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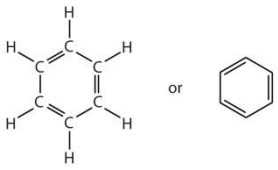
Current State of Benzene Litigation: Recent Legal Decisions and Scientific Studies on Benzene Exposure and Their Impact on Benzene Litigation

I. Chemical Nature of Benzene

Benzene is a hydrocarbon with chemical formula C_6H_6. A molecule of benzene is composed of six carbon atoms joined in an aromatic ring, with a hydrogen atom attached to each carbon atom. Though a simple aromatic organic molecule, it has an ample history of uses and potential exposures, and it has been implicated as a cause in a complex array of human health effects.



Benzene is present in gasoline and many other products—notably, industrial solvents used, for example, to degrease metal parts. Benzene is also used as a solvent for fats, waxes, resins, oils, inks, paints, plastics, and rubber; in the extraction of oils from seeds and nuts; and in certain printing applications. Many manufacturing processes use benzene, including the manufacture of detergents, explosives, pharmaceuticals, and dyestuffs. Benzene can be released to the environment through such means as emissions from burning coal and oil, motor vehicle exhaust, and evaporation from gasoline service stations. These sources contribute to background levels of benzene in the ambient air. Individuals employed in industries that manufacture or use benzene may be exposed to the highest levels of benzene. Some populations may also be exposed to benzene by consuming contaminated water or inhaling benzene released from water, and tobacco smoke also contains benzene. Because of the extensive presence of benzene in many different environments, and the complicated nature of potentially associated lympho-hematopoietic human health effects, numerous types of legal challenges have been raised.

II. Scientific Analysis to respond to the issue of causation

To address claims that exposure to benzene has caused a particular health effect, a systematic analysis of all elements of the risk assessment paradigm is most helpful. A common misunderstanding in litigation is the use of public health agencies' approaches and conclusions to support allegations that low-dose exposures are to blame for a plaintiff's disease. Dr. Anderson will explain why this reliance is incorrect and, further, will discuss appropriate approaches based on risk assessment to define exposure and response, to assess the likelihood that a causal relationship exists.

In 1976, EPA initiated the first broad-scale use of risk assessment by publishing its cancer policy and guidelines for risk assessment to support risk management decisions. Building on this, in 1983, the National Academy of Sciences (NAS) published a document titled, *Risk Assessment in the Federal*

Government: Managing the Process. The NAS document established health risk assessment as the acceptable approach for public health agencies to use in assessing risk associated with exposure to environmental substances. It is now considered an essential text for health risk assessment. The paradigm described is now applied widely, both nationally and internationally, to assess the association of exposure with potential health impacts. This presentation will define the differences between risk assessment, as practiced by public health agencies to reach decisions that are preemptive and protective, compared to assessment of exposure and disease causation and the use of the paradigm to determine general and specific disease causation.

Hazard Identification: Some, but not all, lympho-hematopoietic diseases are causally linked to at some level of exposure to benzene. The weight of evidence that links each disease endpoint to benzene exposure at any level must be addressed.

Dr. Anderson will discuss public health agencies' classification systems (e.g., IARC, NTP, and EPA) and the response to the frequent misunderstanding or misuse of these classifications. The National Toxicology Program (NTP) has classified benzene as "known to be a human carcinogen." The EPA classifies benzene as a known human carcinogen. The International Agency for Research on Cancer (IARC) classifies benzene as "carcinogenic to humans," based on sufficient evidence for acute myeloid leukemia (AML). IARC notes that benzene exposure has been linked with acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma. IARC's preamble to the monographs (IARC 2006) describes the classification process as "the first step in carcinogen risk assessment" and defines a cancer hazard agent as one that is capable of causing cancer "under some circumstances."

Dr. Anderson will discuss the weight of evidence for lympho-hematopoietic endpoints, including: AML (sufficient evidence at high doses); myelodysplastic syndrome (MDS; some evidence at low doses); discussion of progression AML; CLL (e.g., Rushton et al. 2014; no association); chronic myeloid leukemia (CML); multiple myeloma (MM); myeloproliferative disease (MPD); and childhood leukemia. She also will make distinctions between public agency classification intent and a determination of general disease causation

Dose-Response: This step involves assembling evidence in the observed range of dose and health-effect response, usually at high-dose exposures in human or animal studies, to infer risk outside the observed range, where most environmental exposures occur. Public Health Agencies' linear non-threshold model at low doses defines plausible upper bounds on risk at low doses in an inference zone; causal relationships are known only at observed data points that relate significantly to disease observance. Confusion between the observed range and the inferred range of dose often develops in litigation. Clarification is important and will be discussed. Some important observations will be discussed. For example, AML, though significantly associated with benzene exposure, appears to occur only at high cumulative doses (e.g., 40 ppm-years). The weight of evidence that MDS is associated with benzene exposure is far less certain, but potential low-dose association reported in a publication (Schnatter et al. 2012) has encouraged legal challenges involving MDS. The related scientific evidence will be discussed.

Following these examples, it is necessary to investigate benchmarks for other endpoints where issues of cause and effect need to be addressed. Currently, the Mode of Action to define benzene's role in disease causation needs further investigation. The science is sufficiently advanced to propose reasonably expeditious approaches for immediate investigation. A threshold mechanism, if appropriate

(and some evidence indicates it may well be), would define a margin-of-exposure (MOE) approach that is important to address "low-dose" benzene exposure and potential for disease.

Exposure Assessment: To address specific disease causation, it is essential to assess the specific exposures to the agent in question. Exposure must be defined for the individual or groups of individuals involved in claims of benzene exposure and disease causation, to determine whether the exposure is related to the dose-response information indicating a risk, or to levels associated with disease causation, and whether the timing of exposure is relevant (e.g., for AML, the exposure memory is about 15 years). These considerations include concentration, frequency, and duration of exposure for the claimants. Many methods are available to define historical exposures. For claims involving indoor air exposures, exposure can be assessed using monitoring data, complemented by modeling potential releases from sources within and outside of the interior space (e.g., vapor intrusion modeling from soil gas, groundwater, and free-product sources). Ambient air exposures can be assessed using monitoring data and/or model predictions. Results can be compared to background levels (e.g., up to 34 ppb urban, and up to ~1.0 ppb rural). When historical data are lacking, chamber studies can be used to reconstruct exposures; this approach is supported by EPA methods for activity-based sampling and is widely used and reported in the peer-reviewed literature. Bench-scale head-gas studies can be helpful in adjusting for expected benzene concentrations in air from mixtures (e.g., benzene release from mixtures varies with the quantity of other volatile aromatics in the mixture, potentially negating a claim of proportionate exposure according to the mixture concentrations). Because of the varied and complicated nature of specific exposure circumstances, studies must assess specific exposures and time frames relevant to the allegations. Various approaches and examples will be discussed

Risk Characterization: The final step in addressing allegations that diseases have been caused by benzene exposure is overall characterization of the weight of evidence concerning the likelihood that an agent may cause disease, and on the assumption that it does, developing an estimate of the potential consequences of the assessed exposure. In this step, the relationship of exposure to the observed range of the dose-response curve is discussed. The evidence for disease causation and risk is characterized using information garnered in the preceding steps and includes a number of important considerations:

- Evidence that benzene at any level can cause the alleged disease
- Known levels of association for the alleged disease causation, and how these relate to the exposures experienced by individuals or groups of individuals of concern
- Relevant time periods experienced related to the disease
- A comparison of the assessed exposures to background exposures
- Alternative causes that may explain the alleged disease occurrence other than benzene exposures
- Alternative exposures that the individual may have experienced (e.g., ionizing radiation, cigarette smoke, cancer chemotherapy), and assessment of the related exposures and potential role in the alleged disease causation
- Spontaneous tumor occurrence by stem cell errors that progress (e.g., Tomasetti et al. 2015; the two-stage clonal expansion model).

- Implications from the SEER database rates of occurrence for diseases associated with benzene.

III. Helpful Defense Strategies in Benzene Litigation

Over the past two decades, Mr. Tobin has defended companies involved in all aspects of trace benzene litigation. He will begin his portions of the presentation addressing various strategies that have been helpful for defendants in the litigation.

A. Defense Strategy – Narrowing Stream of Commerce

The first strategy he will discuss is the idea of narrowing or cutting off a defendant's position in the stream of commerce. In recent years, in California, there has been a developing body of case law addressing the concept of the role of the bulk or component parts supplier in the litigation. Currently, there is a group of cases pending appeal on this issue, including O'Neil v. Crane Co. (2012) 53 Cal. App.4th 335, Maxton v. Western States Metals (2012) 203 Cal.App.4th 81, Sanchez v. Hitachi Koki, Co., Ltd. (2013) 217 Cal.App.4th 948, and the pending appeal in the Coordinated Cases Involving Safety Kleen Solvent, JCCP 4601.

Each of these cases addresses in different ways, whether a bulk supplier can extricate themselves from a case where they meet the standards for concept that sellers of non-defective raw materials are immune from liability as articulated in the Third Restatement of Torts. Depending on how these appeals conclude, likely in a coordinated fashion in the California Supreme Court, suppliers of raw materials, including kerosene and other solvents, may be able to avail themselves of this doctrine and extricate themselves in cases where they supplied a raw material used in the formulation of some end product. This could have wide-reaching implications for manufacturers and suppliers throughout the country.

Aside from bulk or component parts suppliers, some states have adopted and implemented the sophisticated user or intermediary defense. This defense allows those that supplied products to purchasers that have a level of sophistication equal to or greater than the supplier to, in some cases, negate a failure to warn claim. The concept is that a warning would not have provided any added benefit to the purchaser and thus there can be no causation in failure to warn claims where the purchaser was of a level of sophistication that would obviate the need for a warning. This doctrine is not effective in all states but is available in Florida, Illinois, and some other states. He will discuss one such case from Florida called Pike v. Trinity Industries from the Middle District of Florida.

B. Defense Strategy – Frame Nature of Case Properly

A second helpful defense strategy is framing the nature of the case properly. Most counsel representing plaintiffs in these matters will try to characterize the case as a "benzene exposure" case. We have found that characterizing the exposure to the end product is often times more effective, as the actual levels of benzene in the end product are in most cases at the parts per billion level. Thus, characterizing a case as

a “mineral spirits” or “paint thinner” case is preferred to calling a case a “benzene” or even “trace benzene” case.

C. Defense Strategy – Timing is Key

Another helpful strategy depends on the timing of the alleged exposure. This can vary depending on the case. In certain types of cancer, more recent exposures are more significant in relating to the diagnosis. In others, the latency period is much longer, so recent exposures may not be significant. Also, the historical timing of the claimed exposure can be important, as product formulations and the development of epidemiological literature change over time.

D. Defense Strategies for Particular Diseases at Issue

In this section, Mr. Tobin will discuss how strategies differ depending on the diagnosis. He will address strategies in defending cases involving a number of disease end points. These include:

1. Acute Myelogenous Leukemia (AML)
2. Myelodysplastic Syndrome (MDS)
3. Multiple Myeloma (MM)
4. Non-Hodgkins Lymphoma (NHL)
5. Aplastic Anemia
6. Other Types of Cancer

He will discuss issues regarding latency, the importance of exposure calculation and analysis, and other approaches in these cases. Also, he will address the dangers of using the term “idiopathic.” The disease end point in many ways dictates defense strategy.

IV. Recurring Issues in Trace Benzene Litigation

In this portion of his presentation, Mr. Tobin will address a number of recurring issues he has seen in benzene litigation over the years. These include, first, a discussion of the argument that, in certain geographical areas, background benzene levels are higher than others and how that may impact the defense. He will also discuss the importance of making all efforts to obtain an exposure determination and how that is helpful in defending these cases. Finally, he will address the concept of benzene levels in cigarette smoke and whether one should use that argument in defending cases.

V. What Does the Future Hold for Trace Benzene Litigation

In the final section of his presentation, Mr. Tobin will discuss what we might expect in trace benzene litigation over the coming months and years. He will discuss some recent verdicts over the past several years in California, Missouri, Mississippi, and Texas. He will also discuss the impact of recent articles and studies in Science magazine and other journals. These articles address developments in the epidemiology of a number of disease end points, including AML, MDS, and other forms of blood-related

cancers. Finally, he will discuss some recent filings and activity in the areas of formaldehyde exposure and diesel exhaust exposure.

VI. Coverage considerations for Benzene cases

General liability policies were not intended to address bodily injury resulting from exposure to chemicals, including Benzene. Although most general liability polices contain some form of a pollution exclusion, only two (2) states, New York and Texas, have determined that the Absolute Pollution Exclusion precludes coverage for Benzene claims. The overwhelming majority of courts in most states have held that Benzene is not a "pollutant" even though standard pollution exclusions include the term "chemicals" in the definition of "pollutants". Courts have said that, if carriers intended to exclude coverage for bodily injury claims arising from Benzene exposure, they should have specifically included Benzene in the list of pollutants. Courts also have said that ambiguities are construed against the carriers and it is unclear whether the carriers actually intended to exclude Benzene or other "irritants, contaminants or pollutants" under the pollution exclusion. Needless to say, judges have gone out of their way to find coverage for Benzene cases.

Carriers have been able to deny coverage for Benzene claims based on timing. Specifically, the Insuring Agreements contained in most general liability policies provide that "insurance applies … only if … The "bodily injury" or "property damage" occurs during the policy period." However, courts have taken a very broad view of when the "occurrence" at issue takes place. Generally, courts have adopted what we refer to as the "triple trigger" and have found that all carriers from date of first exposure to date of diagnosis are on the risk. This is why toxic tort claims are called "long tail claims". There are two exceptions: (1) if first exposure to Benzene occurs **after** the expiration date of the policy(ies) at issue, then there would arguably be no coverage; and (2) if claimant is diagnosed **before** policy inception, then there would also would arguably be no coverage.

In addition to timing, carriers have attempted to utilize certain policy forms and endorsements in order to evaluate whether coverage will be afforded for cases involving bodily injury claims resulting from exposure to Benzene. One such form is the Occupational Disease Exclusion Endorsement, which has not been addressed by most courts. Depending on the specific language of the endorsement and the facts at issue, carriers have successfully relied on this exclusion to preclude coverage for chemical exposure claims. A basic Occupational Disease Exclusion states that:

> It is agreed that this insurance does not apply to and the company shall have no duty to defend any claim, demand or suit for bodily injury resulting from any occupational or environmental disease arising out of the insured's operations, completed operations or products.
> "Occupational Disease" is defined as a disease which the natural incident

> or result of particular employment, usually developing gradually from the effects of long continued work at employment where the risk of contracting the disease is greater than the risk that exists in employment and living conditions in general.

Another form that carriers have relied on in exposure cases is the Pre-Existing or Progressive Damage or Defect Exclusion Endorsement. Depending on the specific language at issue, the Pre-Existing or Progressive Damage or Defect Exclusion, can be very effective if the exposure to Benzene began **prior** to the effective date of the policy. Some of the stronger exclusionary endorsements include language to which states that the exclusion applies regardless of whether or not the damages and/or their cause were known before the effective date of the policy and regardless of whether the injuries at issue were known before the effective date of the policy.

VII. General Settlement Strategy

An effective Settlement Strategy depends, in large part, upon who you are insuring. Carriers will necessarily take different approaches depending upon whether the insured is a manufacturer of a product that contains Benzene or a bulk supplier who provides a component part to a manufacturer that may contain no Benzene or trace amounts of Benzene.

Settlement strategy is also dependent on whether you have multiple cases with the same plaintiff's firm or a "one off" case. Carriers may want to take a hard line when dealing with the former in an effort not to create and continue on a slippery slope, or be identified as a defendant that always pays. With a "one off" type case, carriers may look at the efficacy of an early settlement, a cost of defense settlement or a settlement with a slight premium rather than continuing to defend the case. This is particularly true as other defendants begin settling and the defendants that remain in the case are facing joint and several liability, or in states where carriers cannot obtain a set-off for prior payments or settlements.

While generally not agreed to by most plaintiffs' firms that handle multiple exposure cases, mediation can result in favorable results at a cost savings. On the other hand, some carriers are inclined to orchestrate "settlement days" where the carriers meet directly with plaintiff's counsel in an effort to settle multiple cases at the same time.

Finally, the "burr under the saddle" approach to settlement includes taking a hard line, especially when dealing with the same plaintiff's firms handling multiple cases. Motion practice can also be utilized effectively to either dispose of a case early in the litigation or to exert pressure on plaintiffs to become more reasonable in their settlement negotiations. Most plaintiffs' attorneys believe that they have chemical exposure cases down to a science – we name you and you pay. They do not anticipate that the insureds or carriers will spend the time or the money in search of justice. When faced with multiple defense motions, some plaintiffs' attorneys will want to dispose of the "squeaky wheel". The motions must, of course, be well founded and not specious.