

**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. 1:00-cv-00069-JAW

MALLINCKRODT US LLC’S PRE-TRIAL BRIEF

- I. Introduction.....1**
- II. The Study.....2**
- III. The State of the River7**
 - A. The River Is Less Contaminated than the Study Panel Suggests.....7**
 - B. The River is Recovering Faster than the Study Panel Estimates.8**
 - C. Most of the Mercury in the River Is Buried and Poses No Threat.....8**
- IV. There Is No Evidence of Unacceptable Risk to Human Health or Significantly Adverse Effects on Populations of Organisms.9**
 - A. No Evidence of Unacceptable Risk to Human Health.9**
 - B. No Evidence of Significant Adverse Effects on Populations of Biota.....12**
- V. The Remedies the Study Panel Suggests Are Not Feasible and Would Be Ineffective....16**
- VI. The Court Should Order Mallinckrodt to Conduct Focused Study of Potentially At-Risk Birds and Ongoing Monitoring of the River’s Recovery.....22**
 - A. Appropriate Remedial Options Should Be Ordered22**
 - B. The Court Should Require Mallinckrodt to Implement the Remedy.....24**

I. Introduction

At trial, Mallinckrodt US LLC (“Mallinckrodt”) will prove that the Penobscot River system is less contaminated, and is recovering faster, than the Phase II Report suggests. Mercury in the river is not posing an unacceptable risk to human health, nor is it causing significantly adverse effects on populations of organisms. In the absence of any actual harm, elaborate further studies and pilot tests on speculative remedies are unnecessary. The Study Panel has already evaluated and eliminated certain remedial options, such as full-scale dredging and capping, as scientifically infeasible and likely to cause significant harm. These findings (which Mallinckrodt agrees with) make Plaintiffs’ proposal, to conduct an open-ended feasibility study that puts all potential remedial options back on the table, overly broad and misguided. The novel remedial options recommended by the Study Panel for further exploration (digging trenches in the Penobscot to capture sediment and adding activated carbon (charcoal) to Mendall Marsh) are not feasible and pose a significant risk of doing more harm than good.

The Court should not order additional studies that are unlikely to yield helpful results, pursue remedies we know will not speed the river’s recovery, or evaluate options already evaluated and eliminated by the Study Panel. Instead, Mallinckrodt proposes long-term monitoring of system recovery and a focused study of mercury in marsh birds, the only Penobscot biota that might possibly be experiencing significantly adverse effects.

This pragmatic path forward would: (1) confirm that the system is recovering and (2) establish whether or not these birds are being harmed, the significance of any harm, and exposure pathways that may exist. The results of the marsh bird study would allow the parties and the Court to make an informed decision regarding the need for active remediation and what form such remediation should take. It would also provide information for the engineers to

identify and evaluate potential remedial measures. This focused approach would avoid wasting time and money on unnecessary studies and would make more sense than launching a massive engineering experiment in the Penobscot, with a host of potential unintended consequences, to fix a problem that is in the process of fixing itself.

II. The Study

Twelve years ago, this Court found that mercury in the Penobscot 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 previously 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.* (emphasis in original). That was the standard at the liability phase to justify the Penobscot River study Mallinckrodt has funded: not actual harm, but “any risk” of harm.

The standard for the remedy phase is different. In the remedy phase, the Court directed its panel of experts 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 (ECF No. 159 at 1-2) (emphasis added). 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).

It is one thing to demonstrate that there “may be a risk” of harm posed by mercury in the Penobscot. Now, however, Plaintiffs must prove that there is “existing” harm, in the form of an

“unacceptable” risk to human health or “significantly adverse” effects on populations of organisms. (ECF No. 159 at 1-2.) The evidence at trial will show the Plaintiffs have not met that burden. The Court further directed the Study Panel, appointed in 2004, to determine “the need for and feasibility of a remediation plan to effectively address the present effects of such existing harm, if any,” and “the elements of and timetable for the execution of the appropriate remediation plan” *Id.*

Ten years and some \$20 million later, their work warrants some compliments, but also some criticism. On the positive side, the Study Panel has assembled an extensive collection of some high-quality data—including excellent sediment core sample data—that forms the basis for its own opinions as well as opinions formulated by experts the parties have engaged. Using that data, the Study Panel has rightly determined that certain species of biota are not experiencing adverse effects due to Penobscot mercury. It has also correctly concluded that bank-to-bank dredging and capping are not viable remedial options. Mallinckrodt does, however, dispute other positions the Study Panel takes in its Phase II Report.

The Study Panel’s investigation of mercury in the Penobscot has gone on much longer, and has cost far more, than was warranted based on the Court’s order when it started over ten years ago. Yet with the ten years of study, the Study Panel has failed to adequately answer the Court’s ultimate question about the elements of a feasible remediation plan, or to have studied the actual effects of Penobscot mercury on actual Penobscot biota—and given the evidence Mallinckrodt will offer at trial that certain of the Study Panel’s key conclusions are either unsupported or erroneous—it is fair to say that the parties (and the Court) have less to show for their extraordinary investment of time and money than had been hoped.

How did this happen? The evidence at trial will show that the Study Panel misinterpreted some of the data it collected and scientific papers it relied on, and put too much faith in unrealistic assumptions and in untested (and untestable) remedial ideas. Instead of devising a pragmatic and achievable solution to a demonstrated problem, the Study Panel conducted a sprawling, science project that concludes with the recommendation that a new science project be undertaken.

To say this is not to question the talent or integrity of the Study Panel members, who were tasked with answering complex, cutting-edge scientific questions and have done much to increase our understanding of the Penobscot River ecosystem. But this exercise has now run its course. It is time for the Plaintiffs to be put to their burden of proof, and for this litigation to move toward resolution.

The Study Panel's key findings and recommendations with respect to remediation, along with Mallinckrodt's responsive positions and proposals, are outlined below.

Summary of Mallinckrodt's Position on Study Panel Findings and Recommendations

Study Panel Finding or Recommendation	Mallinckrodt Position Summary or Proposal
Finding: Bank-to-bank dredging is not scientifically feasible. (Phase II Report 21-5, 21-6, 23-6)	Agree.
Finding: Bank-to-bank capping is not scientifically feasible. (Phase II Report 19-6, 19-15)	Agree.
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)	Disagree. These proposed multi-year studies will be complex, expensive, and unlikely to support the Study Panel's remedial proposals.
Recommendation: Investigate engineering feasibility of sediment traps (huge trenches in the river bed) to reduce mercury concentrations in mobile pool. (Phase II Report 21-4, 21-5, 21-12, 21-18)	Disagree. The proposed sediment traps are infeasible from an engineering perspective and modeling shows they would be ineffective.
Recommendation: Further investigate feasibility of adding activated carbon to Mendall Marsh to inhibit methylation. (Phase II Report 21-16, 21-17)	Disagree. Geochemistry of the marsh, a multi-year study, and current leading research show that results would not be effective long-term and poses potential harm to marsh plants and biota.
Recommendation: Continued long-term monitoring of the system to verify trends and recovery. (Phase II Report 21-5, 21-17, and Chapter 13)	Agree with modification. Focused long-term monitoring of certain biota is warranted.
Recommendation: Continue Study Panel with ability to bring in engineering capabilities from remedial evaluations.	Proposal: Disband the Study Panel and order Mallinckrodt to fund and conduct a study of Nelson Sparrows (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.

In sorting out differences of opinion between the Study Panel and experts retained by the parties, the Court should remember that although the Study Panel was formed by the Court, in the final analysis its members (and the contractors they hired) are expert witnesses, and their testimony must be evaluated on its merits next to the testimony of the other expert witnesses who testify at trial. The Court should not view the Study Panel members as necessarily offering a neutral or objective perspective, bearing in mind Study Panel Member Nicholas Fisher's testimony at his deposition that instead of Plaintiffs "hav[ing] to prove that [chemicals like

mercury] are having a toxic effect,” mercury “should be regarded as guilty until proven innocent,” (Fisher Dep. 8/21/2013, attached as Exhibit 1, 147:2-5.); se(Bodaly Dep. 10/02/2013, attached as Exhibit 2, 415:14-23.)(explaining that if data results confirmed that HoltraChem was the primary source they would not have raised alternative theories to explain the data). When shown data indicating minimal differences between mercury contamination at Orrington and reference sites, Dr. Rudd reminded the Study Panel members and Dr. Bodaly that “we only need one smoking gun to move on to Phase II.” (April 17, 2007 email from John Rudd to Study Panel members and Dr. Bodaly, regarding “mammal data with preliminary analysis and assessment,” attached as Exhibit 3.)

The Advisory Committee Note to Federal Rule of Evidence 706—the rule governing court-appointed experts, the function the Study Panel has performed in this case—notes the concern that court-appointed experts may “acquire an aura of infallibility to which they are not entitled.” Although this concern did not prevent the adoption of Rule 706, it remains an issue.

As one commentator observed:

if court-appointed experts were perfectly accurate, we might want factfinders to give them complete deference. The problem is that although court-appointed experts avoid the systematic biases induced by litigants, they may have other preexisting biases. Or, they may simply err.

Christopher Tarver Robertson, “Blind Expertise,” 85 N.Y.U. L. Rev. 174, 198-99 (2010) (footnote omitted). While parties may hire their own expert to point out errors made by the court-appointed expert, they may “have a hard time overcoming the testimony of a court-appointed expert . . .” *Id.* at 199 (footnotes omitted); *see also id.* (“Because of this risk of effectively irrebuttable error, litigants rarely request that courts appoint experts.”). As one federal judge put the point, “[t]he presence of a court-sponsored witness, who would most certainly create a strong, if not overwhelming, impression of ‘impartiality’ and ‘objectivity,’

could potentially transform a trial by jury into a trial by witness.” *Kian v. Mirro Aluminum Co.*, 88 F.R.D. 351, 356 (E.D. Mich. 1980). According to the Federal Judicial Center, the same issue exists with bench trials. *See* Joe S. Cecil & Thomas E. Willging, *Court-Appointed Experts: Defining the Role of Experts Appointed Under Federal Rule of Evidence 706*, Federal Judicial Center 1993, at 52 (“Our interviews revealed that juries and judges alike tend to decide cases consistent with the advice and testimony of court-appointed experts.”). To avoid such pitfalls, the Court should evaluate the Study Panel’s testimony the same way it would evaluate any other expert opinion. The question remains the same as in any other civil litigation: have Plaintiffs met their burden of proof?

III. The State of the River

It is undisputed that the Penobscot River has been contaminated with mercury. But the extent and expected duration of that contamination are less than the Study Panel represents.

A. The River Is Less Contaminated Than The Study Panel Suggests

The Study Panel reports that mercury concentrations in surface sediments in the upper estuary are 10 to 20 times higher than background levels. (Phase II Report 23-2.) But as Dr. John P. Connolly will testify, those figures misconstrue the Study Panel’s own data, because (*inter alia*) they were calculated without using the technique of carbon-normalization and the Study Panel made questionable choices defining background. The importance of carbon-normalization (mercury concentration per unit of organic matter) is that it better reflects what mercury levels biota is actually exposed to as biota feed on organic material. By using non-carbon-normalized data, the Study Panel fails 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 has the potential to cause harm. When carbon-normalized data are used, mercury concentrations in the upper estuary are 3 to 5 times higher than background

levels, not 10 to 20 times higher, and concentrations in Mendall Marsh are less than 2 times background. (Connolly Report, attached as Exhibit 4, at 10-14.) In short, the lower Penobscot is not as contaminated as the Study Panel suggests. Background conditions are critically important when defining remedial options as they limit the practical extent of contaminant reductions.

B. The River Is Recovering Faster Than The Study Panel Estimates

The evidence at trial will demonstrate that natural recovery is proceeding at a faster rate than the Study Panel estimates. Contrary to the Study Panel's estimated 22- to-32-year recovery half-time, Dr. Connolly will testify, based on trends in aquatic biota and sediment core analysis, that the actual recovery half-time is 10 to 15 years. (Connolly Report § 5.) Dr. Connolly will explain why he believes the Study Panel's own data demonstrate that the system is recovering faster than the Phase II Report would suggest, and how the Study Panel's recovery-time estimate appears to have been inflated by its failure to acknowledge that the recovery half-time calculation for Mendall Marsh (10-15 years by Dr. Connolly's calculations) is the best indicator of the recovery time for the entire system. Dr. Connolly will explain that the better way to predict the rate of recovery going forward is to examine each sediment core individually to then extrapolate a recovery rate from Mendall Marsh cores. (*Id.* at § 5.2.)

C. Most Of The Mercury In The River Is Buried And Poses No Threat

Dr. Connolly will also testify, 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. He will also explain why "[t]he two sediment trap remedies proposed for further consideration by the Study Panel require the removal of significant volumes of sediment, [and] would result in potentially substantial environmental harm (remobilization of mercury contamination that is

currently buried)” (Connolly Report at 62.) Dr. Connolly concludes that we know enough now to conclude that the Study Panel’s proposed cure would be worse than the disease.

IV. There Is No Evidence Of Unacceptable Risk To Human Health Or Significantly Adverse Effects On Populations Of Organisms

In addition to the River being in better shape than the Study Panel suggests, there is no evidence that mercury in the Penobscot is creating an unacceptable risk to human health, and no evidence of harm to populations of biota. There is certainly no evidence of significantly adverse effects on populations of organisms. (ECF 159 at 1-2.)

A. No Evidence Of Unacceptable Risk To Human Health

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 posing an unacceptable risk to human health?” To the extent the Study Panel made any evaluation of human exposure to Penobscot mercury, it found that exposure to be minimal; Study Panel member Christopher Whipple testified at his deposition that the Study Panel “did not find evidence that significant exposures were occurring due to fish consumption.” (Whipple Dep. 7/29/2013, attached as Exhibit 5, 174:7-14.)

Without performing studies (which may not be necessary), the Study Panel simply references a screening concentration established by the State of Maine for fish caught by recreational fisherman in freshwater lakes and rivers. This reference is unhelpful for evaluating specific risk in the Penobscot, since fish everywhere in Maine exceed this concentration, which lead to State-wide fish consumption advisories for all State freshwater bodies and the entire coastline of Maine.

Mallinckrodt suspects that when the Court directed the Study Panel to determine whether mercury in the Penobscot was “posing an unacceptable risk to human health,” it envisioned the

Study Panel doing more than simply citing to the State of Maine's general screening level for mercury. The Study Panel never establishes any connection between mercury concentrations in Penobscot River biota that may exceed the State's screening level and actual risk to human health. Neither does Plaintiffs' expert Dr. Philippe Grandjean, a research epidemiologist, who never measured human exposure to mercury-contaminated Penobscot biota; instead he advances a novel and untested theory that a single hypothetical meal of Penobscot eel, lobster, or black duck could be dangerous—an approach Dr. Whipple described at his deposition as “not very helpful” (Whipple Dep. Feb. 12, 2014, attached as Exhibit 6, 31:15-16.) *See* Defendant Mallinckrodt US LLC's Motion to Exclude Testimony by Dr. Philippe Grandjean, April 4, 2014 (ECF No. 732.)

Dr. Michael Bolger, a toxicologist who until 2012 was Director of the Chemical Hazards Assessment staff in the FDA's Office of Food Safety, Center for Food Safety and Applied Nutrition, where his job was to assess mercury-related risks in seafood, will testify that Plaintiffs' evidence on the question of human harm (Dr. Grandjean's report) amounts to “a simplistic . . . assessment not performed using standard methodologies or practices in the field of exposure science or risk assessment.” (Bolger Report, attached as Exhibit 7, at 6.) Dr. Bolger will explain that “[t]he notion that a single meal would be an exposure of concern”—which is what Plaintiffs' evidence boils down to—“is not consistent with the known toxicokinetic information on methylmercury.” (Bolger Report at 7.) Dr. Bolger will explain that Plaintiffs and the Study Panel seem to misunderstand the significance of “threshold safety value[s]” like the EPA reference dose for mercury; such screening thresholds are designed, not to draw a line above which harm is expected to occur, but instead to establish highly conservative screening values “using an uncertainty/safety factor which is generally a factor of 10.” (Bolger Report at

8). “If the threshold value is exceeded this does not mean that a margin of safety no longer exists.” (Bolger Report at 8.) Using such an approach is inappropriate to establish harm.

Dr. Russell E. Keenan, who has more than 25 years of experience specializing in chemical risk assessment and toxicology, will testify he agrees with Dr. Bolger that the Study Panel failed to use standard methodologies in the field of human health risk assessment to answer the Court’s question about unacceptable risks to human health, and that the Study Panel’s screening-level analysis “cannot be used to determine that an unacceptable risk is present.” (Keenan Report, attached as Exhibit 8, at x.) Dr. Keenan will explain that the Study Panel’s reliance on a State screening level is misplaced because it is a conservative benchmark designed to signal the potential existence of a risk, not the actual presence of an unacceptable risk. Another problem is that the State screening level is for fish in general, whereas different species of fish and other biota are consumed at different rates, and the rate-of-consumption assumptions are critical in defining the screening level. To fill the gap the Study Panel had left, Dr. Keenan proceeded to perform his own human health risk assessment, and found that Penobscot mercury is not posing an unacceptable risk to human health. *Id.*

In assessing the significance of the State’s recent decision to close a small area of the Penobscot to lobster and crab harvesting, the Court should bear in mind the State’s advice 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.

<http://www.maine.gov/dmr/news/2014/PenobscotClosureFAQ.htm> (emphasis added). Dr.

Whipple also acknowledged at his deposition that “we [the Study Panel] couldn’t really produce much evidence regarding human health risk” (Whipple Dep. 7/30/2013, attached as Exhibit 9, 288:24-289:1), and thus “we didn’t conclude that there is a human health risk here.” (Whipple

Dep. 7/29/2013, 179.) In addition, the Maine Department of Marine Resources noted that the level of mercury in lobsters found in the closed area is similar to the level of mercury found in canned tuna, a household commodity not deemed by federal or state regulators to warrant even a warning label. As for the State's black duck advisory, Dr. Keenan will testify it is based on an assumed rate of black-duck consumption that is unrealistically high, relates to a population of roughly one hundred animals, and ignores the absence of evidence that a single or occasional exposure to food items with the mercury levels measured in black duck could put human health at risk. Indeed, mercury levels in Penobscot black ducks are below those found in swordfish—an item available every day at supermarkets and featured on restaurant menus throughout Maine.

B. No Evidence Of Significant Adverse Effects On Populations of Biota

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?” (ECF No. 159.) Instead of answering this question directly—by performing field or laboratory studies to assess whether the Penobscot River biota are actually suffering significantly adverse effects from mercury exposure—the Study Panel set mercury concentration targets based on a literature review and simply compared mercury concentrations found in the Penobscot River system biota it sampled to arbitrary targets it set based upon ranges of effects reported in scientific literature for different species. The Study Panel opted for this approach notwithstanding the urging of Dr. Fisher that without toxicity testing—to see if actual adverse effects could be identified in actual Penobscot River biota—the Panel would be forced “to rely on . . . old and probably very mediocre toxicity data (often [from studies] performed by folks who didn't know what they were doing in designing, conducting, or interpreting such experimental work[)] . . .” (Fisher Dep. 8/21/2013,

143-44.) Such reliance would, as Dr. Fisher expressed in an email to his colleagues, be “foolish” and “unacceptable.” *Id.* 144:6-7. Yet that is what the Study Panel did.¹ Absent toxic effect studies, the Study Panel “ha[s] no evidence” whether any damage was done to biota even during the period of peak mercury concentration. *Id.* at 146:8-12.

In addition to basing its harm analysis on studies of other biota in other ecosystems, the Study Panel displayed an unmistakable conservative bias in selecting specific mercury concentration targets within published ranges. *See id.* at 120:15-121:7. When the sources it consulted pointed to a range of concentrations where adverse effects might begin to appear, the Study Panel arbitrarily selected a number within the range as its target. Dr. Fisher could not recall there being a scientific method for selecting targets within ranges. (Fisher Dep. 8/21/2013, 97:23-99:21.) Dr. Bodaly agreed that the Study Panel “did not have a rigorous method” for doing this. (Bodaly Dep. 10/2/2013, 475:7-8.)

The Court’s question to the Study Panel directed the Panel to determine if there were significantly adverse effects on “populations of organisms.” Yet the Study Panel did not distinguish between biochemical markers of exposure (e.g., changes in enzyme levels) and effects directly linked to population of a species, effects on survival, growth, or reproduction. As Dr. Whipple explained, ecological risk assessment focuses “on a community basis, not an individual animal basis”—the question being whether a contaminant “affect[s] the reproductive success of the colony and is the population stable or declining.” (Whipple Dep. 7/30/2013,

¹ Why did the Study Panel take this indirect approach to answering the Court’s question? As late as August 2013 Dr. Fisher believed Judge Carter had directed the Study Panel not to perform toxicity studies. *See* Fisher Dep. 8/21/2013, 145:10-17. Project Leader Drew Bodaly testified that “[i]t was always the impression of the panel and I that we were told that we were not doing toxic studies and the subject was closed.” Bodaly Dep. 2/13/2014, attached as Exhibit 16, 32:1-3. In fact, Judge Carter had never issued any such instruction. *See* Fisher Dep. 8/21/2013, Ex. 28, attached as Exhibit 11 (Special Master Calkins explains: “there is no formal order prohibiting further toxicology testing,” so long as “you tie the need for it to remediation.”).

368:12-23.) Dr. Fisher described “serious risks” as those that could cause “population level effects . . . where something like reproduction is impaired.” (Fisher Dep. 8/20/2013, attached as Exhibit 12, 244:23-245:13.) While the precise weight the Study Panel placed on different studies is unclear, the Phase II Report appears to give equal consideration to non-reproductive effects as it does to population-level or reproductive effects; it relies on studies of altered singing (Phase II Report 2-6), decreased swimming ability (*id.* at 2-9), abnormal behavior (*id.* at 2-9), and tissue abnormalities (*id.* at 2-9), none of which have been tied in the scientific literature to population-relevant effects.

The Study Panel determined that five bird species (belted kingfisher, osprey, bald eagle, double-breasted cormorant, and American black duck) are not of concern for mercury-related toxic effects. (Henry Report, attached as Exhibit 13, at 9-10.) Dr. Betsy Henry, a Harvard PhD with 25 years of experience in the field of environmental mercury science and experience on major mercury-contaminated sites, will testify that a sixth bird species, black guillemot, is also not of concern based on the Study Panel’s own threshold, which the Study Panel itself misapplied.

Dr. Henry will also testify that the Study Panel’s threshold blood-mercury concentrations for invertebrate eating birds (such as Nelson Sparrows) are set too high. (Henry Report at 10.) She will explain that the studies the Study Panel cites in support of its blood-mercury threshold do not establish population-level effects. Her testimony will reveal that the Study Panel’s reliance on a study of nest failure among Carolina wrens in Virginia is misplaced because the study did not address potential confounding factors such as the presence of different habitats and different nesting locations, had a woefully insufficient sample size, and placed too much weight on nesting success as a measure of population-level effects. (Henry Report at 11; Henry Supp.

Report, attached as Exhibit 14, at 2.) Dr. Henry is therefore critical of the Study Panel's decision to set a blood-mercury concentration threshold of 1.2 ug/g for invertivorous birds based on the Carolina wren study. She will explain that her own review of the literature on effects that have actual relevance to reproductive success indicates that 3 to 4 ug/g would be a more appropriate (but still conservative) threshold range. (Henry Report at 15.) Just two bird species sampled by the Study Panel—Nelson's sparrow and red-wing blackbird—exceed that threshold, and by just 20 percent. (Henry Report at 17.) Dr. Henry concludes that Nelson's sparrow and red-wing blackbird are "potentially of concern," (*id.* at 18), but that there is no reason for further study or monitoring of other bird species. (*id.* at 19.) Potential harm cannot be ruled out, but nor can it be assumed to be occurring—which is why Dr. Henry recommends further investigation.

Turning to aquatic biota, Dr. Keenan will testify that the Study Panel based its findings on conservative screening-level benchmarks derived from studies of effects that are not relevant to assessing population-level risk. But even using the Study Panel's own fish tissue screening level, all of the fish and shellfish are either below or for one species—eel—very slightly above the Study Panel's own screening level of 0.5 ug/g. The most that could be said based on the Study Panel's screening-level analysis would be that there is "a potential of harm to aquatic biota, as distinguished from evidence of actual harm." (Keenan Report at x-xi.) Dr. Keenan will testify that a screening threshold for fish tissue should be based on population-relevant effects (survival, growth, or reproduction) and using those criteria Dr. Keenan derives a screening level of 1.6 ug/g. All of the fish and shellfish in the study area are far below this level. As for the Study Panel's decision to set a screening level in fish to protect fish predators (i.e., birds and larger fish that eat other fish) of 0.05 ug/g, the Study Panel itself recognizes that this level is unachievable and is far below levels of mercury found in fish in pristine waterbodies. (*Id.* at xi.)

This screening level is also pointless since the Study Panel has direct evidence of mercury concentrations in predators (osprey, eagles, eel), and those predators are not at risk. Dr. Keenan also evaluated the basis for the Study Panel's proposed level to protect fish predators and will testify that there is an alternative screening level which would be protective.

As for mammals, the Study Panel found no elevation in mercury concentrations in two of the species it examined (mink and otter). (Henry Report at 20.) It found what it deemed to be elevated mercury levels in bats, but Dr. Henry will testify that "it is unlikely that bat populations are experiencing significant adverse effects." (Henry Report at 24.) She formed that opinion because the mercury concentrations found in Penobscot bats are below or within the ranges associated with even these non-population-level effects and within ranges of mercury concentration found in bats at reference sites, and because the sources the Study Panel used to set bat mercury-concentration thresholds report effects—such as decreased swimming proficiency in mice—that have no demonstrated relationship to reproductive success. (Henry Report § 4.)

V. 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 such harm caused by mercury contamination in the Penobscot River/Bay system?

(ECF No. 159.) Ten years and some \$20 million 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" (Phase II Report 21-5), but (2) we have no idea if it would be feasible.

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 be feasible. The only evidence that will be presented at trial by a qualified expert (Ed Glaza a practicing sediment-remediation engineer) is that these remediation ideas are not feasible.

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" (Phase II Report 21-5.) The very next paragraph, however, drops the pretense that "further limited" study and design is all that remains to be done:

[W]e 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.

(Phase II Report 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 who knows where it would end) with a gathering of mercury scientists and "engineers experienced in sediment remediation" to "evaluate the feasibility" of the four remediation options the Study Panel has identified. *See* Phase II Report 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). This sounds like the beginning of a new full-blown research project, not "further limited" work at the end of the

current project that might fall under the Court's allowance in its 2003 Implementing Order that the Study Panel could indicate "what additional information is needed in order to design the remediation program." (Docket 159.)

In recommending that a conference of mercury scientists and sediment remediation engineers be convened to "asses[s] the feasibility" of remediation options, and to "design and tes[t]" them, the Study Panel fails to answer the ultimate question put to it. Instead, it punts to what would be a next-generation Study Panel. Plaintiffs can offer no evidence to fill the large gap the Study Panel has left. The testimony of Professor Charles Driscoll is merely a supportive reflection of the Study Panel's inconclusive conclusion.

Hoping to usher this 13-year-old litigation toward an actual conclusion, 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 identifies as candidates for further study. The Study Panel's three key remedial options (a fourth option entails "combinations of" the first three (Phase II Report at 21-17)) 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" (Phase II Report 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." (Phase II Report 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." (Phase II Report 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" (Phase II Report 21-15.)

As to the first two recommendations, Glaza will testify that neither of these remedial options warrants further study, because “it is highly unlikely that these recommendations would be effective, feasible, or implementable.” (Glaza Report, attached as Exhibit 15, at 3.)

The Study Panel seeks to frame the sediment-trap remedy (remedial options 1 and 2) as if it were a sensible middle course between what it describes as “large scale dredging” of the upper estuary—an option so implausible that even the Study Panel does not recommend it for further study (Phase II Report 21-5 & 21-6)—and the monitored natural-attenuation remedy Mallinckrodt supports. The Study Panel rejected “large scale dredging” due to “the risk of aggravating the ongoing [mercury] contamination problem by disturbance and exposure of highly contaminated sediments,” and “the prohibitively high estimated cost of an extensive dredging operation” (*Id.* at 21-6.) But Glaza will testify that the sediment-trap remedy is itself a large scale dredging operation, the magnitude of which the Study Panel fails to acknowledge. *See* Glaza Report at 15 (“The required dredge volume to construct the sediment traps and corresponding required dredge volume to construct the CAD to hold this material . . . would require an estimated 70 acre temporary sediment staging area” on “land with access to the river”). Glaza will testify that the scale of the dredging operation required to implement the sediment-trap remedy would be equivalent to that of a “Superfund dredging ‘Megasite,’” Glaza Report at 12-13, and that the very same risks of “aggravating the ongoing [mercury] contamination problem by disturbance and exposure of highly contaminated sediments” that caused the Study Panel to reject what it called “large scale dredging” of the upper estuary would be present with the sediment-trap remedy.

Moreover, Dr. Connolly will testify that the modeling he performed, using current data on hydrodynamics and river deposition, shows that sediment traps cannot be built large and deep

enough for sediments to settle out and stay in the traps. (Connolly Report at 52-56.) Glaza will also offer numerous specific reasons why the cost of a sediment-trap remedy “could be many times higher than the [Study Panel’s] \$42 million estimate” (Glaza Report at 17.) He will explain the extraordinary degree of uncertainty surrounding the sediment-trap remedy, an “unproven” remediation technique “with no identified precedent” (*id.* at 3,13), and testify that based on his two decades of experience as a sediment-remediation engineer, he does not believe this novel technique would work. Glaza’s analysis shows that any potential benefits are speculative, and it is infeasible to test the sediment-traps short of its full-scale implementation. (*Id.* at 3.) Moreover, “[b]ecause of the extreme size, complexity, and unproven nature” of the sediment-trap proposal, “it would take at least 15 years before design, permitting, and implementation . . . could be completed.” (*Id.* at 3.) By that time, the River will be in a substantially better condition through natural recovery.

The Study Panel’s recommendations are by their own admission conceptual ideas—presented without vetting by practicing engineers. As Project Leader Drew Bodaly’s explained, the Study Panel’s “ideas about remediating in the main stem of the river *were ideas only*, and we said we think people who understand the system should be getting together . . . to find out whether remediation is practical, whether it’s cost effective.” (Bodaly Dep. 2/23/2014, attached as Exhibit 16, 213:5-10 (emphasis added).) Or in Dr. Whipple’s formulation: “One might say that what survived [of the Study Panel’s remedial recommendations] were the ones that weren’t obvious bad ideas.” (Whipple Dep., 7/29/2013, at 217.) The Court should bear this in mind in deciding how to weigh the Study Panel’s tentative outlines of remedial concepts it found not to be “obvious bad ideas” against Glaza’s unrebutted experience-based engineering critique. The weakness of the Study Panel’s remediation analysis reflects the fact that neither its project

leader, nor two of its three members, have experience working on large environmental remediation projects that would qualify them to select and design a remedial plan for a site of this magnitude and complexity.

The Study Panel's alternative recommendation of "further testing of SediMite application to Mendall Marsh" will fare no better at trial. Dr. Dimitrios Vlassopoulos, an expert in environmental geochemistry and contaminant hydrology, will testify that the Study Panel's own testing demonstrates that while adding SediMite (activated carbon— similar to charcoal) to an ecosystem could be somewhat effective in the short term at reducing porewater mercury and methylmercury concentrations, its effects in that media do not hold up over time, disappearing within just two years due to geochemical conditions in the marsh. (Vlassopoulos Report, attached as Exhibit 17, at 5.) He will further testify that the amendments had no measureable effect on methyl mercury in sediments. Dr. Vlassopoulos therefore concludes that pouring SediMite into Mendall Marsh is not a viable remedial option, and that no further study is needed to support this conclusion. (*Id.* at 5-6.)

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 will testify 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." (Henry Report at 25.) Indeed, the Study Panel's own evaluation "indicated that total mercury accounts for only 10% of the variability in methylmercury [the form of mercury that is taken up by biota] concentration in surface sediment on a site-wide basis, and 40% of the variability in Mendall Marsh surface sediment." (*Id.*) Because "it is not clear how potential

sediment mercury reductions may change bird or mammal blood mercury concentrations in the Penobscot,” Dr. Henry expresses concern about “embark[ing] 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.” (*Id.* at 27.) Last, Dr. Henry expresses significant reservations concerning the impact on biota habitat of adding a foreign substance such as sediment to the marsh environments of the Penobscot system. (*Id.* at 28-29.)

VI. The Court Should Order Mallinckrodt To Conduct Focused Study of Potentially At-Risk Birds And 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. The Study Panel and the Parties 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 end.

A. Appropriate Remedial Options Should Be Ordered

The First Circuit declared earlier in this litigation that “a trial court, in an environmental case, should consider the balance of relevant harms before granting injunctive” relief, and that “[t]he familiar four-part framework for injunctive relief is a suitable guide in such situations.” *See Maine People’s Alliance v. Mallinckrodt, Inc.*, 471 F.3d 277, 296 (1st Cir. 2006). “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.* (quotation marks omitted). While the First Circuit held 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.” (*Id.* 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, with the benefit of this 10-year study, 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.)²

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 happen if natural recovery were permitted to run its course. Given the astronomical price tag

² 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.

associated with these untested measures, 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.” *Id.* at 297. Instead, further study of “the extent of the existing harm” should be limited to Nelson’s Sparrows, a representative species for the two species of marsh birds that may be experiencing significantly adverse effects. What the Court should not do is require Mallinckrodt to fund further exploration of the Study Panel’s unworkable remedial ideas.

Mallinckrodt understands that it was the source of some of the mercury in the Penobscot, and that joint-and-several liability applies to this case. But in exercising its equitable powers, the Court should not lose sight of the fact that Mallinckrodt was far from the only source of that mercury. Guy Wm. Vaillancourt, an environmental engineer and expert in evaluating sources of environmental contamination, will testify that the former HoltraChem facility is responsible for less than 10 percent of the mercury found today in Penobscot River sediments, and that other historical sources, in particular mercury found in slimicides used by the pulp and paper industry, contributed far more mercury than did Mallinckrodt. (Vaillancourt Report, attached as Exhibit 18, at 1-2.) Gary Bigham, who has over 20 years of experience studying mercury in the environment, will also testify to sources of mercury other than the HoltraChem facility. This evidence should be weighed in the balance as the Court makes its equitable determination as to the proper remedy in this case. The Study Panel was preoccupied in the Phase II Report with establishing that the mercury at issue in this case is from the HotraChem site (*see* Phase II Report 14-4); the evidence at trial will set the record straight on that score.

B. The Court Should Require Mallinckrodt To Implement The Remedy

The Court may have come to see the Study Panel process—that is, the use of court-appointed experts to conduct scientific inquiry—as natural and inevitable for a case of this

nature. The awkward, time-consuming and inefficient nature of that process, however successful it might have been in eliciting investigatory information, is not appropriate going forward. It is now time to change the paradigm. Even in the case of very large remedial actions conducted under the EPA's Superfund program, "[a]n overriding goal of the Superfund program is for PRPs [potentially responsible parties – here, Mallinckrodt] to expeditiously conduct remedial actions." (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.) "All work is done under the PRP's control and they . . . are responsible for the long term performance of the remedy." *See also 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)).

EPA routinely entrusts responsible parties with implementing Superfund remedies; it is similarly appropriate for this Court to entrust Mallinckrodt with implementing further necessary study and monitoring, subject to technical review by Plaintiffs (paid for by Mallinckrodt) and, ultimately, Court approval. Mallinckrodt's interest lies in achieving a long-term solution to the mercury issues in this litigation. Neither Mallinckrodt nor the environment will benefit from pursuing unnecessary further studies or remedies doomed to fail.

CONCLUSION

The Court should modify the Study Panel's proposal for further study and pilot testing of potentially harmful remedial measures and instead order Mallinckrodt to perform a focused study of the only biota potentially impacted (marsh birds) and further long-term monitoring to measure recovery of the Penobscot River system.

Dated at Portland, Maine this 27th day of May, 2014.

Respectfully submitted,

/s/ Jeffrey D. Talbert

Jeffrey D. Talbert, Esq., Bar No. 4358
David B. Van Slyke, Esq., Bar No. 7333

Attorneys for Mallinckrodt US LLC

Preti Flaherty Beliveau & Pachios LLP
One City Center, P.O. Box 9546
Portland, Maine 04112-9546
Phone: 207-791-3000
Fax: 207-791-3111
jtalbert@preti.com
dvanslyke@preti.com

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
Jeffrey D. Talbert
Attorney for Mallinckrodt US LLC

PRETI FLAHERTY BELIVEAU &
PACHIOS, LLP
One City Center
P.O. Box 9546
Portland, ME 04112-9546
(207) 791-3000
jtalbert@preti.com