R. Dean Hartley
HARTLEY & O'BRIEN
827 Main Street
Wheeling, WV 26003
(304) 233-0777
(304) 233-0774 - Fax
hartley@hartleyobrien.com

SAMPLING METHODOLOGY: TESTING and MEASUREMENT

I. Introduction.

Although elementary, the underlying premise of any chemical exposure case is that the plaintiff was actually exposed to the substance or substances in sufficient quantity to have potentially caused or contributed to her development of the symptoms, injuries or disease. A plaintiff cannot succeed in a chemical exposure case unless she can demonstrate exposure to a toxic substance that was somehow responsible for her damages.

Issues arise as to what type of exposure evidence is sufficient: whether actual monitoring data is necessary; what kind of testing methods adequately account for the varied exposure scenarios; is odor recognition an adequate indicator of exposure; can symptomatology consistent with the subject chemical support an exposure assessment; are mathematical formulas based on chemistry and physics able to supply a sufficient means of determining exposure; and is the temporal relationship between the exposure and onset of symptoms ever sufficient in and of itself to eliminate a need to quantify exposure?

Experts abound that will offer testimony concerning whether there was or was not adequate exposure, sufficient exposure, or quantifiable exposure. Industrial hygienists, safety engineers, forensic chemical engineers, toxicologists, and occupational physicians are some of the potential experts able to support or defend the exposure portion of the claim. Naturally, the expert's methodology, reasoning, and the ultimate admissibility of his/her opinion are governed by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 786, 125 L.Ed. 496 (1993) and its progeny.

II. Background.

The dominate principle of toxicology is that the "dose makes the poison" and all chemical agents are harmful if consumed in large quantities. See *Mancuso v. Consolidated Edison Co. of New York, Inc.*, 967 F.Supp. 1437, 1445 (S.D.N.Y. 1997) citing *Federal Judicial Center: Reference Manual on Scientific Evidence*, "Reference Guide on Toxicology", p. 185 (1994).

The World Health Organization, the National Academy of Sciences and various United States Government agencies have adopted the following methodology for determining the possible effects of a toxin on individuals:

> 1. First, an evaluation is made of the chemicals to which the individual might have been exposed, and of the concentrations of these chemicals in air breathed by the individual.
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> 2. The second step involves an evaluation, based on the published scientific literature, of the exposures necessary to produce the adverse effects associated with the chemicals to which individuals may have been exposed.
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> 3. These two evaluations are then combined in the final step of the risk assessment to provide a estimate of the likelihood that any of the harmful properties of any or all of the chemicals might have been expressed in the exposed individual.

Mancuso, Id. citing *Cavallo v. Star Enter.*, 892 F.Supp. 756, 764 (E.D. Va.), *aff'd in relevant* *part*, 100 F.3d 1150, 1159 (4th Cir.1996) (although affirming the district court's interpretation of the application of *Daubert* to the factual situation, the Fourth Circuit noted that the court's interpretation was "restrictive").

III. Exposure Quantification a Necessity in Causation Analysis.

Courts have consistently followed the pronouncement of the United States Supreme Court in *Celotex Corp. v Catrett*, that "[i]n cases claiming personal injury from exposure to toxic substances, it is essential that the plaintiff demonstrate that she was exposed to harmful levels of such substances." 477 U.S. 317, 319-20, 106 S.Ct. 2548, 2550-51, 91 L.Ed.2d 265 (1986). See, *Bednar v. Bassett Furniture Mfg. Co., Inc.*,147 F.3d 737, 740 (8th Cir. 1998) ("The Bednars had to make a threshold showing that the dresser exposed the baby to levels of gaseous formaldehyde known to cause the type of injuries she suffered"); *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (*en banc*); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 199 (5th Cir. 1996); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106 (8th Cir. 1996); *Abuan v. General Electric Co.*, 329 F.3d 329, 333 (9th Cir. (Guam) 1993); *Mancuso v. Consolidated Edison Co. of New York, Inc., Id*.; and *Maddy v. Vulcan Materials Co.*, 737 F.Supp. 1528, 1533 (D.Kan. 1990) (there is no scientific evidence indicating the level or duration of Maddy's exposure to specific toxins).

However, "precise data on the exact degree of exposure to each chemical is not required." *Harper v. Illinois Central Gulf R.R.*, 808 F.2d 1139, 1141 (5th Cir. 1987). See also, *Bednar, supra*, 147 F.3d at 740 (5th Cir. 1998)("Plaintiffs did not need to produce a 'mathematically precise table equating levels of exposure with levels of harm' in order to show [their daughter's] level of exposure to formaldehyde, but only '*evidence* from which a reasonable person could conclude that [the] defendant's emission has *probably* caused' the harm about which they complain.") (citation omitted); *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 808-809 (3rd Cir. 1997) ("District judge erred in ruling that an expert may rely only on the ambient air test to determine whether [plaintiff] had been exposed to [a toxic substance] . . . it is for the trier of fact to determine what weight to give the ambient air test results as an indication of exposure."); *Wright v. Willamette Industries, Inc., supra*, 91 F.3d at 1107 (8th Cir. 1996) (a mathematically precise table equating levels of exposure with levels of harm is not required); *Abuan v. General Electric Co.*, *Id*.; *Louderback v. Orkin Exterminating Co., Inc.*, 1998 WL 748591, at *8 ("Although the FJC's Reference Manual makes clear that the level of exposure is a significant factor, it does not say that it is essential or that an opinion cannot be based on other relevant criteria when the level of exposure cannot be determined."); *Cavallo v. Star Enterprise*, 892 F.Supp. 756, 766 (E.D.Va. 1995) ("Rule 702 does not necessarily mandate that the expert find a study linking the *exact* chemicals at the *exact* exposure level with the *exact* illnesses at issue. . . ") (emphasis in original); and *Mateer v. U.S. Aluminum*, 1989 WL 60442 at *8 (E.D.Pa. 1989) (Not Reported in F.Supp.).

NOTE: The Fifth Circuit holds that "if a plaintiff's expert does not have scientifically accurate measurements of the level of the plaintiff's exposure,' his causation opinion [will be] suspect even if he ha[s] scientific support for the position that the [chemical compound] could cause [the plaintiff's disease].' Maj. Op. at p. 27 n. 9." *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 287 (5th Cir. 1998) (Dennis, J., dissenting).

A. Proving Exposure.

1. Actual Monitoring Data.

The best exposure evidence results from well-conducted air monitoring of the actual subject atmosphere in which the individual works, plays or rests. Monitoring for exposure levels can be accomplished by conducting personal air sampling, area air sampling, or "grab" sampling the air.

The ideal method for evaluating atmospheric contaminates of a particular individual is through personal monitoring of the breathing zone of that specific individual. Passive dosimeters and compact, battery-operated personal sampling devices for particulate matter and gases can be used to monitor the environment in which the individual is located.

Fixed station area monitoring has been the primary means of determining contamination of a work room. A monitor is stationed in a location so as to provide an adequate flow of air from the entire area. The monitoring will provide an average for the overall area, but will be insufficient for calculating the most dangerous exposures and the least severe exposures.

Brief period sampling or instantaneous sampling are commonly referred to as "grab samples." "Grab samples" are usually taken over a short period of time, and will provide short term exposure data. Generally, brief period sampling is used to determine if additional more sophisticated sampling is necessary.

Sometimes calculations of "zone exposures" are employed to estimate the exposure of non-monitored individuals to a particular substance based on monitoring data from other individuals who were monitored by appropriate monitoring devices in the "zone". To utilize "zone exposures" in calculating exposure of non-monitored individuals, it is necessary to define each exposure zone unambiguously prior to performance of sampling. Normally, an exposure zone is a characteristic grouping based on the individual's job similarity and the similarity of the environment in which they work. Each zone must fulfill four basic attributes when initial assignment of zones is made:

1. Task similarity. Task similarity is based on the potential for similar exposures to the toxic agent. Naturally, exact similarities are not strictly required, but the classification must be consistent. For example, an individual who is in the particular area on a sporadic basis throughout the day should not be included in the same exposure zone as a someone who remains in the area for 8 hours per day. Assignment of individuals to a particular exposure zone is based on knowledge of the delegated tasks. The industrial hygienist must understand what each job classification requires in the affected area. Without such knowledge, extrapolating exposure data across job classification lines results in either an under estimation or over estimation of the risk.;

2. Similarity with respect to hazardous agents, *i.e.*, zone members must utilize the same agent;

3. Environment similarity, *i.e.*, ventilation, process equipment, etc. must be similar or common to all zone members. Environmental similarity includes the considerations that must be given to the major and minor processes involved in the performance of tasks, and lack or presence of ventilation and personal protective devices.; and

4. Identifiability.

See, American Industrial Hygiene Association (AIHA). A Strategy for Occupational Exposure Assessment. (1991).

In reality, "[o]nly rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes. . . Human exposure occurs most frequently in occupational settings where workers are exposed to industrial chemicals like lead or asbestos; however, even under these circumstances, it is usually difficult, if not impossible to quantify the amount of exposure." Federal Judicial Center, *Reference Manual on Scientific Evidence*, p. 187 (1994). Indeed, an Ohio intermediate appellate court noted that "[i]t is highly unlikely that anyone would anticipate the need, or have the degree of sophistication necessary, to maintain daily logs of his moment-by-moment exposure to toxic fumes over an employment period spanning roughly fifteen years." *McGee v. Goodyear Atomic Corporation*, 103 Ohio App.3d 236, 242, 659 N.E.2d 317, 320 (4th Dist. 1995). *Cf. Manuel v. Shell Oil Company*, 664 So.2d 470, 477 (La. App. 5th Cir. 1995) (monitoring data revealed that the plaintiff was exposed from under 1 part per million to over 600 parts per million benzene). Therefore, other means of estimating exposure are necessary.

2. Odor Thresholds. One of the items that can be utilized to determine individual exposure is the individual's perception of the chemical's odor. In reviewing the industrial hygiene literature one can find various references which not only suggest but recommend the use of odor perception in determining whether a worker is over exposed to a particular substance:

a. " . . . Odor thresholds . . . can assist the industrial hygienist in determining when an "odor" may be in excess of the Threshold Limit Value, when an organic vapor respirator is not acceptable due to the lack of an odor warning at the end of a cartridge life, and where odors may not indicate a hazard due to extremely low odor thresholds which may be well below the TLVs." (abstract). Ruth, Jon H., Odor Thresholds and Irritation Levels of Several

Chemical Substances: A Review, *Am. Ind. Hyg. Assoc. J*. 47:A-141--A151 (1986).

"Through an understanding of how the odor data have been developed and knowing the range of odor thresholds, the industrial hygienist can use these odor thresholds intelligently as a tool in the recognition of potential hazards." *Id.* at A-141.

"The range of odor thresholds reported for a given chemical should allow the industrial hygienist to interpret the odor with a proper sense of caution." *Id.* at A-141.

b. NIOSH has suggested that odor threshold is an appropriate method for determining the concentration of a particular chemical in the atmosphere. "The presence of many vapors and gases can be detected by the sense of smell. Trained observers are able to estimate rather closely the concentration of a limited number of solvent vapors and gases in the workroom air by the odor level. For many substances, however, the odor threshold concentration is greater than the permissible exposure levels." Hosey, Andrew D. "General Principles in Evaluating The Occupational Environment" in *the Industrial Environment - its Evaluation & Control*, NIOSH Pub. No. S/N 017-001-00396-4 (1973) [Chap. 10, pg. 96].

c. "Trained observers are able to identify a limited number of solvent vapors and gases in the workroom air by their characteristic odor. . . . Sometimes during the field survey, one can judge that air contaminant concentrations are so low (or so high) that quantitative measurements are unnecessary." Olishifski, Julian B. "Methods of Evaluation," in *Fundamentals of Industrial Hygiene*, Plog, Barbara, Ed., National Safety Council, 3rd Ed., 1988 pg. 403.

d. "[The industrial hygienist] should be able to recognize and identify all the common gases and vapors that possess characteristic odors, tastes, or irritant effects, as well as to judge qualitatively whether the concentration of the substance may be exceeding permissible levels or recommended levels of exposure." Patty's Industrial Hygiene and Toxicology 4th Ed. Vol. 1, Part A, at 78.

e. Odor thresholds are important in selecting respirators. NIOSH recommends that each individual worker appreciate the odor threshold of the chemical he is exposed when using an air-purifying cartridge or canister respirator so that the worker can realize when the cartridge or canister protection fails. *Respirator Decision LOGIC* DHHS (NIOSH) Pub. No. 87-108, pg. 26

f. Court decisions support the use of olfactory sense as a means of determining over-exposure of an individual to a particular substance.

1. In *Bedar .v Bassett Furniture Manf. Co., Inc.*, the Eighth Circuit included as additional evidence of the child's exposure to formaldehyde that individuals in the vicinity of the dresser remarked that the furniture and the clothes contained within produced a strong odor. 147 F.3d at 740.

2. In *Manuel v. Shell Oil Company*, 664 So.2d 470, 477 (La. App. 5th Cir. 1995), a benzene exposure case, the court noted that "the odor threshold [for benzene] is important because, once it is detected by smell, the acceptable level of exposure has been exceeded." This is true for a variety of chemicals. See, Ruth, Jon H., Odor Thresholds and Irritation Levels of Several Chemical Substances: A Review, *Am. Ind. Hyg. Assoc. J.* 47:A-142-

A151 (1986).

3. Human Symptomatology. Simply put, an individual exposed to certain toxic substances demonstrates "classic" acute responses, such as drowsiness, dizziness, headache, vertigo, tremor, delirium, and loss of consciousness, nausea, staggering gait, paralysis, convulsions, and unconsciousness, watery eyes, and running nose. By consulting various treaties symptoms for almost any substance can be located. See, Patty's Industrial Hygiene and Toxicology, Clayton, George D. and Clayton, Florence, Editors (4th ed. 1994); American Conference of Governmental and Industrial Hygienists "Documentation of the Threshold Limit Values and Biological Exposure Indices"; and Agency for Toxic Substances and Disease Registry's toxicological profiles.

Case law supports the use of symptomatology as a means of calculating exposure: *McGee v. Goodyear Atomic Corporation*, 103 Ohio App.3d 236, 242, 659 N.E.2d 317, 321 (4^{th} Dist. 1995). "The decedent testified in his deposition that, throughout his employment, he worked around vats and equipment where cleaning solvents were being used. The decedent stated that the fumes given off by the chemicals used in these buildings frequently burned his nose and throat. . . .The fact that there was no direct evidence of the decedent's exposure to toxic levels of TCE goes only to the issues of weight and credibility to be afforded those expert opinions."

4. Chemical Properties. Known physical properties (density, vapor pressure, concentration, and boiling point) of chemicals can be used to calculate the substance's ability to contaminate the atmosphere. The circumstances of an individual's exposure can be reconstructed by a retrospective study of the situation and environment of use. Basically, as the concentration of the chemical's molecules in the liquid vaporize and diffuse out of the liquid into a gaseous state, the atmosphere becomes contaminated with the chemical.

Using vapor pressures, concentration of chemicals, and evaporation rates a calculation of the substance in the individual's breathing zone can be made. Naturally, the atmosphere, wind velocity, air exchange rates and temperature of the exposure environment are taken into consideration in quantifying the exposure. By using mathematical formulas, a calculation of the contamination above the liquid and in the surrounding area can be determined. See, R. Byron Bird, *et al*., Transport Phenomena. John Wiley & Sons; J. Crank, The Mathematics of Diffusion. Clarendon Press; American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 1993 ASHRAE Handbook, "Fundamentals". (I-P Ed.).

Interestingly, the defendants in *Jeane v. Exxon Corp., et al.*, Jefferson County, Texas District Court No. B-147-774, hired an industrial hygienist to recreated the circumstances modeled by a forensic chemical engineer. The experiment confirmed the air model's prediction. This type of modeling has also sustained a methodology challenge under *Daubert* as well as under *Frye*. See, *Richardson v. Union Oil Company of Calif*., No. 94-0098, D..D.C.; *Radvany v. Union Carbide Corp.*, Docket No. L-11710--90, Camden County, NJ Superior Court.

5. Temporal Relationship. "There may be instances where the temporal connection between the exposure to a given chemical is so compelling as to dispense with the need for reliance on standard methods of toxicology." *Moore v. Ashland Chemical Inc.*, *supra*, 151 F.3d at 278 citing *Cavallo v. Star Enter.*, *supra*, 892 F.Supp. at 773-74. Presumably had the plaintiff been "doused with jet fuel or there had been a massive exposure of jet fuel to many people who in turn suffered similar symptoms," the temporal relationship would have been sufficient to establish causation. See, *Moore, supra*. Absent a dousing of the plaintiff with the toxic substance, the facts of the *Moore* case seem to support a temporal causation relationship, although the Fifth Circuit held otherwise.

IV. Exposures Necessary to Produce Adverse Effects.

Once a determination is made as to the amount of toxic exposure the individual has experienced, proof is necessary to establish whether that exposure is sufficient, based on the scientific and medical literature, to produce the injuries and damages asserted by the plaintiff. The same sources consulted for symptoms can be reviewed once again.

The *Bednar* Court indicated that the plaintiffs "produced evidence [. . . of exposure over] the threshold limit of safe exposure to gaseous formaldehyde approved by the American Conference of Governmental Industrial Hygienists . . . [above] the average safety limit set by the National Institute for Occupational Safety & Health for an eight hour period . . . [as well as] . . .the safety limit recognized by the Occupational Safety & Health Administration" which was sufficient to meet the *Wright* requirements. *Bednar v. Bassett Furniture Mfg. Co., Inc.*,147 F.3d 737, 739 (8th Cir. 1998). In *Wright* the Eighth Circuit held that "At a minimum, we think that there must be evidence from which the factfinder can conclude that the plaintiff was exposed to levels of that agent that are known to cause the kind of harm that the plaintiff claims to have suffered." *Wright v. Willamette Indus., Inc.,* 91 F.3d 1105, 1107 (8th Cir. 1996); citing *Abuan v. General Electric Co.,* 329 F.3d 329, 333 (9th Cir. (Guam) 1993). See also, *McGee v. Goodyear Atomic Corporation,* 103 Ohio

App.3d 236, 242, 659 N.E.2d 317, 320 (4th Dist. 1995) (OSHA standard utilized as comparison).

In *Cavallo* the trial court found that the plaintiff's exposure to petroleum compounds related to jet fuel were below the TLVs establish by the American Conference of Governmental Industrial Hygienists by a factor of 10. Given that this finding was unrefuted by the plaintiff, the court granted defendant's motion *in limine*. *Cavallo v. Star Enter.*, 892 F.Supp. 756, 769 (E.D. Va.). See also, *National Bank of Commerce (of El Dorado, Ark.) v. Dow Chemical Co.*, 965 F.Supp. 1490, 1518(E.D. Ark. 1996) ("There are no adequate exposure, dose or [no observed effect levels] for [the expert's] causation opinions. . ."); and *Manuel v. Shell Oil Company*, 664 So.2d 470, 477-478 (La. App. 5th Cir. 1995) (OSHA benzene standard, industry toxicological data sheet, material safety data sheet, and American Industrial Hygienist Association odor threshold documentation used to establish excess exposure).

V. Conclusion.

Although the dose makes the poison, precise measurements of exposure levels are not necessary to establish causation. Circumstantial evidence based on odor, symptomatology, chemical properties and the temporal relationship between the exposure and the injury are sufficient to establish the dose.