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## **STATE OF THE ART: A DEFENSE PERSPECTIVE - WHO KNEW WHAT AND WHEN?**

Any discussion of the defenses available in a case of benzene-related disease first and foremost centers on diagnosis, exposure, and causation. Integral to these, however, is an historical framework of who knew what on these points, when the points were first suggested or raised, and most importantly, when they came into common acceptance. Finally, it is important to note whether there remain open questions or uncertainties.

This is the “state of the art” defense, which can be asserted in cases of negligence, or strict liability in most states. For example, in both defective design and failure to warn product liability cases in Minnesota, a specific element is whether the manufacturer or seller of the product kept abreast of scientific advances and knowledge in the field. Such knowledge will be imputed under a “should have known” standard. See, Minn. District Judges’ Assoc., Jury Instruction Guides-Civil, Nos. 75.20, 75.25. These requirements derive from Restatement (Second) Torts § 402A. Most other states have variations of similar elements under which the defense may be allowed to develop the state of the art of knowledge as to benzene exposure, disease, and risk assessment.

Thus, it is important to have available a chronology of medical and scientific literature available to consult as the particular issue in a case; i.e., disease type, occupation type during exposure, exposure level, etc. Currently, such literature is readily available through internet sources such as PubMed by the National Library of Medicine ([www.ncbi.nih.gov/entrez](http://www.ncbi.nih.gov/entrez)), or Med

Line ([www.medline.cos.com](http://www.medline.cos.com)). For example, PubMed currently has 15,357 entries available under the search term “benzene.” It is important to note that while these databases are enormous, they are selective, covering approximately 4,800 journals, and going back no further than 1966 (MedLine) or 1950 (Old MedLine), both of which are included in PubMed. Moreover, it is not clear how comprehensive these databases are as one goes back further in time. As a result, when examining historical medical sources, further old fashioned library sleuthing may be necessary. As a rule of thumb, I use these databases back to the early 1990's, but for earlier references, use the traditional method of examining relevant citations and obtaining abstracts complete articles (where necessary) from the medical library.

Attached is an example of our medical article library for benzene, organized chronologically.

In addition to a review of the historical medical and scientific literature, it is important to have a working knowledge of the regulatory standards for benzene exposure and be able to convey how those have changed over time. As in any toxic exposure case, it is our experience that juries and judges rely heavily upon the standards of the regulatory agencies and are very interested to learn when their standards were introduced and how they have changed over time. It is crucial to point out how standards have evolved and to explain that there has been a general decrease in allowable exposure levels based upon evolution of scientific knowledge. It is also important to point out how allowable exposure levels tend to decrease in proportion to the sensitivity of available testing methods.

With respect to benzene, it should be pointed out that the initial permissible exposure level (PEL) for benzene by OSHA (proposed 1971, adopted 1972) was 10 ppm, which was based upon a concern for benzene causing aplastic anemia.

From a defense perspective, we rely heavily upon a review of the standards of the American Conference of Governmental Industrial Hygienists (ACGIH). The ACGIH is a group comprised of industrial and government industrial hygienists and physicians who began setting and publishing standards for exposure to particles and chemicals in occupational settings beginning in 1946. Initially, their standard was referred to as the Maximum Allowable Concentration (MAC), but in 1948 it was changed to the Threshold Limit Value (TLV). While the ACGIH was careful to state that the TLV should not be taken as an absolute ceiling of exposure at or below which disease could not appear, it is nonetheless true that it was generally considered to be a “safe standard, based upon the best scientific judgment of the members of the ACGIH.

The TLV was set as an allowable exposure level for an occupational setting of a 7 to 8 hour workday and a 40 hour work week over a working lifetime. In addition, it was a time weighted average, meaning that it was just that: an average exposure over that time period. The official position of the ACGIH was that while the TLV’s should be used as guides in the control of health hazards, they should not be used as “fine lines” between safe and dangerous concentrations. At the same time, however, the official ACGIH position on the use of the TLV’s stated:

“Threshold limit values refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effect.”

For example, at the time of the first OSHA level for benzene in 1971 of 10 ppm, the ACGIH published its Third Edition, “Documentation of the Threshold Limit Values for Substances in Workroom Air.” It listed TLV’s for nearly 500 substances, including benzene. For benzene, it set the TLV at 25 ppm, and stated:

“A TLV of 25 ppm is believed low enough to prevent serious blood changes, but this limit should be considered a ceiling and exposures to higher concentrations not permitted.”

In addition to its TLV, ACGIH also added a “Short Term Exposure Level” (STEM) for some substances, which was an upper level of exposure which should not be exceeded. For benzene, no STEM was adopted until 1980 (after first being proposed in 1976), at which time the TLV was 10 ppm, and the STEL was set at 25ppm.

ACGIH consistently set TLV’s in excess to the OSHA level. It has been charged by some that the ACGIH was comprised, or controlled, by members of affected industries. While superficially true, it must also be emphasized that its initial standards were prepared by the Division of Industrial Hygiene, National Institute of Health, at that time a part of the United States Public health service, headed by the Surgeon General. Its membership always included and was directed by physicians from NIOSH, NIH, and the Public Health Service. Finally, it should be pointed out that in addition to qualified representatives from industry, it included liaison members from affected labor organizations.

It is important to emphasize the ACGIH standards from a defense perspective, because they may be used as a more scientifically, and “real world” level than the OSHA standard, which can be portrayed as a more pragmatic, and even political, consensus level which is less accurately based upon actual science.

Attached to these materials is a chronological list of the ACGIH standards for benzene from 1946 (100 ppm) to 1992 (10 ppm).

Another valuable source of state of the art information for benzene are the government criterial documents and agency reports issued by the various governmental agencies. These are a very fertile source of data. Not only do they bear the authority of the various government

agencies, but *in every instance* in their discussion of toxicity, disease or risk assessment, they provide information about either a safe level of exposure, or a discussion of uncertainty, risk or causation that can be used.

Attached to these materials is a list of governmental reports I have used in pointing out either a safe level, threshold level, or uncertainty concerning where such levels lay. These are enormously useful for cross examination of experts.

In addition to the reports described above, it is important to remember that benzene has and is regulated by a veritable alphabet soup of regulatory bodies. Some examples follow:

- 1) EPA regulates benzene under the Clean Air Act (CAA), the Toxic Substances Control Act (TSCA), the Clean Water Act (CWA), Superfund Amendments and Reauthorization Act (SARA), Food, Drug and Cosmetic Act (FD &CA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Resource Conservation and Recovery Act (RCRA), and Safe Water Drinking Act (SDWA).
- 2) FDA regulates benzene as a food additive.
- 3) The Agency for Toxic Substances and Disease Registry (ATSDR) of the Public Health Service also regulates benzene.
- 4) International Agency for Research on Cancer (IARC) lists benzene as a human carcinogen.

Again, much useful information may be gleaned from these official sources which is particularly useful for cross examination, such as:

- 1) The CERCLA reporting requirement for benzene is 10 lbs (4.54 kg). I have argued that what this means is that industries handling benzene in lesser amounts must be considered either safe, or at least, unworthy of attention by EPA under this pollution reporting requirement.
- 2) IARC first listed benzene in its IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans series in 1982.

In summary, with respect to benzene state of the art, information is power, and the importance of the historical, and often obscure, documents and reports is critical.

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