclusion is that those levels are safe.

In any event, omega-3 is not the only reason to eat fish. The FDA considered all nutrients in fish (e.g., “easily digestible protein, high levels of the amino acids taurine, arginine and glutamine, micronutrients including vitamins A and D, and minerals such as iodine and selenium”), not just Omega 3 fatty acids, as nutritional benefits, and largely assumed that nutritional benefits are associated with the quantity of fish consumed, not with the type of species. DX 1226, p. 17; Tr. 2298:17-2299:2 (Bolger). Dr. Bolger explained that FDA's assumption that different species of fish offer comparable nutritional benefits, even though Omega-3 fatty acid content is known to vary between species of fish, is “a tenable assumption” made by the agency based “on what we know in terms of science.” Tr. 2399:20-2401:8 (Bolger); DX 1226 at 7 (“The main focus of this modeling continues to be on fish, not omega-3 fatty acids from fish.”) FDA concluded, “[b]ecause the exact combination of nutrients in fish responsible for beneficial effects is not fully understood, in much of our modeling we treated all commercial fish as being alike in terms of benefits conferred.” DX 1226 at 59.

Dr. Whipple agreed that Dr. Grandjean's opinion that there is a substantial excess in human exposure to methylmercury from Penobscot food items, and that this is a serious health problem, "overstates the evidence." Tr. 615:20-616:4. He testified that he considers Dr. Bolger to have a good reputation and to be an expert in mercury risk assessment. Tr. 620:11-22. Dr. Whipple agrees with Dr. Bolger's criticism of Dr. Grandjean's reliance on the single meal theory. Tr. 620:25-621:12.

Dr. Bolger explained that risk from consumption of mercury at levels found in the Penobscot (and in seafood everywhere) arises only after "ongoing exposure over a period of time of weeks to months." Tr. 2295:21-2296:2 (Bolger). This is so because the relevant parameter for assessing risk to fetal health—the most sensitive scenario—is the mother's steady-state blood-mercury level, and the amount of mercury in a single serving of seafood is not enough to cause a meaningful change in that level. Tr. 2328:24-2329:2 (Bolger). Because mercury that is ingested is diluted in 4.5-to-5 liters of blood, a single meal would not be enough to create dangerous levels; instead, sustained consumption (repeated meals) over time would be required. Tr. 2345:4-2345:17 (Bolger). To simply divide the amount of mercury in a single meal by the reference dose is a "math exercise," one that is "not based on the biology" of what it actually takes to achieve and sustain a steady-state blood-mercury level. *Id.* Such calculations treat the reference dose, a threshold screening value based on epidemiological studies assessing steady-state blood-mercury levels, as if it were instead an indicator of acute toxicity. Tr. 2345:18-2346:1 (Bolger). This is a misapplication of the reference dose, which is based on chronic, not acute, exposure. Tr. 2327:2-13 (Bolger).

The Court need not take Dr. Bolger's or Dr. Keenan's word that Dr. Grandjean's single-meal theory is unfounded, as the federal government has repeatedly advised the American public

that the mercury contained in one meal of seafood does not put their health at risk. The FDA has advised the public that “[o]ne week’s consumption of fish does not change the level of methylmercury in the body much at all.” JX 84; Tr. 2295:15-2296:6 (Bolger).

Plaintiffs would have the Court break new policy-making ground by ruling, in effect, that the federal and state governments have been wrong to recommend that it is safe for pregnant women to eat tuna with mercury levels akin to the levels found in Penobscot lobster. The Court should decline that invitation.

**C. Dr. Keenan’s exposure assessment further demonstrates the absence of any substantial risk to human health.**

Even if it made sense to use the reference dose as an indicator of substantial risk to human health, the exposure assessment and risk analysis performed by Dr. Keenan demonstrates that actual patterns of consumption of Penobscot food items are not high enough to pose a risk to actual human consumers. An exposure assessment is based on estimates of the magnitude, duration, and frequency of consumption. Tr. 2325:5-19 (Bolger); Tr. 2460:2-9 (Keenan). It aims to “[g]et as close as you can to what people are actually eating, how much they’re eating, and how frequently they’re doing so.” Tr. 2389:20-22 (Bolger). One cannot accurately characterize risk without an exposure assessment. Tr. 2459:19-2460:14 (Keenan).<sup>10</sup>

To determine how much Penobscot lobster, eel, and black duck a person could eat without exceeding the reference dose, Dr. Keenan used the same methodology used by the State to issue fish consumption advisories (Tr. 2462:19-2463:25; 2464:11-2465:3 (Keenan)), but with estimates of the rate at which these particular food items are actually consumed (Tr. 2464:1-9;

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<sup>10</sup> Dr. Grandjean did not perform a dietary exposure assessment and as a result his assessment of risk is “fraught with all kinds of problems,” is “incorrect,” and “imprecise.” Tr. 2325:23-2326:6. (Bolger).

DX 1071). Dr. Keenan used the best available exposure information to estimate consumption rates. DX 1071; Tr. 2467:23-2469:25 (Keenan).

Dr. Keenan erred on the high side in estimating consumption rates. For lobster, he used a meal frequency of 52 lobsters per year. Tr. 2466:14-23 (Keenan). The Maine Bureau of Health used this same figure in its assessment of human health risk after the *Julie N* oil tanker spill in Portland Harbor, which is “the only information we have in the entire state, or anywhere, on lobster.” *Id.* Dr. Keenan also considered information in a study that surveyed fish and shellfish consumption by 594 Maine women. DX 1080; Tr. 2470:9-2472:4 (Keenan). That study reported that Maine women consumed on average 17 meals of all types of shellfish over a 12-month period (Tr. 2471:22-2472:4 (Keenan)); Dr. Keenan’s figure of 52 meals of lobster is threefold higher and therefore provides a more conservative number. Tr. 2472:2-10 (Keenan).

Regarding black ducks, Dr. Keenan assumed 10 meals per year, based on federal duck hunter success data. Tr. 2472:11-2473:5 (Keenan). According to U.S. Fish and Wildlife Service data, the average duck hunter bags 10 ducks per year, and black duck are about 9% of the harvest. *Id.* Although the average hunter could therefore be expected to bag one black duck per year (Tr. 2473:6-15), Dr. Keenan assumed that a duck hunter would eat 10 Mendall Marsh black duck meals per year. Tr. 2473:16-25 (Keenan). Dr. Keenan also conservatively assured that all black duck consumed would be from the study area, which is unlikely, given the very limited population of black duck in the study area (only about 135 or so black duck are found in Mendall Marsh). Tr. 1965:15-24 (Kopec). The likelihood that one person might eat more than 10 meals of Mendall Marsh black duck in a year approaches nil. Tr. 2474:1-20 (Keenan); Tr. 601:5-8 (Whipple) (agreeing with Dr. Keenan).

Regarding eels, the Study Panel found that there is little, if any, human consumption of Penobscot River eel. Tr. 606:1-4, 8-13; 608:13-25; 609:7-9 (Whipple) (sustained exposure to Penobscot eel is unlikely). Erring on the high side, Dr. Keenan assumed consumption of 22.6 eels per year, even though he agrees with the Study Panel that few (if any) people in Maine eat Penobscot River eel. Tr. 2467:23-2469:11 (Keenan); 2046:12-23; 2047:5-25 (Kopec).

Dr. Keenan proceeded to derive species-specific mercury concentration levels that would cause an exposure at the reference dose at the assumed consumption levels based on data gathered from independent sources. Tr. 2478:7-11; 2479:14-1480:2; 2480:21-2481:6; 2481:23-2485:24 (Keenan); DX 1072. Dr. Keenan assessed risk based on these conservatively estimated mean concentration levels, rather than the maximum concentration of mercury detected in the study area. Using maximum concentrations would have been “uninformative,” and would have misrepresented “the potential public health risk,” because “we’re not dealing with an acute hazard here[,] [w]e’re dealing with . . . a contaminant [that] requires a steady-state level of exposure over a period of weeks to months.” Tr. 2343:23-2344:4 (Bolger). Although occasional exposures to food items with high mercury concentrations may occur, “the likelihood that someone would eat that high level all the time is exceedingly remote, and . . . you can’t use the highest level to represent . . . the range of values that are found in that food on a day-to-day basis.” Tr. 2344:5-9 (Bolger). The vast majority of lobster in the study area have low levels of mercury (less than albacore tuna), with a much smaller number of higher-mercury specimens. DX 1085; Tr. 2490:3-11 (Keenan). The probability of repeatedly consuming lobster with high mercury levels is low. DX 1084; Tr. 2490:15-1491:16 (Keenan).

When the analysis is conducted based on actual rates of consumption and mean mercury concentrations, it turns out that none of the Penobscot food items under study would cause

consumers to exceed the reference dose. DX 1082. The gap between the species-specific mercury concentration thresholds Dr. Keenan derived and the mean mercury concentrations the Study Panel observed in lobster, eel and black duck represents a “margin of safety.” Tr. 2487:4-13 (Keenan). Dr. Keenan therefore concludes that mercury concentrations in Penobscot food items do not pose a substantial human health risk, even if the appropriate yardstick for measuring risk is the reference dose.

To test the margin of safety for lobster, Dr. Keenan also considered how many meals of lobster one could eat without exceeding the reference dose. He concluded that one could eat 142 lobster per year from within the study area (or 97 lobsters per year only from the upper estuary). DX 1083; Tr. 2487:23-2488:9 (Keenan). By comparison, the average Maine woman eats 17 meals per year of all types of shellfish. Tr. 2488:10-17 (Keenan). Few if any women in Maine eat 100 or more lobster meals per year, and even that population (if it exists) would not plausibly eat only lobster from upper estuary (which is only open for fishing for four months out of the year, mid-July through the first of November, Tr. 1831:11-15, 1833:11-21 (Wyman)).<sup>11</sup>

Dr. Keenan considered, but decided against, factoring background mercury levels into his screening assessment. He explained that his assessment is already “very conservative,” and that because background exposures “come from eating seafood,” the issue here is substitution (of lobster for other seafood items), not additional exposure.<sup>12</sup> Tr. 2488:18-2489:6. Dr. Keenan’s

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<sup>11</sup> Even during the time when the upper estuary is a productive lobstering ground, fishermen do not set traps only in that area. For example, Mr. Wyman testified that he set 115-150 out of his 800 traps in the closed area, i.e., less than 20% of his total traps. Tr. 1833:22-1835:3 (Wyman). It might be reasonable to assume now, therefore, that 80% of his catch was of lobster outside the closed area.

<sup>12</sup> For example, it would not be reasonable to assume that a person with an existing background mercury exposure would start eating an additional 52 lobster meals per year, and that the mercury exposure from those lobsters would be added to a constant level of background exposure. Instead, a reasonable assumption would be that a person eating 52 lobster meals per year would be substituting lobster for other types of seafood. The question then becomes how much more mercury is in lobster than in whatever seafood would otherwise have been consumed. If Penobscot lobster is being substituted for albacore tuna, it does not change a person’s overall exposure; if Penobscot lobster is

screening methodology is the same methodology used by the State (and by extension the Study Panel, which merely adopted the State's Fish Tissue Action Level). That methodology does not consider background. Tr. 2489:12-19 (Keenan).

In contrast to Dr. Grandjean's unsupported speculation about what the effects of a single meal of Penobscot lobster, eel, or black duck might be, Dr. Keenan tested whether a single meal at mercury levels found in the Penobscot would put human health at risk, and concluded that it would not. Tr. 2295:24-25 (Bolger). Dr. Keenan ran a toxicokinetic model to assess how consumption of two randomly selected 2½ pound lobsters from within the study area within 48 hours would change blood mercury levels. Tr. 2491:17-2495:12. The model showed that eating two 2½ pound lobsters in 48 hours did not cause any meaningful elevation in blood mercury in humans. Tr. 2492:11-2493:5; 2494:9-19 (Keenan).

**V. There is No Evidence of Significantly Adverse Effects on Populations of Organisms.**

The Court directed the Study Panel to determine “the extent of the existing harm resulting from mercury contamination to the Penobscot River/Bay system” by answering the question: “Is any mercury in the Penobscot River/Bay system having significantly adverse effects on populations of organisms in the lower Penobscot River/Bay system?” JX 2 at 2. As the Court's question makes clear, the key question for purposes of making remedial decisions at contaminated sites is whether effects are so “significantly adverse” as to threaten “populations of organisms,” not whether scientists can demonstrate any effects at all associated with mercury exposure.

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substituted for swordfish, it would decrease overall exposure; if lobster is substituted for cod, overall exposure could increase. Dr. Keenan testified, however, that this sort of complex assessment is unnecessary. Tr. 2488:18-2489:19; 2495:2-12 (Keenan).

The Study Panel's screening-level ecological risk assessment reveals that neither mammal nor fish populations are at risk of significant adverse effects. The Study Panel also evaluated both fish-eating birds and insect-eating birds. It found that fish-eating birds are not at risk (Tr. 2763:12-2764:6; 2762:10-2763:7 (Henry)), but the parties agree that we cannot rule out a possibility of risk to two species of insect-eating songbirds in Mendall Marsh. Tr. 2771:5-12; 2776:2-20 (Henry). Although potential harm cannot be ruled out based upon the current evidence consistent with ecological risk assessment, the only way to know if a specific population is being harmed is by conducting site-specific studies of that population and measuring endpoints that are indicative of population-related effects. Tr. 432:22-433:2 (Rudd); 624:8- 625:23 (Whipple); 711:15-25 (Fisher); DX 1; JX 40 at 153:25-154:9 (Sandheinrich); JX 33 at 58:7-60:15 (Bridges); DX 20; 2776:17-20; 2795:14-2796:5 (Henry); 3245:4-16 (Connolly).

Ecological risk assessment is a distinct professional discipline practiced by natural resource agencies (e.g., U.S. EPA) and applied scientists in the decision-making process at contaminated sites. Tr. 2741:17-1743:5 (Henry). The Study Panel members and the Project Leader are mercury scientists, not ecological risk assessors Tr. 2743:12-2744:1 (Henry); "the academic research community, of which the Study Panel belongs, have no concept of ecological risk assessment." Tr. 2855:23-2856:9 (Henry). This disconnect is the root cause of much of the difference of opinion between Dr. Keenan and Dr. Henry, on the one hand, and Dr. Wiener, Dr. Kopec, and Dr. Evers, on the other. Dr. Wiener and Dr. Evers have academic or research backgrounds, rather than applied backgrounds as ecological risk assessors making decisions on clean-up of contaminated sites.

The U.S. EPA has developed "an extensive set of guidance on ecological risk." Tr. 2500:15-23 (Keenan); DX 759. This guidance is intended to assist "risk assessors and risk

managers” in making decisions “based on sound science” and to ensure “consistency throughout the United States” in assessment of ecological risk and related decisions. Tr. 2501:24-2502:8 (Keenan).

An ecological risk is characterized by its “magnitude, severity, [and] distribution.” Tr. 2504:9-17; 2505:22-2506:8 (Keenan). A risk is also assessed by the likelihood of recovery, whether a threat is transient, and whether the affected population is likely to recover within a reasonable period of time. Tr. 2504:9-17; 2506:6-11 (Keenan). The goal in ecological risk assessment is to protect “thriving and sustainable populations.” Tr. 2503:4-12 (Keenan). Dr. Evers suggested a rule of thumb that a twenty percent impact on a population would be significant to the sustainability of a population. Tr. 1938:2-6 (Evers), Tr. 1881:14-23 (Evers).

The first step in an ecological risk assessment is a screening level risk assessment (Tr. 2507:14-2508:14 (Keenan)), which involves a comparison of tissue levels found in the organism of concern with values found in the ecotoxicology literature. Tr. 2508:9-14 (Keenan). To set a screening value, best practices in ecological risk assessment call for looking at studies of whether exposure to a contaminant causes impaired growth, diminished survival, or reproductive effects. Tr. 2511:17-2512:8 (Keenan). These are the endpoints used by “any of the population models for looking at . . . sustainable populations.” Tr. 2512:9-14 (Keenan). By contrast, “we have no way of knowing whether” effects on biochemical markers (such as enzyme levels) or behavior may actually be “adverse to individuals . . . let alone to populations in the natural environment.” Tr. 2512:15-2513:16 (Keenan); Tr. 2851:15-2852:7 (Henry). The Study Panel itself recognized that evidence of biochemical effects on organisms as a result of exposure to a chemical does not necessarily translate to adverse effects on population: “The population significance of biochemical effects is less clear than those that directly affect parameters such as growth and

spawning behavior.” JX 6-2 at 2-5. Even Dr. Wiener conceded that behavioral and biochemical endpoints are “very hard to interpret from the standpoint of population-level significance.” Tr. 1433:8-9 (Wiener); Tr. 1542:9-20 (Wiener); DX 750 at 1537.

If evaluation at the screening stage indicates that a risk may be present, a more comprehensive ecological risk assessment is performed, referred to as a “baseline eco[logical] risk assessment.” Tr. 2509:6-18 (Keenan). A baseline ecological risk assessment may include population and community studies and site-specific toxicity studies. Tr. 2509:12-18 (Keenan). With the results of a baseline ecological risk assessment in hand, the extent and severity of the risk may be characterized and a judgment made concerning whether the risk is unacceptable or acceptable. Tr. 2510:3-15 (Keenan).

The Study Panel never got beyond a screening level ecological risk assessment. “They had an extensive set of data on tissue concentrations, which they then compared to screening values . . . .” Tr. 2510:17-21 (Keenan). But rather than determine that risk may be present based on a screening assessment, and proceeding to conduct a baseline ecological risk assessment—and the further population and community studies and site-specific toxicity studies that would entail—the Study Panel stopped, skipping straight to a risk management recommendation to pursue active remediation. “Stopping at this stage and suggesting remedial action is just not appropriate.” Tr. 2510:25-2511:2 (Keenan). Here, a screening assessment does not provide enough information to make an informed decision on the severity of the risk to populations and, therefore, the need for remedial action. Tr. 2511:3-10 (Keenan).

**A. Mammal populations in the Penobscot are not at risk of significantly adverse effects associated with mercury exposure.**

The Study Panel evaluated potential risk to three species of mammals in the study area: mink, otter, and bats. The Panel determined that mink and otter (both fish-eating mammals) are

not at risk. JX 6-1 at 1-31, Table 1-4; Tr. 2747:5-17 (Henry). Dr. Bodaly explained that mink and otter “did not have elevated concentrations in contaminated areas of the river compared to uncontaminated areas of the River.” Tr. 1044:4-8 (Bodaly). Although the Phase II Report lists bats as a species of concern, Dr. Whipple was equivocal on that subject, testifying that the data collected on mercury in bats did not reveal “much of a pattern” indicative of exposure as a result of proximity to the Penobscot – and the Panel dropped further study of bats as a result. Tr. 522:24-523:2 (Whipple). The Plaintiffs accept that there is “more uncertainty about whether the data establish harm to bats” and only mention bats in a footnote, indicating that risk to bats is not an important concern to them either.<sup>13</sup> Pls. Br. at 25, n.8.

**B. Fish populations in the Penobscot are not at risk of significantly adverse effects associated with mercury exposure.**

The Study Panel used two screening values to assess risk to fish: a 500 ng/g threshold for risk to general fish health; and a tenfold lower 50 ng/g (i.e. 50 ppb)<sup>14</sup> threshold for prey fish that might be eaten by predators. JX 6-2 at 2-5–2-6, 2-8–2-9. Fish in the study area are not at risk under the 500 ng/g value or under an alternative screening value derived by a statistical method used in ecological risk assessment. The Court should not use the prey fish value (50 ng/g) to screen risk because the prey fish value is a novel and untested approach to screening ecological risk at contaminated sites. It is also unnecessary, given that the Study Panel collected direct

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<sup>13</sup> In fact “more uncertainty” with respect to bats is charitable; bats in the study area are not at risk of significant adverse effects associated with mercury. To screen risk to bats the Study Panel set a screening threshold (10 ppm in bat fur) and compared that threshold to mean mercury concentrations in bats. The Panel reported an exceedance of the threshold as a risk. Yet Dr. Evers suggested 10 ppm in bat fur as a lowest observed effect level – not a lowest observed adverse effect level, and agreed that we cannot conclude that there are adverse effects to bats at 10 ppm. Tr. 1936:22-1937:7; 1938:22-1939:8 (Evers). Science simply cannot tell us much about mercury effects on bats, as “there’s actually been very little work done on bats, either in terms of exposure, that is, mercury concentrations in bats, or in terms of effects.” Tr. 2749:16-20 (Henry). There have been no studies on mercury levels associated with effects on bat growth, survival, or reproduction.

<sup>14</sup> Tr. 1524:25-1525:10 (Wiener).

evidence of mercury concentrations in predators. And that level falls below even concentrations found in pristine populations of fish throughout Maine.

**1. Fish health is not at risk.**

The Study Panel's screening value for fish health was 500 ng/g in fish muscle. Tr. 2515:5-19 (Keenan); JX 6-2 at 2-5-2-6. The source for this value is a recent book chapter by Sandheinrich and Wiener reviewing studies of mercury effects on fish. *Id.*, JX 77. The Study Panel wrote that the book chapter reports a mercury effects range of between 400 ng/g and 900 ng/g in fish muscle, but the book chapter actually reports a higher range, between 500 ng/g and 1,200 ng/g. Tr. 2515:20-2517:14 (Keenan); JX 77 at 185.<sup>15</sup> This 500-1,200 ng/g range is based not just on studies of effects relevant to populations (reproduction, survival, or growth), but also on more obscure biochemical effects of unknown relevance to populations. Tr. 2517:1-14 (Keenan); Tr. 1442:22-1443:1 (Wiener). Because the Sandheinrich and Wiener range (500-1,200 ng/g) includes effects that cannot be directly connected with population health, it is "conservative" (Tr. 2517:11-14 (Keenan)) for purposes of assessing significant adverse effects to fish populations, the issue here. Tr. 2517:11-14 (Keenan).

Even accepting at face value the Study Panel's very conservative 500 ng/g screening value, all but one of the fish species are below that value, which is the lowest end of the Sandheinrich and Wiener range (up to 1,200 ng/g). Tr. 2519:1-5 (Keenan); DX 1091. The only fish above the Study Panel's value are eel, but mean concentrations of mercury in eel are just 7%

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<sup>15</sup> Plaintiffs continue to push the wrong value in their brief. Plaintiffs argue that "Dr. Sandheinrich recommended a range of . . . approximately 400 to 900 ng/g in muscle." In fact, Dr. Sandheinrich references in Appendix 2-1 to Chapter 2, his then-forthcoming book chapter, and writes "[i]n a separate review of the literature on the toxicity of methylmercury to fish, Sandheinrich and Wiener (in press) concluded that alternations in biochemistry, organ histology, and reproduction in fish occur at methylmercury concentrations of . . . about 0.5 to 1.2 ug g<sup>-1</sup> wet weight in axial muscle." JX 6-2 at App. 2-1, 31. Dr. Wiener confirmed that the range of values in the book chapter he co-authored with Dr. Sandheinrich is 500 to 1,200 ng/g in muscle. Tr. 1516:7-16 (Wiener). The Study Panel did not chose a value *within* this range, but rather misrepresented the range, and selected the lowest value within the actual range.

higher than 500 ng/g—“just slightly higher than the very lowest end” of the Sandheinrich and Wiener range. Tr. 2519:6-10 (Keenan). Plaintiffs argue that mean eel concentrations “exceed” the Study Panel’s target, but fail to mention the slight extent of the exceedance. Pls. Br. at 29. Nor do Plaintiffs mention that mean mercury concentrations in many species of fish across the United States exceed 500 ng/g; in fact these levels are “common in piscivorous fish throughout North America.” Tr. 1509:19-1510:21; 1514:6-18 (Wiener); JX 77 at 185. As Dr. Wiener testified:

Q: So the Study Panel’s target to protect fish health is set at a level that’s commonly found in fish throughout North America?

A: Yes.

Tr. 1514:15-18 (Wiener). Many populations of fish in North America contain mercury at twice the Study Panel’s screening value (i.e., 1,000 ng/g). Tr. 1514:23-1515:6 (Wiener).

The magnitude and severity of the exceedance of the Study Panel’s 500 ng/g value is exactly the sort of information needed to assess whether there are significant adverse effects on eel populations. A seven percent exceedance of a very conservative target at the lowest end of the range suggested by Dr. Sandheinrich and Dr. Weiner does not present a risk of significant adverse effects for the population of eel in the Penobscot River.

An additional line of evidence supporting the conclusion that fish health is not at risk is the fish health screening value derived by Dr. Keenan using well-accepted statistical ecological risk assessment methodology. Tr. 2521:17-2523:14 (Keenan). The method used by Dr. Keenan, described in the Beckvar et al. paper (2005) (JX 101 at 2096, the “third method”), has the advantage of not making any “a priori decisions about which authors, which studies, which laboratories” or methods are most appropriate for setting a screening level among the myriad of published studies, and of incorporating effects results from all relevant studies. Tr. 2523:1-

2524:14 (Keenan). The method also recognizes that available studies involve fish other than eel, and that it is unknown whether eel are more or less sensitive to mercury than other species studied by aquatic ecotoxicologists. Tr. 2526:13-18, 2684:20-23 (Keenan). The method includes studies assessing growth, survival, and reproduction, because these are all endpoints relevant to assessing the health of a population. Tr. 2722:18-2723:6 (Keenan).

Dr. Wiener criticized Dr. Keenan's use of studies assessing fish growth and survival, but that is exactly the same approach taken by Beckvar in her published paper. Tr. 1542:21-1544:17 (Wiener). Further, it is unknown whether growth or reproduction is actually a more sensitive endpoint with respect to fish exposure to mercury. Tr. 1540:12-1541:1 (Wiener); DX 750 at 1541. The resulting toxic effects level threshold calculated using the statistical method employed by Dr. Keenan is a level at which the incidence of effects is predicted to be rare. Tr. 2522:11-14 (Keenan). Using this statistical approach, Dr. Keenan derived a toxic effects level to protect fish health at 1,600 ng/g. Tr. 2525:9-11 (Keenan).

To address the possibility that any one study might bias the screening value too high (or low) Dr. Keenan ran a sensitivity analysis, calculated error bars, and found that the toxic effects level is stable, i.e. the result is not sensitive to the inclusion or exclusion of any one study. Tr. 2526:22-2527:15 (Keenan); DX 1095. Although diminished survival is an important endpoint in addressing the health of a fish population, Dr. Keenan was criticized on the grounds that survival is a relatively insensitive endpoint as compared to reproduction. Yet even if all studies evaluating diminished survival are excluded, the statistical screening level remains stable. Tr. 2545:15-19; 2582:16-2583:24 (Keenan).

Dr. Keenan's statistically derived screening value provides an additional line of evidence supporting the conclusion that would have been reached even under the Study Panel's own screening value: fish health is not at risk as a result of mercury exposure in the Penobscot.

**2. Mercury levels in prey fish do not pose a risk to predator fish health.**

The Study Panel proposed a far lower screening value of 50 ng/g as a concentration of mercury that "could be present in prey species [of fish] and not affect the health of predacious fish species." Tr. 2528:6-11 (Keenan). The concept behind this value is that one can assess risk to predacious fish based on the concentration of mercury in their diet. But we do not have information on the make-up of the diet of fish predators in the Penobscot (or in comparable systems), so it is impossible to know how much of what food sources (containing various levels of mercury) might be eaten by any (much less all) species of fish predators in the River. Tr. 2528:19-2529:9 (Keenan).<sup>16</sup> We also do not know how much of the mercury in the diet of different species of fish predators is excreted, as compared to the amount that is actually metabolized and assimilated.<sup>17</sup> *Id.* Screening risk based on mercury in fish prey is therefore "inappropriate," and fraught with uncertainty. *Id.* It is a novel and untested approach, and there is no evidence that it has ever been used to inform a remedial decision. Tr. 2528:12-18 (Keenan). The Depew paper itself, which is the basis for the Study Panel's threshold, suggests caution given "the lack of high-quality toxicological studies on the adverse effects of dietary [methylmercury] exposure to fish." JX 750 at 1545. Dr. Wiener explained that this is a "very

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<sup>16</sup> For example, predators like salmon and striped bass are only present in the Penobscot River for "a short period of time," and get most of their mercury exposure from "the marine food webs[,] the ocean, not the River. Tr. 2529:15-20 (Keenan); Tr. 1493:17-20 (Wiener) (striped bass get most of their mercury exposure from marine food webs outside the study area). Mercury in fish prey in the River is not an important source of mercury exposure to these species.

<sup>17</sup> Different species of fish may assimilate methylmercury at different rates. Tr. 1522:3-8 (Wiener); DX 750 at 1544.

new area of investigation” and that “we need more studies with more species to – to nail things down more firmly.” Tr. 1529:19-1530:2. The Court should not break new ground here.

A screening value for fish prey species is also unnecessary because we have direct evidence of mercury concentrations in eel, which is a predacious fish (as well as in fish-eating birds and mammals—which the Study Panel finds are not at risk). JX 6-2 at 2-8 - 2-9. There is no need to extrapolate or make assumptions about the exposure of predators to mercury in prey fish when we have actual data on mercury concentrations in predators themselves. Tr. 2529:10-14; 2530:1-14 (Keenan). Dr. Wiener agreed that a more direct way of assessing the risk of fish predators is to sample the concentrations of mercury in the predators. Tr. 1523:20-24 (Wiener).

The 50 ng/g value is in excess of levels found in fish populations in remote and pristine waterbodies throughout Maine and elsewhere, as the Study Panel recognized. Tr. 2530:15-2532:12 (Keenan); JX 6-2 at 2-9. Dr. Bodaly testified that this value is “surprisingly low” and is “shocking.” Tr. 1015:15-17 (Bodaly); JX 107 at 6:18-7:6 (Fisher). Given that “natural fish populations of Maine fish throughout the State” exceed 50 ng/g, that figure is not a useful screening value “to make any type of remedial decision.” Tr. 2530:22-25 (Keenan); JX 101 at 2096. Or, put another way, if 50 ng/g is a value that screens for risk sufficient to justify remedial action, fresh-water bodies across the State would require a mercury clean-up. No one takes that position.

The 50 ng/g value is also problematic because it is not based on any evidence suggesting that fish reproduction, growth, or survival are actually harmed by exposure to a diet containing 50 ng/g mercury. The basis for the Study Panel’s 50 ng/g value is one study of one species of freshwater fish not present in the study area reporting no effects at 40 ng/g. DX 750 at 1539, Table 2 and 1542; Tr. 1531:1-4 (Wiener). Even if effects had been found in that one study at

that level (they were not), setting a general screening level based on one study of one species is contrary to best practices and amounts to speculation. Tr. 2683:21-2684:23 (Keenan). There is no scientific basis to screen for risk based on a 50 ng/g mercury level in fish prey.

Although a screening value for mercury in fish prey is unnecessary, because “we have our answer by looking at the predators themselves” (Tr. 2540:17-20 (Keenan)), Dr. Keenan derived a toxic effects level to protect fish health. Tr. 2532:18-2533:1 (Keenan). He derived a screening value of 680 ng/g for fish prey. Tr. 2533:12-14 (Keenan).

### **3. Fish-eating bird populations are not at risk.**

The study panel sampled two categories of birds: piscivorous (fish-eating) birds and insectivorous (insect-eating) birds in Mendall Marsh. As they had with other species, the Study Panel then compared mean mercury concentrations found in each species of birds against proposed screening values to assess risk.

All of the fish-eating birds in the study area are below the Study Panel’s 2 ppm screening value<sup>18</sup> for such birds. Tr. 2761:14-17 (Henry). The fish-eating birds not at risk are belted kingfisher, osprey, bald eagle, double-breasted cormorant, and black guillemot (also a fish-eating bird, contrary to how guillemot are categorized in the Phase II Report). Tr. 2761:18-2763:11 (Henry). Black duck eat small fish and invertebrates, but their blood mercury concentrations are below both the Study Panel’s fish-eating bird threshold (2 ppm) as well as the Panel’s insect-eating bird threshold (1.2 ppm). Tr. 2763:12-2764:22 (Henry). Based on the Study Panel’s own screening values, none of these six species of birds are at risk of significant adverse effects.

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<sup>18</sup> Dr. Henry did not comment on the piscivorous bird threshold proposed by the Study Panel. Tr. 2819:20-21 (Henry). She simply observed that concentrations were below that value and, therefore (using the Study Panel’s own value) not at risk.

**C. Two species of insect-eating birds in Mendall Marsh may be at risk, but the magnitude and extent of risk is unknown and actual harm is unproven.**

The other category of birds is insect-eating birds in Mendall Marsh (song sparrow, swamp sparrow, Nelson's sparrow, red-winged blackbird, and Virginia rail). Plaintiffs devote much of their argument to disputing Dr. Henry's opinions on risk to birds, seeking to portray her as an unreliable hired gun (despite the fact that she had never testified prior to this case). In fact, Dr. Henry concludes that two species of migratory songbirds in Mendall Marsh (Nelson's sparrow and red-winged blackbird) are at potential risk. Adverse reproductive effects on these two species cannot be ruled out based on the screening level ecological risk assessment performed so far. But Dr. Henry concludes that three other species of birds in Mendall Marsh (song sparrow, swamp sparrow, and Virginia rail) are not at risk. Tr. 2775:15-2776:1.

Dr. Henry set a screening value of 3-4 ppm for songbirds in Mendall Marsh based on several studies of the tree swallow at a mercury-contaminated site, the South River. Tr. 2771:16-23 (Henry). Dr. Henry explained that she focused on the tree swallow studies because they involve "migratory songbirds" and are, therefore, "most relevant" to the bird population of concern. Tr. 2835:12-19 (Henry). Like the songbirds in Mendall Marsh, tree swallows are migratory. Tr. 2771: 16-23 (Henry).

Dr. Henry summarized relevant studies in a chart (DX 1054) and reported their varying results, which may be summarized as no effects below 3ppm, and effects in the range of 3-4 ppm. Tr. 2772:21-2774:7 (Henry). Based on this range of values, Dr. Henry set a screening threshold for risk of diminished reproductive success at 3 to 4 ppm. Tr. 2774:8-13 (Henry). Dr. Henry's range is consistent with Dr. Sandheinrich's recommended value of 3 ppm. Tr. 2774:14-18 (Henry); JX 6-2, App. 2-17 ("blood of adults, 3.0 ug g<sup>-1</sup> wet weight"). Plaintiffs argue that Dr. Henry agreed that a reasonable scientist could "hypothetically" set a lower standard (Pls. Br.

at 28), but she also emphasized that “the most relevant studies for the invertivorous bird populations” involving multiple aspects of reproductive success “strongly supported” a 3-4 ppm screening level. Tr. 2840:21-2841:9 (Henry).

Dr. Henry was critical of the Study Panel’s 1.2 ppm insect-eating bird screening value for three primary reasons: (1) it is below levels at which no effects were found in the tree swallow studies; (2) it is based on studies that are not useful in assessing the health of bird populations; and (3) it is based on a study of Carolina wren by Jackson et al. that is not sufficiently strong for use in ecological risk assessment purposes. Tr. 2770:24-2771:4 (Henry). Taking these points in order, the 1.2 ppm value cannot be reconciled with the results of the tree swallow studies. As noted, several studies of the tree swallow suggest that mercury has no effects below 3 ppm and that reproductive effects might be seen in the range of 3-4 ppm. Tr. 2772:21-2774:7 (Henry). There are significant differences between the non-migratory Carolina wren and the migratory songbirds in Mendall Marsh, and these differences may affect their ability to tolerate mercury exposure. Tr. 1950:14-1951:4 (Evers). The tree swallow is a more relevant comparison to the birds of concern in Mendall Marsh, as the swallow is also migratory (unlike the Carolina wren).

Second, the studies referenced by the Study Panel in section 2.4 of Chapter 2 (JX 6-2 at 2-6 – 2-8) are not relevant (e.g., a report on bald eagle concluding that mercury is not affecting Maine’s bald eagle population), or examined effects that cannot be used to assess the health of a population (i.e., growth, survival, or reproduction). Tr. 2776:21-2782:21 (Henry) (commenting on each study). For example, a McKay and Maher paper referenced by the Study Panel examined singing behavior in Nelson’s sparrow, but singing behavior is not an effect on growth, survival, or reproduction and the authors themselves suggested that further study would be necessary to understand whether their results might be connected to reproductive success. Tr.

2782:12-21 (Henry). Dr. Evers testified that it is unknown whether that study is meaningful in assessing adverse effects (Tr. 1937:18-19 (Evers)), yet the Study Panel nevertheless cites that study in Chapter 2.

Third, the Jackson et al. study of mercury effects on nest success of the Carolina wren, which is the primary study on which Dr. Evers relied in proposing a 1.2 ppm threshold (Tr. 1885:16-19 (Evers)), should not be used to set a screening threshold for purposes of ecological risk assessment.<sup>19</sup> The raw data underlying the paper, evaluated in this case for the first time by anyone other than the authors,<sup>20</sup> shows that “for the first three years of study, so 2007 to 2009, the nest success was identical between upstream [lower mercury] and downstream [higher mercury] portions of the site.” Tr. 2784:11-19 (Henry). An impact on nest success was only found in one year, 2010. Tr. 2784:20-22 (Henry). And whether this is due to variability in the system for reasons unrelated to mercury is unknown. Tr. 2785:10-24 (Henry). The paper suffers from a flaw in its treatment of predated nests (nests destroyed by snakes or possums). Tr. 2786:11-23 (Henry). It acknowledges that nest failure due to predation had nothing to do with mercury exposure, but nevertheless includes predated nests in its analysis of the effects of mercury exposure on nest success. Tr. 2786:11-23 (Henry). “[B]ecause their own modeling has shown that predation has nothing to do with contamination, they have basically weighted the findings in favor of saying that mercury contamination is reducing nest success” by included predated nests in their analysis. *Id.* The problem is compounded because the paper is based on a “very limited data set” (Tr. 2789:12-24 (Henry)); when predated nests are excluded, there are

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<sup>19</sup> Dr. Henry’s expert report detailing her comments on the Carolina wren paper is JX 54.

<sup>20</sup> Tr. 2783:17-24 (Henry); Tr. 1953:19-24 (Evers); DX 544 (subpoena); DX 545 (response); DX 546 (authorization from Department of Interior to share raw data). The raw data itself was not subject to peer review. Tr. 1954:3-13 (Evers).

only six failed nests,<sup>21</sup> two upstream (lower mercury) and four downstream (higher mercury)—a difference of only two nests. Tr. 2788:8-24, 2789:7-24 (Henry). Further, the distribution of nest failures is largely constant over the range of measured mercury concentrations, which is significant because “if you’re expecting to see increased nest failure with increasing mercury concentrations, you would anticipate seeing more failed nests at the upper range than you would at the lower range, and that’s not what we see when we look at the actual data.” Tr. 2788:25-2789:6 (Henry).

The Jackson et al. paper fails generally to assess confounding factors. Tr. 2790:3-6; 2872:8-11 (Henry). For instance, habitat can affect the success of a nest, but the paper does not report any information on whether the effect of habitat was considered, and none was forthcoming from Dr. Evers. Tr. 2790:7-2791:13 (Henry). Likewise, nest cavity type (artificial or natural) is known to affect nest success (Tr. 2791:14-15 (Henry)), and Dr. Henry found that nest cavity is a confounding factor. Dr. Henry has been involved in several major mercury remediation projects in the United States, and explained that the Carolina wren paper has “not being used to set screening thresholds or remedial targets” at any of them. Tr. 2783:11-16 (Henry). In sum, the Carolina wren paper is “not ready for prime time,” and “just not strong enough for us to use in making decisions at contaminated sediment sites.” Tr. 2795:1-5 (Henry).

Dr. Henry compared concentrations of mercury measured by the Study Panel in the various species of birds in Mendall Marsh against a 3-4 ppm screening threshold. Tr. 2765:24-2768:15; 2774:19-2776:14 (Henry); DX 1055. She found that mercury concentrations in Virginia rail, swamp sparrow, or song sparrow in the study area are below the 3-4 ppm range, and concluded that there is no risk to these species. Tr. 2775:15-2776:1 (Henry). However,

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<sup>21</sup> There were only 10 total nest failures if predated nests are included. Tr. 2788:5-7 (Henry).

concentrations of mercury in Nelson's sparrow and red-winged blackbird are above 3-4ppm, which means that we cannot rule out the possibility of adverse effects on reproductive success and should "look more closely at the possible impacts to reproductive success for these two species." Tr. 2776:2-20; 2795:20-23 (Henry).

**D. The next step in assessing risk to songbirds is a field study to determine whether there are adverse impacts to Nelson's sparrows in Mendall Marsh.**

Most of the ecological risk questions at the outset of the study have been answered and lead to the conclusion that mercury does not pose a risk of significant adverse effects on populations of organisms in the study area. What remains is the "possibility of impacts to reproductive success" for two species of songbirds in Mendall Marsh. Tr. 2795:20-23 (Henry). The question, then, is what should come next?

Dr. Henry, Dr. Fisher, and Dr. Evers all endorse field study to evaluate whether mercury is actually causing adverse effects on bird populations in the Marsh. Tr. 2809:10-14 (Henry); 724:9-12 (Fisher). "I would have preferred to have further toxicological information to help guide us in possible remediation actions that we would suggest to the court."). Dr. Evers testified:

Q: And from a scientific standpoint of better understanding the effects of mercury at a population level on Nelson's sparrows, would you recommend additional field study?

A: I would. I don't think there's enough information from a demographic standpoint to build a model. There would also need to be a reference site so we can build that model without a stressor, like mercury.

Q: And would such a study give us not only information on whether there are impacts, but also the nature, extent, magnitude of impacts?

A: Yes.

Tr. 1946:16-1947:1 (Evers). In fact, Dr. Evers had proposed that the Study Panel commission a field study of reproductive success in the Mendall Marsh population of Nelson's sparrow (DX 571 at 3-8), but the study was never performed. Tr. 1949:12-13 (Evers). Dr. Evers suggested that without such a study there is a significant hole in our understanding of potential adverse effects on bird reproduction or populations. Tr. 1949:21-1950:13 (Evers).

As Dr. Fisher explained, the question is not just whether there is harm to songbirds as a result of mercury exposure, but whether the extent and gravity of that harm is sufficient to justify taking the risks (and incurring the substantial costs) associated with a remediation. "I felt I needed to know how badly impaired the resident organisms were before spending a lot of money on a remediation program. . . . if I felt that we unearthed evidence [of] . . . serious population effects, then I thought we would have a stronger argument for a large and expensive remediation program, and all remediation programs are expensive." Tr. 711:14-712:23 (Fisher). "If, on the other hand, I thought that the system was just sort of coughing and limping along, but it was not really that dangerously impaired, then maybe it would be best to . . . leave everything to clean itself up, even if it were to – to take decades." *Id.* Dr. Henry put her perspective on risk in the study area in context:

[I]f we were talking about a small site where... risks were possible, but there was some uncertainty there, but the site was small and a remedial action was obvious, then a lot of times in that context, action can be taken.

At the Penobscot River, we're talking about a large, complex, both hydrodynamically and biogeochemically large, complex system with a functioning resource of Mendall Marsh that is extremely valuable.

So I think at this point we've really got to nail down whether or not there are risks to these birds. That information then goes into making a determination as to what to do next.

Tr. 2809:20-2810:7 (Henry). A field study would allow us to understand “whether or not there actually is an impact to reproduction for the Nelson’s sparrow in the marsh, and if there is, the magnitude of that.” Tr. 2795:24-2796:5 (Henry).

There are no informative mercury effects studies on the particular bird species of concern in the Penobscot. Tr. 711:14-25 (Fisher). Inferences concerning risk to one species based on studies of other species are problematic because all birds are not created equal when it comes to mercury risk and “we know that different species have different degrees of sensitivity to any contaminant, including mercury.” *Id.*; Tr. 1939:20-24 (Evers). Even within the same species, mercury effects vary among different populations of birds in different locations, depending on environmental factors. Tr. 1939:25-1940:5 (Evers).

Without a field study of potential adverse effects on songbirds, we are left to rely on screening values derived from the published literature. But “[o]ur knowledge of effects levels in invertivorous birds I would characterize as still in its infancy. We do have some field studies from, in particular, the South River which is a mercury-contaminated site, that can help to inform, but, again, we have very few definitive studies for invertivorous birds.” Tr. 2765:11-16 (Henry). “There is a fair degree of uncertainty on mercury effects to migratory songbirds. . . . The idea that these songbirds could even be impacted by mercury is relatively new information.” Tr. 2771:7-11 (Henry).

The uncertain state of our knowledge regarding mercury impacts on the birds of concern should be evaluated in the context of the abundant Nelson’s sparrow population actually found in Mendall Marsh. Tr. 2899:2-3 (Henry). The Study Panel selected Nelson’s sparrow for study because “there were so many of them in Mendall Marsh” (Tr. 2797:16-24 (Henry)) and in fact it had sampled 322 Nelson’s sparrows prior to 2012. Tr. 2768:1-4 (Henry). Mendall Marsh

remains a “tremendous” functioning ecological resource. Tr. 2797:20-24 (Henry). In light of the Study Panel’s finding that most of the mercury released to the system occurred by the early 1970s, the fact that the marsh continues to support large populations of Nelson’s sparrow should give us pause in considering whether there is in fact a population level risk to these birds.<sup>22</sup>

Nelson’s sparrows and red-winged blackbirds residing at the Penobscot have enough in common that further study of Nelson’s sparrows would provide a sufficient basis for drawing conclusions about red-winged blackbirds too. Dr. Fisher supports this approach. DX 334 at 1 (Dr. Fisher explains that “the Nelson’s and redwing birds get their Hg from basically the same source, namely insects or spiders from the marsh. Therefore, if the food supply Hg levels decline, it should more-or-less affect both birds to approx. the same extent. We’re not looking for subtle differences between the two birds’ diets or physiologies. I would therefore suggest that you choose one of these two species to monitor, and let’s not follow the other.”); Tr. 2898:8-9 (Henry) (“it’s pretty much standard practice...to select one representative species”).

Dr. Henry and Dr. Evers identified Nelson’s sparrow as the representative songbird since it is an obligate marsh feeder, so it is likely to derive the majority of its mercury exposure from sources in the marsh itself (rather than upland areas, for example). Tr. 2895:13-22 (Henry). It is good practice to pick a representative species since reproductive studies are “quite labor-intensive.” Tr. 2896:5-7; 2898:8-9 (Henry); DX 334 (Fisher) (suggesting it would be redundant to study both Nelson’s sparrows and red-winged blackbirds). A field study on a representative species in Mendall Marsh, like the Nelson’s sparrow, would provide information on risk to all comparable birds in that particular area.

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<sup>22</sup> Mr. Duchesne, a fact witness for Plaintiffs, testified that he guided bird watching tours to Mendall Marsh due to the abundance of Nelson’s sparrows at that location. Tr. 1662:1-11, 1677:7-15 (Duchesne).

Dr. Evers made clear that the design and completion of a field study of Nelson's sparrow in Mendall Marsh is feasible. Tr. 1941:13-1942:1. Such a study would also provide useful information, including:

- various measures of reproductive success (Tr. 1942:2-25 (Evers));
- changes in population, including whether the population is subject to significant migration (Tr. 1943:20-24 (Evers));
- sources of mercury effecting Nelson's sparrows, including information on whether mercury in the birds is the result of atmospheric deposition or legacy contamination in sediment (Tr. 1944:3-12 (Evers));
- the diet of the birds, the food web, and where birds may be getting their mercury exposure (Tr. 1944:21-24 (Evers)); and
- Mercury levels in birds when they migrate to the site and the extent to which their mercury burdens may be derived from off-site sources (Tr. 1945:11-19 (Evers)) (identifying as a "gap" in our knowledge mercury concentrations in birds upon arrival to Mendall Marsh).

A properly designed and executed field study would tell us whether there are significant adverse effects on insectivorous bird populations in Mendall Marsh and whether the population is growing, stable, or declining. Tr. 1944:13-20 (Evers). As Dr. Henry explained, a study would tell us "whether or not there actually is an impact to reproduction for the Nelson's sparrow in the marsh, and, if there is, the magnitude of that." Tr. 2796:1-5 (Henry).

## **VI. It is Unclear What Controls Recovery of the Penobscot River System.**

### **A. The Mobile Pool.**

It is currently unclear what mechanisms are responsible for the rate at which the system recovers. The Study Panel hypothesizes that a mobile pool of sediments prevents the system from recovering more quickly. JX 6-1 at 1-3; 1-15. But if the mobile pool were controlling recovery of the system "the recovery half-time of Hg concentrations in the mobile pool should

equal the recovery half-time of Hg concentration in the surface sediments” (so called “mass budget”). JX 6-1 at 1-19; Tr. 3343:13-20 (Connolly). But that is not what the evidence shows. Dr. Connolly and Dr. Harris calculated a turnover rate/residence time for the mobile pool of approximately 5 years. Tr. 3343:21-3344:8 (Connolly); JX 6-18 at 18-29. Dr. Geyer estimated that the residence time of sediment in the mobile pool was between 6 and 25 years. Tr. 1255:10-17. The Study Panel’s half time of 32 years for the main stem of the lower Penobscot River and 22 years for Mendall Marsh is inconsistent with turnover rate/residence times calculated for the mobile pool, indicating that the mobile pool is not controlling recovery of the system and that “there is still some work to be done ...before ... remediation ...should be implemented.” JX 6-1 at 1-19. As Dr. Harris concluded in Chapter 18 after testing various hypothesis through modeling, using the field data, “field estimates of the mobile solids mass and turnover rate are not consistent with the hypothesis that the mobile solids pool controls the field-estimated rate of decline of Hg concentrations in sediments (mobile and depositional) in the upper estuary.” JX 6-18 at 18-2. In other words, the mobile pool does not appear to be controlling the rate at which the system recovers. If the mobile pool is not controlling recovery there must be other mechanisms delaying recovery of the system (including contributions of mercury from above the Veazie dam, mercury from tributaries, atmospheric deposition of mercury, erosion and other sources not amenable to remediation). JX 6-18 at 18-2, 18-18, 18-20; Tr. 364:14-365:3 (Rudd).

Dr. Geyer testified that he is not certain how much sediment is in the mobile pool, but he believes it is probably on the order of five centimeters deep. Tr. 1155:24-1156:2. His uncertainty about the size of the mobile pool is due to uncertainty about how much of it is subject to interannual, as opposed to seasonal, variation. Tr. 1232:15-24. Dr. Geyer testified that it would be very difficult to quantify that variation, and stated that “it’s really a research

question.” Tr. 1234:12-23. He also explained that he does not know precisely how much of the sediment that enters the estuary is joining the mobile pool. Tr. 1195:3-16. Nor does he know precisely how long sediments reside in the mobile pool. Tr. 1196:3-1199:8.

One way to get a better understanding of the location and size of the mobile pool would be to take sediment cores during moderate river flow; on the order of three hundred samples would be required. Tr. 1239:22-1240:24 (Geyer). Specifically, more work needs to be done to survey the region between Fort Point and the South end of Verona Island to “try to come up with some sense of what the ... actual mobility of that sediment is.” Tr. 1241:6-10 (Geyer). Based on current understanding, there is a thirty percent probability that the mobile pool would not be in its expected location. Tr. 1247:8-15 (Geyer). Future investigation is important to understand the locational attributes of the mobile pool. As Dr. Geyer agreed, it would likely be a better idea to try and capture the mobile pool in areas where it has been found as opposed to constructing a trench in an arbitrary location in hopes of trapping it. Tr. 1253:3-9. Dr. Geyer suggested that samples be taken south of Winterport. Tr. 1240:23-24. He indicated that these samples should be taken “where we were... expecting to find more mobile sediment and then where we actually do find sediment.” Tr. 1244:8-16. Without conducting further investigation of the mobile pool, the Court cannot conclude on the present record that the mobile pool is solely responsible for preventing the system from improving more quickly. We cannot conclude that active remediation is appropriate, or convene a panel of experts to explore remedial options, without first understanding what impacts recovery rates in the river.

#### **B. Hot Spots.**

Dr. Connolly evaluated whether hot spots were present in the system and therefore delaying its recovery. Tr. 3344:13-15. He defined hot spots as “localized areas that are

significant sources of mercury to the system because there are high mercury concentrations at the surface, and that mercury is being made available to the system likely through periodic erosion events.” Tr. 3344:16-3346:4. After evaluating the data, Dr. Connolly found no evidence of hot spots. *Id.* The concentrations of mercury at the surface are generally lower than mercury buried under it. *Id.* And surface concentrations are variable from core to core, as opposed to being consistently elevated at a particular location. *Id.* Nor does analysis of the water column data provide any evidence of hot spots. *Id.* The absence of hot spots is consistent with the presence of a mobile pool, as a mobile pool would essentially take hot spots and make them warm spots. Tr. 1264:23-1265:5 (Geyer). In other words, differences in concentrations in surface sediments in the system are “eliminated...by that continual remobilization...and re-deposition.” Tr. 1153:15-17 (Geyer). Without any evidence that they exist, no further investigation of hot spots is warranted. Tr. 3346:5-3347:1 (Connolly).<sup>23</sup>

### **C. Erosion.**

The Study Panel suggested (without study or evidence) that erosion of mudflats could be an additional source of mercury that delays recovery of the system. JX 6-1 at 1-15 n.14. Dr. Connolly reviewed the data and considered whether erosion of mudflats is a significant ongoing source of mercury. Tr. 3347:2-3348:17. He explained that for erosion of mudflats to be a significant source, they would have to be similar to hot spots. *Id.* Dr. Connolly testified that while there is evidence of erosion of mudflats, in the form of tiny rills, the mudflats overall are accreting: the rills occur, but then fill back in. *Id.* There is no evidence of erosion of deeper sediments where higher concentrations of mercury reside. *Id.*

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<sup>23</sup> In addition to the absence of data evidencing hot spots, the Study Panel found that “[t]he main reason that hot spot removal is not recommended is that the apparent size of the pool of mobile sediments (Chapter 7) suggests that such an approach would not work.” JX 6-22 at 3.

If erosion were a significant source of mercury to the system, it would be evidenced in the core data or water column data, and this evidence does not exist. Tr. 3349:1-6. Dr. Connolly explained that it would be very difficult to try to quantify mercury coming from erosion (Tr. 3349:7-20), as well as expensive and time-consuming. Tr. 3349:21-3350:1. Absent any evidence that erosion is a significant source of mercury that could delay recovery of the system, and because any mercury that might be associated with erosion would be minimal and very hard to quantify, further study of the impacts of erosion is not justified.

**VII. Large-Scale Dredging and Capping are Scientifically Infeasible and Should Not be Considered Further.**

The Study Panel and the parties all agree that large-scale dredging should not be considered further as a possible remedial option. Dr. Rudd testified that the Study Panel considered the possibility of bank-to-bank dredging as a remedial option and unanimously agreed not to recommend it. Tr. 275:9-16; 281:3-11 (Rudd) (“The Study Panel unanimously decided not to recommend bank-to-bank dredging”); Tr. 659:22-660:7 (Whipple) (“Everyone on the Study Panel agreed that wholesale dredging was not something that should be pursued further”); JX 6-21 at 21-5 and 21-6. The Study Panel’s concerns regarding bank-to-bank dredging would apply to any large-scale dredging project. Tr. 295:5-10 (Rudd). Mallinckrodt’s experts agreed with these conclusions. Tr. 3107:8-19 (Glaza); 3350:15-3351:6 (Connolly). And the Plaintiffs’ agreed that “No one is contemplating bank-to-bank dredging.” Pls. Br. 48 n.13.

Witnesses described their experiences with problems caused by large-scale dredging. Dr. Rudd described his experience with Lavaca Bay, Texas, where mercury concentrations in fish escalated after dredging resuspended contaminated sediments. Tr. 276:10-24. He testified that similar resuspension occurred from dredging on the Hudson River. Tr. 280:1-11. Dr. Whipple agreed that dredging can disturb buried sediment that is high in mercury. Tr. 578:7-12. Dr.

Gilmour described dredging as “expensive and potentially destructive.” Tr. 1591:11-12. She testified that “one thing that’s really obvious is there’s really no good remediation tools for mercury.” Tr. 1591:7-8. Mr. Glaza testified that there is a well-documented set of concerns with dredging, summarized by the U.S. Army Corps of Engineers’ four Rs: resuspension, release, residual, and risk. Tr. 3097:9-3100:9. Dr. Bridges also explained the four Rs of dredging and harm from dredging at other sites. JX 33 at 44:15-45:13.

Witnesses also testified as to their concerns with large-scale dredging of the Penobscot system in particular. Dr. Rudd explained that much of the contaminated sediment in the Penobscot is buried deeply enough that it is unavailable for cycling and methylation. Tr. 277:14-278:9. Dredging, however, could resuspend those buried materials or expose a contaminated layer of sediment that was previously unexposed. Tr. 278:10-15 (Rudd). Compounding the risk, the mobile pool could make resuspension particularly problematic because resuspended, previously unavailable buried materials could enter the mobile pool and become trapped in the system (Tr. 279:17-22 (Rudd)) and therefore available for methylation. In short, witnesses explained that wide scale dredging on the Penobscot given the size and complexity of the system, the diffuse nature of contamination, the fact that the most highly contaminated material is buried, and the fact that the mobile pool would spread any resuspended material and make it hard to capture, would make dredging extremely expensive and harmful. Tr. 280:12-24 (Rudd); 3350:22-3351:6 (Connolly); 3100:10-19 (Glaza); 3101:15-3102:13 (Glaza); 3097:24-3098:4 (Glaza); 3100:20-3101:4 (Glaza); 3101:5-12 (Glaza).

In addition to large-scale dredging, Drs. Rudd and Whipple testified that the Study Panel considered and rejected large-scale capping. Tr. 282:12-21; 435:3-10 (Rudd) (“I think what we’re suggesting is . . . that wholesale or bank-to-bank capping not be done”); Tr. 660:8-20

(Whipple). Dr. Rudd explained that capping could actually increase mercury methylation. Tr. 282:22-283:9. A storm event or currents could erode the cap and allow that high methylmercury to escape into the environment. Tr. 283:10-13 (Rudd). He continued that a cap would make marsh mudflats and platforms more subject to erosion and could disrupt vegetation and bird populations. Tr. 283:14-284:12. Dr. Whipple testified that “first, [a cap] wouldn’t deal with the mobile sediment pool which is, of course, mobile; and, second, capping has been applied . . . in lakes, but whether it . . . could be installed and endure in an energetic system like the Penobscot was something we thought unlikely.” Tr. 660:8-20 (Whipple). Dr. Gilmour described capping as “really destructive and expensive.” Tr. 1591:8-9 (Gilmour). Mallinckrodt’s experts agreed that capping should not be considered a viable remedial option. Tr. 3202:20-22 (Glaza); Tr. 3375:4-6 (Connolly).

The testimony at trial made clear that both large-scale dredging and large-scale capping should be categorically removed from consideration as possible remedies for mercury contamination in the Penobscot system. Tr. 275:13-276:9; 281:3-11; 282:12-284:14 (Rudd); 659:22-660:7; 659:22-660:20 (Whipple); JX 107 at 4:5-10 (Fisher); JX 33 at 179:2-8 (Bridges).

### **VIII. The Remedies the Study Panel Suggests Are Not Feasible and Would Be Ineffective.**

The Study Panel was directed to answer this threshold question with respect to remedial options:

Do the scientific data lead to the conclusion that a mercury remediation program is necessary and feasible to effectively remediate the effects of any . . . harm caused by mercury contamination in the Penobscot River/Bay system?

JX 2. If it found remediation necessary and feasible, the Study Panel was then to ascertain “the elements of and schedule required for the execution and completion of . . . a remediation program. . . .” *Id.* Nine years and some twenty million dollars later, the Study Panel’s two-

pronged answer to the Court's question is that (1) a mercury remediation program is needed, "[b]ased on the degree and extent of existing contamination" and the "slow rate of natural mercury . . . attenuation" (JX 6-21 at 21-5), and (2) we have some very preliminary ideas about potential remedies, but we don't know if they would be feasible or effective.

As explained above, the Study Panel overstates the extent of mercury contamination in the Penobscot and the ensuing harm, and understates the river's rate of natural recovery. As for what to do going forward, the Study Panel acknowledges that it has no idea whether the remediation ideas it has outlined would work. JX 6-22; Tr. 287:14-22 (Rudd); Tr. 2228:1-8 (Driscoll). Dr. Whipple testified that "there is not . . . a one-size-fits-all solution that has been applied at contaminated sites." Tr. 647:8-16. Dr. Bridges advised the Study Panel that "there is no silver bullet remedy at these sites." DX 19, DX 20. He also cautioned the Study Panel against "thinking about active remedies first and MNR [monitored natural attenuation] as an afterthought." *Id.* As noted above, Dr. Gilmour testified that "one thing that's really obvious is there's really no good remediation tools for mercury." Tr. 1591:1-12. The only evidence the Court heard from a practicing sediment-remediation engineer regarding remediation of the mobile pool to accelerate system recovery is that these remedial approaches would not be feasible or effective. Tr. 3063:15-17; 3066:4-23; 3070:19-3071:1 (Glaza).

In its "Recommendations to the Court" chapter, the Study Panel outlines, in broad conceptual strokes, "four remediation options" that it proclaims "are scientifically sound, but need some further limited scientific study and engineering design before full-scale implementation . . . ." JX 6-21 at 21-5. The very next paragraph, however, drops the pretense that "further limited" study and design is all that remains to be done:

we strongly recommend that scientists familiar with Hg cycling in the Penobscot estuary be teamed with engineers to test and design any active remediation

procedures ordered by the Court. . . . [W]e recommend that the first element of a future Remediation Program should be a meeting of scientists familiar with Hg cycling in the Penobscot estuary and engineers experienced in sediment remediation in order to merge the scientific bases of each approach with the engineering expertise needed to evaluate the feasibility of each approach.

JX 6-21 at 21-5. In other words: the “further limited” study and design work the Study Panel envisions is not “limited” at all, but would start (and end where?) with the creation of a team of mercury scientists and “engineers experienced in sediment remediation” to “evaluate the feasibility” of the four remediation options the Study Panel has identified. JX 6-21 at 21-5 (“[W]e further recommend that the first step of this Remediation Program be an assessment of the feasibility of the science-based remediation procedures outlined below - followed by their design and testing . . . .”) (italics in original). In essence, the Study Panel proposes a new research project on the scale of the 2003 Implementing Order that created the Study Panel.

In short, the Study Panel fails to answer the ultimate question put to it. Plaintiffs likewise ask the Court to rule simply that active remediation is appropriate and order that engineers and scientists be tasked with figuring out what form it should take. Dr. Rudd cautioned that if engineers start working on remedies before it has been determined that an effective remedial scheme is scientifically feasible, there could be big problems. Tr. 266:15-23.

Mallinckrodt engaged Edward C. Glaza, P.E., a sediment-remediation engineer with over two decades of experience, to evaluate the remedial options the Study Panel identified as candidates for further study. Tr. 3063:15-17, 3066:4-23. Over the past decade, Mr. Glaza has focused exclusively on mercury-contaminated sediment sites. Tr. 3066:24-3067:2. His job entails providing technical leadership and project management on large sediment remediation

projects, spanning from site investigation through technology evaluation, feasibility study, remedial design, and implementation. Tr. 3066:8-13.<sup>24</sup>

The Study Panel's three key remedial options (a fourth option entails "combinations of" the first three) are:

- (1) "the trapping of mobile sediments in large sediment traps excavated at known sites of natural short-term mobile sediment deposition," which would then be "pumped or barged to CADs ["large *in-situ* disposal pits dug in soft sediments at contaminated locations" (JX 6-21 at 21-8)] in Penobscot Bay for long term burial and capping," with "the materials removed during the digging of the CADs" to be "moved north into the upper estuary . . . to replace the previously trapped contaminated material." (JX 6-21 at 21-9)
- (2) "[T]he design, testing and installation of a sediment trap at the mouth of the Marsh River to hasten the recovery of Mendall Marsh." (JX 6-21 at 21-13)
- (3) "[F]urther testing of SediMite [a chemical that may "inhibit the movement of the methyl Hg into the soil porewaters"] application to Mendall Marsh . . . ." (JX 6-21 at 21-15).

#### **A. Sediment Traps.**

The Study Panel's sediment trap idea (remedial options (1) and (2)) would involve the same type of large-scale dredging that it deemed impractical and too risky when it rejected bank-to-bank dredging as an option. Tr. 282:12-21; 275:13-277:13; 278:10-16 (Rudd); Tr. 659:22-660:25 (Whipple); JX 107 at 4:11-19 (Fisher). Dr. Rudd testified that the Study Panel's concerns regarding bank-to-bank dredging would apply to any large-scale dredging project. Tr. 295:5-10. The Study Panel was not aware of the amount of dredging their proposed sediment traps would entail. Tr. 652:3-9 (Whipple). In fact, the sediment traps the Study Panel proposed would

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<sup>24</sup> For example, he has a project management role at Berry's Creek, a large mercury impacted tidal estuary and marsh located in New Jersey. Tr. 3067:3-13. He is also the project manager and certifying engineer at Onondaga Lake, a large mercury-contaminated lake and wetland system in New York. Tr. 3067:24-3068:11. He has also been significantly involved in four other mercury-impacted sites in the vicinity of Onondaga Lake. Tr. 3068:1-3069:3. Other projects include the Con Edison Arthur Kill site, a sediment remediation site on the tidally influenced portion of the Hudson River, where Mr. Glaza was the project manager and certifying engineer for the feasibility study and a certifying engineer for the design. Tr. 3067:18-23.

require “one of the largest dredging projects in the nation.” Tr. 3107:20-24 (Glaza). It would therefore give rise to the same concerns the Study Panel had about bank-to-bank dredging. Tr. 3109:1-7 (Glaza).

Mr. Glaza evaluated, from an engineering perspective, the Study Panel’s two sediment trap ideas. Tr. 3069:13-22. He reviewed information about the Penobscot system as well as scientific and engineering literature and guidance documents. Tr. 3070:2-18. Mr. Glaza then applied a feasibility study framework, which is commonly used by EPA and state regulators to evaluate remedies at contaminated sediment sites, to the Study Panel’s proposed sediment trap remedies. Tr. 3087:23-3088:6. These criteria make sense from a logical standpoint, have “stood the test of time,” and are applied at every contaminated sediment site. Tr. 3090:21-3091:7; 3088:7-11. Mr. Glaza concluded that neither sediment trap option was feasible and that further investigation was unwarranted. Tr. 3070:19-3071:1.

Dr. Connolly used modeling to evaluate whether the sediment traps could effectively capture mercury-contaminated sediments. Tr. 3353:1-3367:9. He examined settling velocities and the size a sediment trap would have to be to collect fine-grain sediment containing the highest mercury concentrations. *Id.* He concluded that “sediment traps are just impractical....” Tr. 3367:10-15.

No Study Panel member or contractor is a practicing engineer qualified to evaluate the sediment trap proposal.<sup>25</sup> The one Study Panel scientist with expertise in hydrodynamics, Dr. Geyer, expressed concern that the sediment traps would not work because the river is so energetic. Tr. 1253:19-25. Dr. Geyer explained that “it might be hard to... permanently trap

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<sup>25</sup> Plaintiffs’ expert, Dr. Driscoll, testified that he does not evaluate field operations of practicing engineers. Tr. 2232:4-16. Rather, he considers himself to be an academic (Tr. 2234:14-18), and his primary focus is teaching and research. Tr. 2192:1-3.

sediment in this region, which is presently a mobile pool.” Tr. 1254:1-3, 12-19. Altering a natural system in a way that is not fully understood would be a concern. Tr. 1265:25-1266:3.

The Study Panel presented its sediment-trap idea as if it were a sensible middle course between large-scale dredging of the upper estuary—an option rejected by the Study Panel (section VII *supra*)—and a natural-attenuation remedy. But Mr. Glaza testified that the sediment-trap remedy is itself a large-scale dredging operation, requiring removal of so much material as to put it on the scale of a “mega site.” Tr. 3107:20-3108:25. Moreover, the required dredge volume to construct the sediment traps and to construct the confined aquatic disposal (“CAD”) facility to hold this material would require an estimated 70-acre temporary sediment staging area on land with access to the river. Tr. 3126:5-3128:20. Mr. Glaza further testified that any potential benefits would be speculative, and that there would be no way to pilot test the sediment trap remedy short of full-scale implementation. Tr. 3119:23-3121:3. In applying the feasibility study criteria, Mr. Glaza determined that site-specific considerations created considerable risks. *See, e.g.*, Tr. 3100:10-14 (discussing logistical problems posed by working in a deep water environment with fine grained material).

Despite efforts to “optimize” the Study Panel’s concept, Mr. Glaza identified “significant implementability challenges.” Tr. 3130:18-23; 3139:16-22; 3074:5-14; 3114:14-21. For example, he noted that “sediment traps work best for those particles that settle the fastest,” but in the Penobscot “the most contaminated particles...are the finest-grained.” Tr. 3079:22-25. With respect to the sediment trap proposed for the main stem of the river, Mr. Glaza assumed a conservative size for the trap (Tr. 3080:14-16), and did not account for the likelihood of remobilization from the bottom of the trap. Tr. 3079:7-20. With respect to the sediment trap proposed at the mouth of Mendall Marsh, Mr. Glaza noted that this trap would need to be “much

larger,” and would require a “massive removal” to achieve its goal, but would probably only be marginally effective. Tr. 3138:5-3139:15. He found that neither sediment trap idea “would be effective or provide long-term protection of human health and the environment.” Tr. 3070:19-23. He also found that the Study Panel had “significantly underestimated” the schedule for implementing the remedy. Tr. 3109:8-21. Mr. Glaza believes that a project of this magnitude “would take at least 15 years,” which he believes is “an aggressive minimalist schedule.” Tr. 3109:16-23. This is important because, as Dr. Rudd testified, timing can render remediation impractical, depending on how long it takes to get underway. Tr. 290:3-10 (Rudd). Though it was not a main component of his analysis, Mr. Glaza also noted that the Study Panel underestimated costs of implementing the remedies “by several factors.” Tr. 3108:20-23.

Instead of solid remedial recommendations, Dr. Whipple explained that the remedial alternatives in the Phase II Report are “the ones that weren’t obvious bad ideas.” Tr. 648:18-20. By their own admission, the Study Panel members are not engineers and do not even know if these remedies are feasible. JX 6-21 at 21-4. Mr. Glaza, a practicing engineer with 23 years of experience evaluating remedial measures at mercury-contaminated sites concluded they were not. Tr. 3136:16-3140:8.

**B. Amendments to Mendall Marsh.**

The Study Panel’s alternative recommendation of “further testing of SediMite [activated carbon] application to Mendall Marsh” is similarly misguided. Dr. Vlassopoulos, an expert in environmental geochemistry and contaminant hydrology (Tr. 2961:21-23; 2963:7-12), evaluated the effectiveness of SediMite and other amendments tested in Mendall Marsh. Tr. 2965:3-9. Dr. Vlassopoulos has worked on dozens of contaminated sediment sites. Tr. 2963:13-2964:11. He spends about three-quarters of his professional time evaluating site-specific remedial work. Tr.

2964:20-22. He has worked for clients of all sorts, including federal government agencies. Tr. 2964:12-17. Dr. Vlassopoulos also reviewed the Study Panel's plot study of in-situ amendments. Tr. 3013:20-3014:1. After conducting an evaluation of the Study Panel data related to various amendments applied to Mendall Marsh, Dr. Vlassopoulos concluded that none were effective at reducing total mercury or methylmercury two years after they were applied. Tr. 3017:16-3023:8. He testified that the Study Panel's contractor, Dr. Gilmour, ignored the diminishing effectiveness of the amendments over time. Tr. 3024:2-22. Modeling conducted by Dr. Vlassopoulos also showed that the effectiveness of activated carbon levels off as more activated carbon is added. Tr. 3025:10-3029:3.

Dr. Vlassopoulos identified factors that would likely limit the duration of activated carbon's effectiveness in Mendall Marsh, including continuous mercury fluxes into the treatment zones and organic matter fouling the surface of the carbon. Tr. 3032:14-3033:17. Because of its limited longevity, activated carbon would have to be repeatedly applied, and in a relatively short period of time the marsh would be predominantly comprised of carbon, rather than sediment. Tr. 3030:20-3031:4. Dr. Vlassopoulos concluded that none of the amendments tested in the Penobscot study represent feasible options for in-situ remediation in Mendall Marsh. Tr. 3037:3-23. Plaintiffs' expert, Dr. Driscoll, noted that the jury is still out on interpreting results of activated carbon in mercury remediation. Tr. 2227:22-25. Similarly, even Dr. Gilmour testified at trial that using activated carbon as a tool to remediate mercury is in its "early days." Tr. 1590:23-1592:2.

**C. Reducing mercury levels in sediments would not necessary reduce mercury levels in biota.**

Even if the Study Panel had identified a remedial strategy that had the potential to reduce mercury concentrations in sediments, it is unclear what impact that would have on the ultimate

endpoint of interest: mercury concentrations in biota. Dr. Henry testified that she could find no direct support in the sediment data for the Study Panel's assumption that reducing mercury concentrations in sediment will proportionally reduce mercury concentrations in birds and mammals. Tr. 2801:24-2802:5. The Study Panel's own evaluation indicated variability between total mercury and methylmercury (the form of mercury that is taken up by biota) concentration in surface sediment on a site-wide basis. *Id.* This is especially true in wetlands and marsh environments such as Mendall Marsh. Dr. Vlassopoulos explained that a number of factors affect the mercury methylation process. Tr. 2968:6-2970:7.

Dr. Driscoll agreed, explaining that "I think that wetlands are...complicated...[T]he methylation responds to a variety of factors. And...it's possible that...you could reduce...the inorganic mercury, and you could see a limited or even no response [in methylmercury levels]." Tr. 2208:8-14. Using the same data Dr. Gilmour relied upon, Dr. Vlassopoulos concluded that total mercury concentration is a poor predictor of methylmercury in Mendall Marsh. Tr. 2981:22-2982:10; 2985:11-20; 3039:23-3040:8. He showed, for example, that many individual samples contained high total mercury and low methylmercury concentrations, and vice versa. Tr. 2984:23-2985:16. Dr. Vlassopoulos' analysis showed that total mercury concentrations explain only 11 percent of the variability in methylmercury concentrations. Tr. 2987:3-2988:8. The variability is more fully explained by the conditions and processes that create methylmercury, such as porewater chemistry and sediment-water partitioning. Tr. 2969:2-2977:10, 3008:3-3009:18 (Vlassopoulos).

Because it is not clear how potential sediment mercury reductions may change bird or mammal blood mercury concentrations in the Penobscot, Dr. Henry expressed concern about embarking on an active remedial program focused on reducing sediment mercury concentrations

only to find that mercury concentrations in birds and mammals are not meaningfully affected, or that effects take place over a sufficiently long time frame that reductions would have been similar without active remediation. Tr. 2804:9-2805:1. Dr. Henry also noted the potential for adverse effects on biota associated with the addition of activated carbon to Mendall Marsh. Tr. 2807:3-2808:1.

**IX. The Court Should Not Create a New Study Panel at This Time or Rule on Whether Active Remediation is Necessary.**

Lacking a remedial solution of their own, Plaintiffs ask the Court to order a whole new study involving “a panel of independent engineers and mercury scientists” who would “design and propose to the Court a suite of active remedies...” Pls. Br. at 65. Plaintiffs only expert with engineering and remedial evaluation credentials, Dr. Driscoll, testified that he was not asked to come up with remedial options. Tr. 2274:24-2275:5. Hence Plaintiffs’ position, after thirteen years of litigation seeking a remedy for mercury contamination in the Penobscot, boils down to this: we don’t have experts on this topic with any specific remedial proposal, but maybe some other experts could come up with something. Tr. 2164:13-2165:5 (Driscoll).<sup>26</sup>

Mallinckrodt, for its part, did reach out to scientists with specific expertise in remediating mercury-contaminated sites across the country, including a practicing engineer with experience in evaluating and selecting remedial options for mercury-contaminated sediments. Mr. Glaza and several other experts—including members of the Study Panel and scientists—all testified to the need for additional information prior to evaluation of remedial options or deciding whether active remediation is necessary. Tr. 323:3-18; 327:11-328:6 (Rudd); 712:1-21; 744:17-19;

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<sup>26</sup> Plaintiffs quote Dr. Weiner’s observation that “there are a lot of smart people out there” who could presumably figure out a remedy. Pls. Br. 46. It is unclear why in the last nine to thirteen years neither the Study Panel (in its remediation workshop) nor Plaintiffs have identified these “smart people” and obtained a viable remediation option from them.

758:25-759:22 (Fisher); 1239:22-1240:24 (Geyer); 3201:2-6; 3089:18-3090:17; 3140:9-25 (Glaza); JX 36 at 214:21-215:13 (Harris); JX 38 at 33:13-34:10; 34:15-19; 25:23-24 (Harris); 2795:24-2796:10 (Henry); 3367:20-24; 3368:2-3369:23 (Connolly).

Although the Study Panel members themselves are not remediation experts, they did spend time and effort to evaluate remedial options. In fact, the Study Panel has been considering remedial options since 2007. Tr. 267:7-9 (Rudd); DX 589. The Study Panel had the ability (and budget) to hire and consult with experts on remediation, and they did so. In June of 2009, the Study Panel held a two-day meeting in Bangor specifically to discuss remediation (the “Remediation Workshop”).<sup>27</sup> Tr. 271:14-16 (Rudd). Several experts and consultants attended this meeting, including Dr. Bridges, a remediation expert from the Army Corps of Engineers with experience at contaminated sediment sites around the country. JX 15; JX 33 at 5:14-6:14. Dr. Bridges, who testified by deposition, explained that there are few remediation tools for contaminated sediment sites, and that at sites like the Penobscot, where contamination is moderate and diffuse, the typical remedies (dredging and capping) are usually not effective. JX 33 at 176:25-179:21 and 52:14-53:2. He encouraged the Study Panel to carefully define the risks—including the nature and extent of harm to biota—prior to evaluating remedial options. JX 33 at 58:7-14; DX 70; JX 33 at 58:7-60:15. In contrast to Plaintiffs’ position (Pls. Br. 55), the mobile pool, which spreads contamination in the system (making it more diffuse) and makes dredging particularly problematic, is a primary reason system-wide remedies should not be considered further. The Study Panel continued to evaluate remedial options after the Remediation Workshop and specifically found that system-wide remedies such as bank-to-bank

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<sup>27</sup> Dr. Whipple explained the outcome of the Remediation Workshop as a “case of the dog that didn’t bark,” as there was a lack of new ideas. Tr. 528:2-9.

dredging and capping were scientifically infeasible in the Penobscot. Tr. 275:13-276:9; 281:3-11; 282:12-284:14 (Rudd); 659:22-660:25 (Whipple); JX 107 at 4:11-19 (Fisher).

The Study Panel was not, however, able to identify a viable remedial option. Tr. 648:7-23 (Whipple) (Phase II Report options are the options that “weren’t obvious bad ideas”); Tr. 3070:19-3071:1 (Glaza) (concluding further evaluation of sediment traps is not warranted); Tr. 3037:3-23 (Vlassopoulos) (concluding that in-situ amendments are not a feasible remedial alternative at the Penobscot). Furthermore, the Study Panel did not obtain information in what is usually the “remedial investigation phase” that is necessary to evaluate and select remedial options and determine if active remediation is appropriate. Tr. 3088:12-3090:20; 3091:8-3092:9 (Glaza). In particular, the Study Panel did not perform site-specific studies to determine whether harm is occurring to certain songbirds and if so, what the extent of that harm might be. Tr. 708:14-24 (Fisher); Tr. 762:19-763:7 (Fisher); Tr. 744:17-19 (Fisher); Tr. 712:17-21 (Fisher).

Dr. Fisher, who advocated for site-specific studies throughout the study (Tr. 708:21-709:6; DX 1), testified how this could be very important to evaluating remedial options and making a decision regarding whether active remediation is appropriate:

The question was whether in the field the organisms were just sort of limping along, but no one was dropping dead currently, and so ... I needed to know ... how badly impaired the resident organisms were before spending a lot of money on a remediation program. So if I felt that we unearthed evidence that organisms were ... dying or not breathing properly or ... some serious population effects, then I thought we would have a stronger argument for a large and expensive remediation program, and all remediation programs are expensive. If, on the other hand, I thought that the system was just sort of coughing and limping along, but it was not really that dangerously impaired, then maybe it would be best to ... leave everything to clean itself up, even if it were ... to take decades.

Tr. 712:1-21.

Not knowing if there is harm to Nelson’s sparrows or red-winged blackbirds is particularly important here where the Court articulated a threshold question of whether mercury

in the Penobscot is “posing an unacceptable risk to human health” or “having significantly adverse effects on populations of organisms.” JX 2 at 1-2. As explained previously, there is enough information to determine that mercury is not posing an unacceptable risk to human health, but in the absence of site-specific studies, there is insufficient information to determine whether mercury is “having significantly adverse effects on populations of organisms.” *Id.* The only way to know if a specific population is being harmed is by conducting site-specific studies of that population and measuring endpoints that are indicative of population-related effects. Tr. 432:22-433:2 (Rudd); Tr. 624:8- 625:23 (Whipple); Tr. 711:15-25 (Fisher); DX 1; JX 40 at 153:25-154:9 (Sandheinrich); JX 33 at 58:7-60:15 (Bridges); DX 20; Tr. 2776:17-20, 2795:14-2796:5 (Henry); Tr. 3245:4-16 (Connolly). Determining that active remediation is appropriate based upon this record would be unfounded, and empaneling a team of engineers to design and test potential remedies would be premature. Tr. 3372:6-3373:8 (Connolly).

In addition to addressing the question of harm, more information, including information regarding harm to songbirds, is needed prior to evaluating remedial options, including the appropriateness of active remediation. Mr. Glaza, the only practicing engineer, and an individual who Dr. Driscoll agreed is the type of person who could add value on a new panel of remediation experts (Tr. 2236:22-2237:13), testified that before he could identify remediation options, he would need to know the following:

[Y]ou really need to know what problem you’re trying to fix. You really need to know what those risks are ... you need to know how significant those risks are. And then you need to know what’s causing those risks. If there is a certain level of mercury present in biota or in a receptor, how is it getting there? Is it getting there from the water column? Is it getting there from the sediment? Is it getting there from widespread, diffuse sources? Are there localized areas? Is it coming from a mudflat versus a marsh? So to get to the point where you’re able to start identifying and going through an evaluation process, you really need to get to that point, and ... we’re certainly not at that point yet.

Tr. 3140:9-25; 3201:2-6. Dr. Connolly, who also has extensive experience with remedial decision-making at contaminated sediment sites, echoed Mr. Glaza's comments, testifying that before remedial alternatives can be evaluated, harm has to be identified and the pathways through which contaminants get from the environment into biota must be understood. Tr. 3367:20-24; 3368:2-8 (Connolly). Once this relationship is understood, engineers can begin looking at alternatives and evaluating whether various measures will reduce mercury concentrations in the biota of interest. Tr. 3368:9-18 (Connolly). Without this understanding, the benefits of an action would be unknown, making it impossible to weigh each remedial option against negative environmental consequences. Tr. 3368:19-24; 3369:24-3370:9.

While a lot of valuable information has been gained from the Penobscot River Mercury Study, and provides a basis for narrowing the universe of remedial alternatives considered going forward (Tr. 3202-3203:1 (Glaza), additional information on certain issues is necessary. Focused and targeted further study to determine whether mercury is having significantly adverse effects on populations of Nelson's sparrows (as a surrogate bird) in Mendall Marsh and continued monitoring of certain species in the river is the correct path forward. If the requisite harm is shown, and the mechanisms delaying recovery are understood—then a review and evaluation of specific remediation options can be conducted. In a complex system like the Penobscot where contamination is moderate and diffuse, it is possible that on balance, even if harm exists, that (1) the harm associated with active remediation outweighs the benefits; (2) the system will recover faster than any alternative could be implemented; or (3) the remedy is extremely costly, is potentially harmful, and the benefits are speculative. In that case, natural attenuation or a "passive" remedy would be the best remedial option. Tr. 644:9-15; 645:1-12; 654:10-14 (Whipple). Therefore, a decision regarding whether active remediation is appropriate

should not be made until after significantly adverse effects on the population of Nelson's sparrows have been shown and an evaluation (including balancing harms) of remedial options has been conducted.

**X. The Equities Do Not Favor the Relief Plaintiffs Seek.**

Plaintiffs argue that the four-part framework for evaluating requests for injunctive relief tilts in their favor. Pls. Br. 59-65. Mallinckrodt disagrees. Plaintiffs claim to have demonstrated irreparable injury because mercury in lobsters, black ducks, and eel "exceed[s] the threshold the State of Maine deems safe for human consumption," and because "[s]ongbirds in the marsh have blood mercury levels higher than any ever recorded." Pls. Br. 59. But as explained in section IV *supra*, the "threshold" Plaintiffs cite is not a level above which food is unsafe to eat; it is a conservative screening threshold designed to signal the need for further inquiry into the potential for harm. That inquiry has now been conducted, and no unacceptable risk of harm to human health has been found. The State has indeed closed a portion of the fishery as a precautionary measure, but has made clear that lobsters from the closed area remain safe to eat. Section IV *supra*. As for songbirds, Plaintiffs have identified the need for further study of their mercury levels, but have not demonstrated actual harm to these populations of birds. Section V *supra*. Nor have Plaintiffs identified any actual harm to "several species of fish." Pls. Br. 59; Section V *supra*. Contrary to Plaintiffs' assertion that "irreparable injury is clear" (Pls. Br. 60), irreparable injury of the type the Court directed the Study Panel to look for has been effectively ruled out with respect to human health and most biota. The potential for irreparable injury to a few populations of songbirds remains, but further study is necessary before a conclusion can be drawn.

Plaintiffs point out that “[m]oney damages will not restore the river.” Pls. Br. 60. That may be, but the Court has made clear that the issue to be decided is not whether the River is to be restored to a pristine, pre-industrial state; the issue is whether mercury in the Penobscot is “posing an unacceptable risk to human health” or “having significantly adverse effects on populations of organisms” (Implementing Order for Penobscot River Study Pursuant to Memorandum of Decision and Order, July 29, 2002 (JX 2 at 1-2), and if so, what can be done to address those specific harms. Absent actual proof of the alleged harms—which Plaintiffs have yet to provide—there is, as the Court has framed the issues, nothing yet to remedy, either at law or at equity.

Plaintiffs assert that the balance of hardships weighs in their favor because “[t]he harm to plaintiffs is palpable and severe” (Pls. Br. 60), whereas Mallinckrodt “does not assert an inability to pay” for the remedies Plaintiffs have requested. Pls. Br. 61. As explained above in connection with the irreparable injury requirement, Plaintiffs have not come close to proving harm of the type the Court directed the Study Panel to look for. The balance of hardships tilts evermore in Defendant’s favor to the extent that the relief being sought is the implementation of remedies that have been demonstrated to be unworkable or counterproductive, as is the case with most of the remedies Plaintiffs wish to continue to pursue. Sections VII and VIII *supra*. Mallinckrodt’s status as a successful business does not excuse Plaintiffs from their burden to prove an irreparable injury substantial enough to justify the enormous cost of the expansive remedial efforts Plaintiffs seek.

To meet the public interest prong of the injunctive relief analysis, Plaintiffs rely on testimony by a handful of lay witnesses: a lobsterman who believes lobsters he sold may have had harmful levels of mercury; a “nature enthusiast” under the impression that swimming in the

Penobscot could be dangerous because of mercury; a “local birding guide” who says he is unable to “enhance recreational opportunities” on the Penobscot due to mercury, and a Penobscot Nation Elder, Mr. Phillips, who testified that Mallinckrodt had “diminished the spiritual power of the river . . . .” Pls. Br. 63-64. However, Mr. Phillips also testified that “any improvement in any type of pollution or taking out of dams . . . is a great improvement” (Tr. 1857:3-5), and that he “never thought in my lifetime that I would see the Penobscot River being cleansed and/or dams taken out so that the sea-run fish and other fish could move up the river.” Tr. 1856:25-1857:2. Mallinckrodt understands that members of the public have concerns about mercury in the Penobscot. But there is a reason why the Court appointed a panel of scientists to investigate its effects: answering these questions requires the application of scientific principles and methods. The anecdotal testimony of Plaintiffs’ lay witnesses, however sincere and well intentioned, establishes only that these four people believe mercury in the Penobscot is causing them harm. The Study Panel was appointed to develop scientific evidence on the effects of mercury in the Penobscot; the public interest lies in basing remedial decisions on what this scientific inquiry has found.

**XI. The Court Should Order Mallinckrodt to Conduct Focused Study of Potentially At-Risk Birds, the Mobile Pool, and the Orland River, and to Undertake Ongoing Monitoring of the River’s Recovery.**

The Study Panel has had every opportunity to explore the questions the Court put to it, and Mallinckrodt has paid for a decade of study. We now know far more than we knew before about the state of the river and its biota. There is always more that could be learned, but at some point the investigation must become focused on remaining open issues and then be brought to an end.

While the First Circuit held earlier in this litigation that this Court had not abused its discretion in ordering the establishment and funding of the Study Panel, it made clear that it was *not* saying that “the costs associated with injunctive relief are immaterial,” and that it could “imagine circumstances in which the expense entailed in carrying out a particular remedial plan might dwarf the potential benefits to the environment or to human health.” *Maine People’s Alliance*, 471 F.3d at 297. The First Circuit noted that its conclusion that this Court had not abused its discretion was “reinforced by the fact that Mallinckrodt has not identified any less burdensome, more cost-effective remedy that the court could have imposed to address the perceived environmental harm.” *Id.* at 298.

This litigation has reached a point where the expense entailed in carrying out the remedial plan the Study Panel is proposing would in fact dwarf the potential benefits to the environment or to human health. Two major factors limit the potential benefits to the environment or to human health from the Study Panel’s proposal: (1) the demonstrated harm caused by mercury in the Penobscot ranges from non-existent (for human health) to possible but as-yet-unproven adverse effects on two bird species, and (2) the proposed remedies would be ineffective in hastening the river’s recovery beyond the natural recovery that is underway and progressing. These are, then, “circumstances in which the expense entailed in carrying out a particular remedial plan” would “dwarf the potential benefits to the environment or to human health.” *Id.* at 297. And this time Mallinckrodt does have a “less burdensome, more cost-effective remedy that the court could . . . impos[e] to address the perceived environmental harm.” *Id.* at 298.<sup>28</sup>

The remedial options the Study Panel submits for further evaluation are not good options, and do not stand a realistic chance of reducing mercury concentrations any faster than would

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<sup>28</sup> To be clear, Mallinckrodt does not have to establish that the cost of a particular remedy would “dwarf the potential benefits”; the point is that this Court would abuse its discretion if it imposed such a remedy.

happen if natural recovery were permitted to run its course. Given the astronomical price tag associated with these untested measures, the length of time many of these remedies would take to implement, the very limited harm mercury in the Penobscot may now be causing, and the extraordinary complexity of the Penobscot ecosystem, proceeding as the Study Panel recommends would not strike a proper “balance of hardships between the [parties].” 471 F.3d at 296. Instead, prior to determining whether active remediation is feasible or appropriate, the Court should order further study of the extent of the existing harm to Nelson’s sparrows, as a representative of the two populations of biota that may be experiencing significantly adverse effects. The Court should also order further study to quantify the size and location of the mass of the mobile pool through sediment core samples to determine whether the mobile pool is large enough to delay recovery of the system, and if it is, whether a significant mass of the mobile pool resides in a predictable location such that it could be remediated.

The Orland River was not a primary focus during the Penobscot River Mercury Study. Dr. Rudd testified that, “in retrospect, I wish we’d spent a little more effort on the Orland.” Tr. 182:11-183:13 (Rudd). Because very few sediment samples were taken from the Orland, it is difficult to draw conclusions about its condition at this time. Additional samples are therefore needed to understand the Orland River; these could be taken in conjunction with the additional sampling Mallinckrodt proposes to better characterize the mobile pool.

Keeping track of the status of recovery of the Penobscot system as it continues to improve is a prudent future course of action. A focused plan to track and report key parameters of recovery should be developed and implemented.

In summary, the Court should order: (1) additional study to determine whether there is any harm to population of Nelson’s sparrows, and if so, to what extent; (2) additional study of

the mobile pool to quantify the size of the mobile pool and determine its location; (3) additional sediment samples in the Orland River (in conjunction with sediment samples to quantify the size of the mobile pool); and (4) Penobscot system recovery monitoring. What the Court should not do is require Mallinckrodt to fund further exploration of the Study Panel's unworkable remedial ideas.

## **XII. Mallinckrodt, Not Court-Appointed Experts, Should Perform Any Additional Work.**

The use of court-appointed experts or panels to evaluate remedial options is uncommon. At EPA, where “[a]n overriding goal of the Superfund program is for PRPs [Potentially Responsible Party] to expeditiously conduct remedial actions,”<sup>29</sup> all work is typically “done under the PRP’s control and they . . . are responsible for the long term performance of the remedy.” *United States v. E.I. Dupont De Nemours & Co.*, 432 F.3d 161, 183 (3d Cir. 2005) (quoting Guidance on EPA Oversight of Remedial Designs and Remedial Actions Performed By Potentially Responsible Parties, OSWER Directive 9355.5-01 (April 1990)). Several witnesses testified at trial that responsible parties normally lead the investigation and evaluation of remedial options.

Mr. Glaza testified that in his experience, it is the “responsible parties that always lead the effort. . . . [T]hose are the people that have the lead in evaluating, designing, and implementing these remedies.” Tr. 3144:12-18 (Glaza). Dr. Connolly agreed, testifying that “the responsible party is typically intimately involved. In most sites, it conducts the remedial investigation to characterize the site, the risk assessment, and then the feasibility study.” Tr. 3221:4-10 (Connolly).

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<sup>29</sup> Memorandum by the Director of EPA’s Office of Site Remediation Enforcement on “Negotiation and Enforcement Strategies to Achieve Timely Settlement and Implementation of Remedial Design/Remedial Action at Superfund Sites,” July 17, 1999, p. 2.

Mallinckrodt can move quickly and efficiently perform the necessary work, avoiding excessive administrative costs, delays, and quality problems. Although useful information was obtained over the last nine years, the study took too long, was extremely costly, and inefficient.<sup>30</sup> Mallinckrodt requests that it be given the opportunity to conduct any further investigation the Court may order as responsible parties are given in the typical case. Such opportunity, of course, would entail obligations to report progress to the Court and to the Plaintiffs, and Mallinckrodt would not be opposed to funding Plaintiffs' expert Dr. Driscoll, or another Plaintiffs' expert, to review and comment on the plans and proposals concerning implementation of the work.

### **XIII. Conclusion.**

In summary, Mallinckrodt requests that the Court address the following Study Panel findings and recommendations as follows:

<b>Study Panel Finding or Recommendation</b>	<b>Mallinckrodt Request to Court</b>
Finding: Bank-to-bank dredging is not scientifically feasible. (Phase II Report 21-5, 21-6, 23-6)	Accept finding.
Finding: Bank-to-bank capping is not scientifically feasible. (Phase II Report 19-6, 19-15)	Accept finding.

<sup>30</sup> The Study Panel and its contractors spent nine years studying the system (Tr. 76:16-19 (Rudd)), and close to twenty million dollars. DX 886. Administrative costs associated with handling contracts were in excess of one million dollars. Tr. 633:4-634:1; 635:18-23 (Whipple); DX 885; DX 886. The Study Panel spent around seventy thousand dollars on a study to examine uptake of mercury and toxicity to plankton, phytoplankton, and zooplankton. Tr. 1117:4-11; 1116:18-25 (Bodaly). However, the results of this work were of poor quality and were not usable. Tr. 1117:4-11 (Bodaly); JX 107 at 11:20-14:12 (Fisher). The Study Panel experienced problems with its total organic carbon data. Tr. 1112:16-24; 1113:4-10 (Bodaly). The Study Panel spent exorbitant time and resources pursuing a multi-cell model of the system, an effort that was ultimately abandoned. Tr. 1118:8-15; 1120:4-19; 1119:12-16; 1119:2-5 (Bodaly). The Study Panel's study of food webs of bird species in Mendall Marsh was another flawed effort; it cost over one hundred thousand dollars and problems with field sampling resulted in unreliable data on bird feeding behavior and severely limited the ability of the Study Panel to compare trends. Tr. 1077:10-1078:10; 1102:22-1103:10; 1078:11-17; 1086:21-1087:5; 1083:16-24; 1087:12-14; 1089:21-23 (Bodaly).

<p>Recommendation: Undertake further study to determine what controls recovery of the system, quantify the size of the mobile pool, quantify contribution from erosion, and identify hot spots. (Phase II Report 21-4, 21-10, 21-11, 21-12)</p>	<p>Accept portions of recommendation related to focused investigation of the size, areal extent, location, characteristics and impact on system recovery of the mobile pool. Require further investigation and evaluation of mercury in the Orland River. Reject study of erosion or search for hot spots.</p>
<p>Recommendation: Investigate engineering feasibility of sediment traps to reduce mercury concentrations in mobile pool. (Phase II Report 21-4, 21-5, 21-12, 21-18)</p>	<p>Reject recommendation. The proposed sediment traps are infeasible from an engineering perspective and modeling shows they would be ineffective.</p>
<p>Recommendation: Further investigate feasibility of adding activated carbon to Mendall Marsh to inhibit methylation. (Phase II Report 21-16, 21-17)</p>	<p>Reject recommendation. Geochemistry of the marsh, a multi-year study, and current leading research show that results would not be effective long-term and that activated carbon poses potential harm to marsh plants and biota.</p>
<p>Recommendation: Continued long-term monitoring of the system to verify trends and recovery. (Phase II Report 21-5, 21-17, and Chapter 13)</p>	<p>Accept recommendation with modification. Focused long-term monitoring of certain sediment and water or chemical parameters and biota is warranted.</p>
<p>Recommendation: continue Study Panel with ability to bring in engineering capabilities from remedial evaluations.</p>	<p>Modify proposal. Disband the Study Panel and order Mallinckrodt to conduct a study of Nelson’s sparrow (a representative species) to determine if and to what extent there is harm to populations and to better understand exposure pathways. If there is significant harm, evaluate options to address it.</p>

Dated at Portland, Maine this 18th day of September, 2014.

Respectfully submitted,

*/s/ Jeffrey D. Talbert*

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**CERTIFICATE OF SERVICE**

I, Jeffrey D. Talbert, attorney for Defendant Mallinckrodt US LLC, hereby certify that on the above date, I electronically filed the foregoing document in this matter with the Clerk of Court using the CM/ECF system which will send notification of such filing electronically to the registered participants.

/s/ Jeffrey D. Talbert  
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