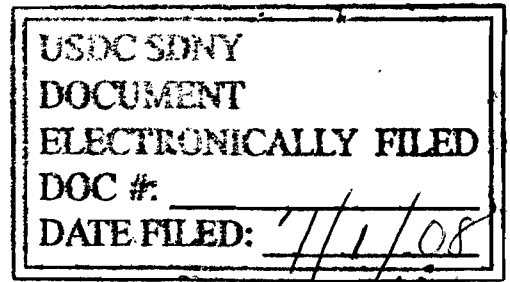


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



----- X
:
IN RE: METHYL TERTIARY BUTYL
ETHER ("MTBE") PRODUCTS
LIABILITY LITIGATION

OPINION AND ORDER

Master File No. 1:00-1898
MDL 1358 (SAS)
M21-88

This document relates to:

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:
Tonneson, et al. v. Sunoco, Inc., et al., 03
Civ. 8284
Basso, et al. v. Sunoco, Inc., et al., 03 Civ.
9050

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

In 2000, it was discovered that the gasoline additive methyl tertiary butyl ether ("MTBE") had contaminated almost fifty private wells in Fort Montgomery, New York. Individuals who had been exposed to MTBE-contaminated water then sued the owners of two nearby gas stations and their suppliers.¹ At trial, plaintiffs propose to offer the expert opinion of Dr. Myron Mehlman to testify to the following:

(1) Plaintiffs for whom I was provided MTBE exposure data more probably than not experienced genetic or subcellular

¹ See generally *In re MTBE Prods. Liab. Litig.*, 528 F. Supp. 2d 303, 306-08 (S.D.N.Y. 2007) (discussing the background of this action).

damage as a result of that exposure, (2) there is credible, scientific, medical, and toxicological evidence that MTBE is a probable human carcinogen[,] and (3) therefore, any plaintiff who is concerned that their [sic] past exposure to MTBE or benzene has a reasonable basis for their [sic] concerns.²

Defendants have filed a motion *in limine* to exclude Dr. Mehlman's testimony on the ground that it does not satisfy the requirements of Rule 702 of the Federal Rules of Evidence.³

For the reasons below, defendants' motion is denied in part and granted in part.

II. BACKGROUND ON DR. MEHLMAN'S REPORT

Dr. Mehlman has submitted a thirty-eight page expert report along with various attachments.⁴ The content of Dr. Mehlman's report generally falls

² 2/2/07 Expert Report of Myron A. Mehlman, Ph.D. ("Mehlman Rep.") at 38. *See also* Plaintiffs' Response to Defendants' Motion in Limine to Exclude the Testimony of Myron Mehlman, Ph.D. ("Pl. Mem.") at 6 ("Dr. Mehlman will testify at trial that MTBE causes adducts to form on DNA, and that MTBE is a probable carcinogen.").

³ *See* Memorandum of Law in Support of Defendants' Joint Motion In Limine to Exclude the Opinions of Plaintiffs' Expert Myron A. Mehlman, Ph.D. ("Def. Mem."); Defendants' Reply in Support of Defendants' Joint Motion In Limine to Exclude the Opinions of Plaintiffs' Expert Myron A. Mehlman, Ph.D. ("Def. Reply"). The motion *in limine* is filed pursuant to Rule 104 of the Federal Rules of Evidence.

⁴ "Dr. Mehlman is the former Director of Toxicology in the Department of Environmental Affairs and Toxicology of Mobil Corporation." Pl. Mem. at 5.

into four categories. *First*, Dr. Mehlman describes various external symptoms that people have developed when exposed to MTBE:

Serious adverse effects known to be caused by exposure to MBTE include respiratory disorders (asthma, shortness of breath, chronic inflammation of the sinuses, etc.); neurological effects (nausea, dizziness, headaches, light-headedness, insomnia, anxiety, palpitations, etc.); and allergic reactions (skin rashes, eye irritation, etc.)⁵

Dr. Mehlman also lists nineteen studies that “have found a causal relationship between adverse health effects and MTBE” and further describes three of these studies.⁶ One of these studies demonstrates that “MTBE causes damages to cell cycle progression in humans from drinking contaminated water”⁷ while another study suggests that “when plaintiffs ingest MTBE and benzene in water, they may have impairment of their immune system.”⁸ In the third study, “[the] participants reported headaches, bloody noses, dizziness, anxiety, inability to concentrate,

He is also “the former Chief of Biochemical Toxicology at the Bureau of Goods in the U.S. Food and Drug Administration.” *Id.* at 6. Therefore, he is “a witness qualified as an expert by knowledge, skill, experience, training, or education.” Fed. R. Evid. 702.

⁵ Mehlman Rep. at 2 (citation omitted).

⁶ *Id.* at 3. Twelve of the nineteen studies have been authored by Dr. Mehlman. *See id.* at 3-4.

⁷ *Id.* at 5.

⁸ *Id.*

lightheadedness, ear, nose and throat complaints, rashes, sneezing, breathing problems, bronchitis, and neurotoxic adverse effects.”⁹

Second, Dr. Mehlman discusses studies showing that “MTBE and/or its metabolites, tertiary butyl alcohol and formaldehyde, cause cancers in experimental animals.”¹⁰ Dr. Mehlman cites twenty-three articles that “contain scientific reports showing carcinogenicity of MTBE and its metabolites in experimental animals”¹¹ He concludes that “MTBE has been shown to be carcinogenic in animals.”¹²

Third, Dr. Mehlman explains that benzene has long been known to be a carcinogen. “There are between 4,000 and 6,000 published scientific, epidemiological, medical reports, technical documents on the metabolism, and the mechanisms of action, toxicity, carcinogenicity, teratogenicity and mutagenicity of benzene.”¹³ After listing over nine pages of “landmark reports,”¹⁴ Dr. Mehlman

⁹ *Id.*

¹⁰ *Id.* at 9.

¹¹ *Id.* at 7.

¹² *Id.* at 9.

¹³ *Id.* at 11.

¹⁴ *Id.* at 12. *See also id.* at 12-21.

states that “[t]hese reports confirm that benzene is a known carcinogen in experimental animals”¹⁵ and that studies have “reported significant increases in human cancers from exposure to benzene.”¹⁶

Fourth, Dr. Mehlman concludes that plaintiffs exposed to MTBE “more probably than not experienced genetic or subcellular damage as a result of that exposure” and that “MTBE is a probable human carcinogen.”¹⁷ Dr. Mehlman’s opinion is largely based on a study entitled “Formation of MTBE-DNA Adducts in Mice Measured with Accelerator Mass Spectrometry” or “MTBE-DNA Adducts Study.”¹⁸ The study was published in *Environmental Toxicology* in 2005 and authored by seven scientists: H.F. Du, L.H. Xu, H.F. Wang, Y.F. Liu, X.Y. Tang, K.X. Liu, and S.X. Peng. Relying on this study, Dr. Mehlman states:

Du et al. (2005) of Fudan University in Shanghai, China reported formation of MTBE-DNA adducts in liver, kidney, and lung in a linear, log/log, dose response relationship. This is consistent with MTBE-caused tumors in rats and mice observed by Belpoggi et al. (1995) and others. In the Du et al. Study (2005), the MTBE-DNA adduct formation peaked at twelve hours after

¹⁵ *Id.* at 21.

¹⁶ *Id.* at 26.

¹⁷ *Id.* at 38.

¹⁸ 20 *Environmental Toxicology* 397–401 (2005).

administration of MTBE. Adducts declined rapidly five days after administration. This study is important because it demonstrates that MTBE can cause cancer in humans by the same DNA adduct formation as benzene.¹⁹

In concluding that MTBE is a probable human carcinogen, Dr.

Mehlman also relies on a “warning about MTBE” issued in 1995 by “the Collegium Ramazzini, an organization comprised of scientists and physicians who are highly regarded in their field”²⁰ According to this organization, “[t]here is a general agreement among experts in chemical carcinogenesis that a substance which causes cancer in significant numbers of experimental animals in well-conducted assays poses a presumptive carcinogenic risk to some humans, even in the absence of confirmatory epidemiological data”²¹ Finally, according to Dr.

Mehlman:

Criteria established by the National Toxicology Program, part of the National Institute of Environmental Health Sciences, for listing agents in the Report on Carcinogenesis specify that an agent be listed in the report as “reasonably anticipated to be a human carcinogen” if:

“There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant and/or combination

¹⁹ Mehlman Rep. at 4.

²⁰ *Id.* at 6.

²¹ *Id.*

of malignant and benign tumors: (1) in multiple species or multiple sites; (2) by multiple routes of exposure[;] or (3) to an unusual degree with regard to incidence, site or type of tumor, or age of onset.”²²

III. DEFENDANTS’ MOTION *IN LIMINE*

Rule 702 of the Federal Rules of Evidence provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.²³

The party offering the expert must prove by a “preponderance of proof” that the proffered testimony satisfies this rule.²⁴

Defendants argue that Dr. Mehlman’s opinion should be excluded for two reasons. *First*, his opinion does not “satisfy the reliability requirements of Rule 702 because it is not generally accepted in the scientific community.”²⁵

²² *Id.* at 10 (quoting National Toxicology Program).

²³ Fed. R. Evid. 702.

²⁴ *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592 n.10 (1993) (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987)).

²⁵ Def. Mem. at 5.

Second, Dr. Mehlman has not applied the principles and methods reliably to the facts of the case.²⁶

A. Dr. Mehlman’s Testimony Is the Product of Reliable Principles and Methods

Under Rule 702, an expert’s testimony must be “the product of reliable principles and methods.”²⁷ In the context of evaluating scientific evidence, the Supreme Court has offered four factors to guide courts in determining the reliability of an expert’s method: (1) whether the theory can be and has been tested; (2) whether the theory has been subjected to peer review; (3) any known error rate; and (4) general acceptance in the relevant expert community.²⁸ These factors are non-exclusive and the final question for the court to answer is whether the expert has “employ[ed] in the courtroom the same level

²⁶ *See id.* at 10-14. Defendants also argue that Dr. Mehlman’s “opinion regarding benzene exposure should be excluded because it is irrelevant given that there is no evidence that any Plaintiff was ever exposed to benzene.” *Id.* at 14. However, because “Plaintiffs do not intend to offer Dr. Mehlman’s opinions about benzene at trial,” Pl. Mem. at 3, this argument is not addressed.

²⁷ Fed. R. Evid. 702. *See also In re MTBE*, No. 00 Civ. 1898, 2008 WL 1971547, at *3-*5 (S.D.N.Y. May 7, 2008) (describing the history of Rule 702).

²⁸ *Daubert*, 509 U.S. at 592-94. *See also id.* at 590 n.9 (“In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*.”) (emphasis in original).

of intellectual rigor that characterizes the practice of an expert in the relevant field.”²⁹

Defendants argue that Dr. Mehlman’s opinion does not “satisfy the reliability requirements of Rule 702 because it is not generally accepted in the scientific community.”³⁰ However, the Supreme Court and Second Circuit have made it clear that Rule 702 allows expert scientific testimony even if it is not “generally accepted” by the relevant community.³¹ As the Supreme Court explained in *Daubert*:

Nothing in the text of this Rule establishes “general acceptance” as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that Rule 702 or the Rules as a whole were intended to incorporate a “general acceptance” standard . . . and a rigid “general acceptance” requirement would be at odds with the liberal thrust of the Federal Rules and their general

²⁹ *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

³⁰ Def. Mem. at 5.

³¹ See *Daubert*, 509 U.S. at 596; *Federal Deposit Ins. Corp. v. Suna Assocs., Inc.*, 80 F.3d 681, 687 (2d Cir. 1996) (permitting an expert to testify about a valuation method that was not generally accepted as it was “a hybrid of two widely-recognized methods”). Cf. *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995) (explaining that in *Daubert* “the Court expressed its faith in the power of the adversary system to test ‘shaky but admissible’ evidence, and advanced a bias in favor of admitting evidence short of that solidly and indisputably proven to be reliable”) (citing *Daubert*).

approach of relaxing the traditional barriers to opinion testimony.³²

Of course, if a method has not gained general acceptance, it “may properly be viewed with skepticism.”³³ But viewing a method with skepticism is a far cry from the bright-line rule of exclusion that defendants advocate.

Dr. Mehlman’s testimony is reliable because he has demonstrated that he is employing “the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”³⁴ In particular, Dr. Mehlman relies heavily on the MTBE-DNA Adducts Study. This study has been tested and subjected to peer review and bears all of the characteristics of having employed a scientific methodology. According to this study:

The conclusion that MTBE can form adducts with DNA in mice after a single administration in a wide range of doses with a good linear correlation has not yet been reported in literature. In such a low dose . . . the measured number of adducts is considered sufficiently high to possibly imply a high risk of carcinogenesis from MTBE

Generally, chemical assays do not always precisely predict the biological response, but an increase in adduct burden within a cell places the cell at a greater risk of malignant mutation. In most

³² *Daubert*, 509 U.S. at 588 (quotation marks and citation omitted).

³³ *Id.* at 594 (quotation marks and citation omitted).

³⁴ *Kumho Tire*, 526 U.S. at 152.

cases DNA adduct level is positively correlated with the genotoxicity of the chemicals. Therefore, on the basis of our results, we suggest that MTBE is probably genotoxic.³⁵

In addition, Dr. Mehlman relies on the fact that almost two dozen studies support the conclusion that MTBE causes cancer in animals. Indeed, in this motion, defendants do not contest that MTBE is carcinogenic in animals. Nor do defendants contest that the U.S. Department of Health and Human Services' National Toxicology Program states that a chemical should be classified as "Reasonably Anticipated to Be a Human Carcinogen" if "[t]here is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant and/or combination of malignant and benign tumors: (1) in multiple species or multiple sites"³⁶ Finally, at least one organization has stated "[t]here is a general agreement among experts in chemical carcinogenesis that a substance which causes cancer in significant numbers of experimental animals in well-conducted assays poses a presumptive carcinogenic risk to some humans"³⁷

³⁵ MTBE-DNA Adducts Study at 399-400.

³⁶ Mehlman Rep. at 10.

³⁷ *Id.* at 6 (quoting the Collegium Ramazzini). *Cf.* Carl F. Cranor, "A Framework for Assessing Scientific Arguments: Gaps, Relevance and Integrated Evidence," 15 *J.L. & Pol'y* 7, 37 (2007) ("National and international consensus

Defendants respond by arguing that “Dr. Mehlman fails to acknowledge that the U.S. Environmental Protection Agency has issued revised guidelines for carcinogen risk assessment”³⁸ However, the ultimate question is not whether a scientist followed the EPA’s guidelines but whether the scientist is using “the same level of intellectual rigor that characterizes the practice of an

scientific committees routinely rely upon animal evidence for judging the toxicity of substances. Consider carcinogens as an example, which is an especially well developed area. The International Agency for Research on Cancer lists about sixty-six substances or groups of substances, excluding mixtures and exposure conditions, as probable human carcinogens. For more than forty of these substances (about 60 percent), evidence of carcinogenicity in humans is inadequate or limited. Nonetheless, the overall classification is based on sufficient evidence in animal studies plus “other data relevant to the evaluation of carcinogenicity and its mechanisms.” The U.S. National Toxicology Program lists about 185 substances as ‘reasonably anticipated to be a human carcinogen.’ Of these, a large percentage has been identified on the basis of good animal studies. This has been confirmed by agency personnel.”).

³⁸ Def. Mem. at 6 (citing “Environmental Protection Agency, Guidelines for Carcinogen Risk Assessment, EPA/630/P-03/001F (2005)). The guidelines on which defendants rely state: “EPA generally takes public health protective default positions regarding the interpretation of toxicologic and epidemiologic data: animal tumor findings are judged to be relevant to humans, and cancer risks are assumed to conform with low dose linearity.” Environmental Protection Agency, Guidelines for Carcinogen Risk Assessment A-10-A-11 (2005). Moreover, “[t]he United States Environmental Protection Agency may have found that MTBE is a “likely” cause of cancer in humans such as leukemia and lymphoma, although this conclusion has not yet received official agency approval.” *In re MTBE*, 241 F.R.D. 435, 437 n.2 (S.D.N.Y. 2007) (citations omitted).

expert in the relevant field.”³⁹ In this case, Dr. Mehlman has relied on (1) numerous studies showing inhalation and consumption of MTBE has led to cancer in animals such as mice and rats, (2) the agreement among experts that when a substance causes cancer in significant numbers of experimental animals, the substance is presumed to pose a carcinogenic risk to some humans, and (3) a scientific study published in a peer-reviewed journal that shows MTBE can cause cancer in humans by the same DNA adduct formation as is caused by exposure to benzene.⁴⁰

At trial, defendants may attack Dr. Mehlman’s methodology as well as its underlying assumptions. As the Supreme Court stated in *Daubert*: “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”⁴¹ After evaluating the evidence from both sides, the jury may well agree with defendants that MTBE does not cause cancer in humans. This would not be surprising if only because “science itself

³⁹ *Kumho*, 526 U.S. at 152.

⁴⁰ In their reply brief, defendants concede that benzene is “a known human carcinogen.” Def. Reply at 5.

⁴¹ *Daubert*, 509 U.S. at 596.

may be highly uncertain and controversial with respect to many of the matters that come before the courts.”⁴²

However, regardless of the jury’s ultimate decision, plaintiffs have proven by a preponderance of the proof that Dr. Mehlman’s “testimony is the product of reliable principles and methods.”⁴³

B. Dr. Mehlman May Not Testify that Specific Plaintiffs Suffered Subcellular Damage or Have a Reasonable Fear of Cancer

Defendants also argue that Dr. Mehlman has failed to apply the principles and methods reliably to the facts of the case.⁴⁴ In particular, Dr. Mehlman did not “specifically analyze each plaintiff’s drinking water habits and patterns to determine if they [sic] actually used their well as a drinking water source.”⁴⁵ “Moreover, the sampling data upon which Dr. Mehlman relies in

⁴² Justice Stephen Breyer, “Introduction,” in Federal Judicial Center, *Reference Manual on Scientific Evidence* at 4 (2d ed. 2000). *See also Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007) (“in epidemiology hardly any study is ever conclusive”).

⁴³ Fed. R. Evid. 702.

⁴⁴ *See* Def. Mem. at 10-14.

⁴⁵ *Id.* at 11 (quoting transcript of Dr. Mehlman’s deposition). *See also* Def. Reply at 8 (“Plaintiffs’ failure to provide Dr. Mehlman with the complete sampling results, which show that no MTBE entered the Plaintiffs’ homes on the overwhelming majority of sampling events, amounts to a poorly concealed effort to manipulate the data and Dr. Mehlman’s opinion to reach a desired conclusion.”).

forming his opinion that Plaintiffs were actually exposed to MTBE from their well water are incomplete and, therefore, misleading.”⁴⁶ Finally, defendants object to the fact that:

Dr. Mehlman intends to opine at trial that any exposure will result in genetic damage, and that, just because nearly all Plaintiffs had detection of MTBE in their raw water at some point in time – regardless of whether they had a [water filter] system in place and regardless of whether they actually drank water from their taps – they all have suffered an injury on a subcellular level.”⁴⁷

Plaintiffs respond that “[a]s the Federal Judicial Center’s Manual on Scientific Evidence and established case law recognize, however, levels of exposure to toxic substances can seldom be precisely quantified because measuring devices are not typically present at the time of exposure.”⁴⁸

While exposure levels are often difficult to “precisely quantify,” this does not excuse Dr. Mehlman from attempting to analyzing plaintiffs’ exposure levels if he intends to testify that they have a basis for their fear of cancer.⁴⁹

⁴⁶ Def. Mem. at 11.

⁴⁷ *Id.* at 13.

⁴⁸ Pl. Mem. at 8.

⁴⁹ Plaintiffs also argue that “[t]he Court previously determined: ‘Plaintiffs have provided sufficient evidence to allow a jury to find that they were exposed to MTBE through the well water they used in their homes for drinking, cooking, bathing and cleaning.’” Pl. Mem. at 4 (quoting *In re MTBE*, 528 F. Supp. 2d at 313). But the fact that this Court has found that the evidence demonstrates that plaintiffs were generally exposed to MTBE does not excuse Dr. Mehlman

Courts understand that individuals exposed to various chemicals are often unaware of their exposure until after the fact, and frequently there are no direct measurements of the exposure that occurred. In such situations, it is acceptable for an expert to estimate an individual's exposure level based on the available evidence.⁵⁰ This is especially true in light of the "liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony."⁵¹

Yet, it would be absurd to allow Dr. Mehlman to testify that "any plaintiff who is concerned that their [sic] past exposure to MTBE . . . may cause cancer has a reasonable basis for their concerns" if that plaintiff only had consumed one glass of filtered water on one occasion.⁵² Without attempting to analyze plaintiffs' exposure to MTBE and considering all of the available

from analyzing plaintiffs' exposure levels when offering the expert testimony that they "more probably than not experienced genetic or subcellular damage as a result of that exposure." Mehlman Rep. at 38.

⁵⁰ See *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 157 (3d Cir. 1999) ("[E]ven absent hard evidence of the level of exposure to the chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff's illness. The medical expert [in a previous case] relied primarily on the temporal relationship and the nature of the plaintiff's complaints, as in the present case."). Accord *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1059-61 (9th Cir. 2003).

⁵¹ *Daubert*, 509 U.S. at 588.

⁵² Mehlman Rep. at 38.

evidence, Dr. Mehlman cannot reliably testify that the plaintiffs have a reasonable fear of cancer due to their exposure to MTBE.⁵³ As one court has explained, “to the extent that any witness has based their [sic] opinions on studies, models, or experiments, it is their [sic] burden to connect those analyses to the facts of this case.”⁵⁴

Nonetheless, Dr. Mehlman may still testify about the MTBE-DNA Adducts Study, the studies demonstrating that MTBE causes cancer in animals, and that “there is credible, scientific, medical, and toxicological evidence that MTBE is a probable human carcinogen.”⁵⁵ In other words, “Dr. Mehlman [may] testify at trial that MTBE causes adducts to form on DNA, and that MTBE is a probable carcinogen,”⁵⁶ but he may not testify that “any plaintiff who is concerned

⁵³ See *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 401 (S.D.N.Y. 2007) (“Thus, even if the methodology used by the expert is considered to be reliable, the expert’s testimony will nevertheless fail to meet the ‘fit’ requirement and should be excluded if the data relied upon by the expert is materially different from the data relevant to the facts of the case.”).

⁵⁴ *Id.* (citing *General Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997)). See also *Finestone v. Florida Power & Light Co.*, No. 03 Civ. 14040, 2006 WL 267330, at *12 (S.D. Fla. Jan. 6 2006) (excluding expert who “did not use all 59 samples from Glades Cutoff. When asked by the Court why he did not include the samples that did not contain Co-60, he did not have a justified answer.”).

⁵⁵ Mehlman Rep. at 38.

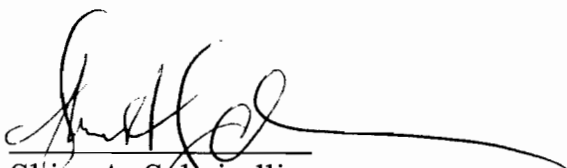
⁵⁶ Pl. Mem. at 6.

that their [sic] past exposure to MTBE or benzene has a reasonable basis for their [sic] concerns.”⁵⁷

IV. CONCLUSION

For the reasons above, defendants’ motion is denied in part and granted in part. The Clerk of the Court is directed to close this motion (docket # 1758).

SO ORDERED:


Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
July 1, 2008

⁵⁷ Mehlman Rep. at 38.

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