

The Past Suppression of Industry Knowledge of the Toxicity of Benzene to Humans and Potential Bias in Future Benzene Research

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Petrochemical industry representatives often withhold information and misinterpret positive evidence of toxicity of benzene, even from their own research, also discouraging or delaying disclosure of findings of adverse effects to the public. They now appear to be attempting to influence study results in industry's favor by offering predetermined conclusions about study results as part of an effort to draw financial support for the studies. The American Petroleum Institute is currently raising funds for benzene research being conducted in China for which it has already announced the intended conclusions. *Key words:* benzene; industry ethics; leukemia; blood disease; bias; petrochemicals.

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Several publications have recently addressed the issue of the role of industry and its researchers in the evaluation of the toxicity of industrial exposures to workers. Gennaro and Tomatis concluded that epidemiologic research funded by the petrochemical industry is likely to underestimate or fail to detect increased risks of cancer and other diseases among industrial workers because of the use of inappropriate methods and study design protocols.¹ They claim that these results in turn have negatively impacted public health. More recently, Michaels et al. have provided information showing that the chemical industry withheld from the Occupational Safety and Health Administration (OSHA) epidemiologic study results that demonstrated a significantly elevated risk of lung cancer among workers exposed to low levels of hexavalent chromium (CrVI).² As a result, the findings were not included in OSHA's analysis of data related to its recently promul-

gated standard to protect workers from exposure to CrVI.³ On the other hand, Barrow and Conrad have argued that a wide variety of mechanisms enable policymakers and the public to assure themselves that studies performed or funded by industry are identified as such, meet high scientific standards, and are not suppressed when their findings are adverse to industry's interests.⁴

My 27 years of experience through employment with a federal research agency (NIOSH) and regulatory agency (OSHA) leads me to conclude that petrochemical industry representatives and their contractors often withhold information from the Federal Government and misinterpret positive study findings by others. To support my view, I present examples of the petrochemical industry's behavior related to toxicological research on benzene. These examples, drawn from professional experience as a health scientist, demonstrate that industry representatives often have not readily disclosed information about the toxicity of benzene from their own research. They have also tried to discourage or delay disclosure to the public of findings by their own researchers who observed adverse effects from low-level exposures to benzene.

In two of the examples presented, the senior investigators resigned from their industry research positions because their research findings of toxicity from low-level benzene exposures were being withheld from submission to scientific journals. In the third example, the industry tried to intimidate a government employee from doing his job of seeking toxicological data related to benzene exposure and toxicity while a standard was being developed by the Federal Government.

Negative industry influence on data related to benzene toxicity may not be limited to the past. Industry representatives give the appearance of attempting to influence study results in industry's favor by offering predetermined conclusions about study results as part of an effort to draw financial support for the studies; specifically, the American Petroleum Institute (API) is currently raising funds for benzene research being conducted in China for which it has already announced the intended conclusions.

INDUSTRY'S IMPEDING RELEASE OF RESEARCH DATA ADVERSE TO ITS INTERESTS

Example 1—Dow Chemical Company Withholding Data from OSHA. In 1977, while OSHA was engaged in rule-

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making to lower the eight-hour time-weighted average (TWA) exposure limit for benzene from 10 ppm to 1 ppm,⁵ the Dow Chemical Company initially withheld from OSHA, and the public in general, information that indicated that Dow Chemical workers exposed to benzene levels below the exposure limit in effect at the time (10 ppm) demonstrated a significantly elevated risk of chromosomal breakage.⁶⁻⁸ The official hearing record to receive evidence for the benzene standard closed on September 2, 1977. The final standard was issued on February 10, 1978.⁹ Only after several exchanges of correspondence between NIOSH and Dow Chemical Company representatives that took place between October 31, 1977, and March 1, 1978, did the company finally release the study results to NIOSH, and to EPA, under Section 8(e) of TSCA.¹⁰⁻¹⁵ The release of the information, however, took place on March 1, 1978, more than four months *after* the benzene record closed. Yet, the study results were available by March 1977, six months *prior* to the close of the hearing record.^{16,17} This delay likely constituted a legal violation of TSCA reporting, which requires the information to be submitted within 15 working days.

A dispute between Dr. Picciano, the senior author of the study, and Dow Chemical Company over the benzene exposure data related to the adverse chromosomal effects seen in the workers resulted in his resignation from the Dow Medical Research Department. Dr. Picciano has stated that the peer-review process for the benzene study, which showed adverse effects on the DNA of blood lymphocytes, took nine months, while a study of another chemical that showed no adverse effect sailed through in six weeks even though the latter study was based on similar atmospheric sampling data.¹⁷

Because the Dow cytogenetic study of benzene-exposed workers was not part of the hearing record, Department of Labor attorneys could not introduce it as evidence of benzene toxicity to DNA resulting from exposure below 10 ppm, e.g., the occupational limit in effect at the time, as part of the benzene case before the 5th Circuit Court of Appeals. OSHA's Director of Health Standards at the time was of the opinion that if the information had been obtained earlier, "it would have been useful evidence."^{17*}

Example 2—The Chemical Industry Institute of Toxicology Withholding Data from OSHA. In 1980, the U.S. Supreme Court upheld the 5th Circuit Court of Appeals' stay of the OSHA 1978 Final Benzene Standard. Therefore, in 1983, OSHA began working on the development of a new benzene standard.^{18,19} In view of the fact that OSHA was considering proposing a 1 ppm eight-hour TWA exposure limit for benzene, the Agency wrote to the Chemical Industry Institute of Toxicology (CIIT) to inquire about the results of a cytogenetic study that sup-

posedly demonstrated sister chromatid exchanges (SCE) in peripheral blood lymphocytes and micronucleus induction in bone marrow erythrocytes in rats exposed to *1 ppm benzene for a single six-hour period*. Through exchanges of correspondence with CIIT, government scientists made several attempts to obtain the data, but to no avail.²⁰⁻²⁴ The study results were finally released on the day following the appearance of an article in the *Durham Morning Herald* entitled "Park Lab Denies Delaying Results of Benzene Tests."^{25,26} Yet, these study results were available months prior to the release of the data (personal communication Dr. Andrew Kligerman).²⁷

In a situation similar to Dr. Picciano's resignation over the withholding of the Dow cytogenetic study results, the senior investigator of the CIIT study, Dr. Kligerman, left the organization over a dispute with upper-level management revolving around the study findings and the withholding of the data from the public. Prior to the release of the study, however, researchers at the CIIT were required to add an additional statistical test to the results related to the findings (Dr. A. Kligerman, personal communication). This new test did not show a statistically significant result for SCEs and micronuclei related to the 1 ppm benzene exposure level in the rats. Thus, the report was released with two statistical tests for the same data points, one demonstrating a statistically significant result from benzene exposure of 1 ppm for a single six-hour period and the newly added test indicating no significant excess of chromosomal breakage at the 1 ppm level.

Example 3—Shell Oil Company Withholding Data from OSHA. In 1983, OSHA published a Request For Information (RFI) concerning benzene exposure in the workplace.¹⁸ In response, the Shell Oil Company provided OSHA with preliminary analyses from a mortality study of workers employed at its Wood River, Illinois, and Deer Park, Texas, facilities.²⁸ The studies indicated an elevated risk of leukemia among both refinery populations. Since Shell researchers had previously published a report describing a health surveillance system for Shell employees,²⁹ an OSHA official requested data from the Shell Safety and Industrial Hygiene Department for individuals employed at its Wood River refinery. He requested information for individuals who demonstrated blood abnormalities along with their benzene exposure levels.^{30,31} OSHA was informed on two occasions that Shell had no workers exposed to benzene who demonstrated blood abnormalities.^{32,33} Further, the Shell Manager of Safety and Industrial Hygiene wrote to the Director of OSHA asking that he stop the employee from requesting such data because it was putting a strain on Shell's working relationship with OSHA. As stated by Mr. Kusnetz:

It appears to us that Infante is seeking data to support a conclusion he has already drawn . . . this, we find unscientific and harassing . . . the kinds of tac-

*The API sued OSHA for a stay of the 1977 Benzene Standard in the 5th Circuit Court of Appeals. OSHA lost the case.

tics used by Infante put an unnecessary strain on . . . cooperation . . . we hope that you will assist in alleviating that condition.³⁴

This letter was clearly an attempt on the part of Shell Oil Company to intimidate a government official so he would not pursue the data on benzene exposure and blood abnormalities among the Shell Wood River workforce. Subsequently, a third letter was written to the Shell Medical Department requesting its data on benzene exposure and blood abnormalities.³⁵ The letter further stated that Shell's personal attacks on the character of the government employee in their previous letters served only to divert attention from issues related to the toxic effects of benzene on workers. The tactic also gave the appearance to OSHA that Shell might be withholding data from OSHA. In response to this letter, Dr. Joyner and Mr. Kusnetz provided OSHA with data for their workers with blood abnormalities who were assigned benzene-exposure jobs along with their benzene exposure levels—data the company had claimed did not exist in responses to earlier requests.³⁶

Above, I provide three examples of situations in which industry and its researchers withheld important data from a Federal Government regulatory agency during rulemaking. These data were important because they demonstrated an elevated risk of chromosomal breakage in workers and in experimental animals resulting from benzene exposure levels close to or at the newly promulgated TWA limit of 1 ppm. They also indicated that benzene exposures prevailing in refineries at the time were resulting in blood abnormalities among benzene-exposed workers, who were being followed in a medical surveillance program similar to one that had been proposed by OSHA.

The Irony of the Behavior of a Shell Corporate Employee. In the case of the Shell Oil Company, the Corporate Medical Department not only withheld data, but also tried to intimidate a government employee, who was acting on behalf of the Agency, from doing his job. The irony of the latter situation is that shortly after the Shell corporate employees withheld data on blood abnormalities from OSHA, Shell's Manager of Safety and Hygiene, H. L. Kusnetz, published an editorial accusing NIOSH of acting in a "blatant scientifically unethical manner" because NIOSH had released a pre-publication update of its study of Pliofilm workers exposed to benzene prior to the report's having undergone "the agency's review process."^{37†}

The new study included a quantitative risk assessment for benzene exposure and leukemia—an assessment that

OSHA needed to consider in its benzene rulemaking.³⁸ One can only suspect that Mr. Kusnetz wrote the editorial criticizing the "premature release" of the NIOSH benzene risk assessment because he did not want OSHA to rely upon it during its evaluation of data related to the development of its 1987 Benzene Standard.^{19,39}

INTERPRETATION OF EXISTING DATA, AND BIAS IN FUTURE BENZENE RESEARCH

Misinterpretation of Existing Data. Concern about the toxicity of benzene is not an issue of the past. Since the late 1980s, publications have appeared that have evaluated the toxicity of benzene exposure among workers in China, resulting from studies conducted jointly by the U.S. National Cancer Institute (NCI) and the Chinese Academy of Preventive Medicine (CAPM). Their study results have *demonstrated a dose response for leukemia as well as one for non-Hodgkin's lymphoma (NHL) among benzene-exposed workers.*⁴⁰ The levels of exposure associated with elevated risks of leukemia and other blood diseases were much lower than those previously reported. (The dose response for benzene exposure and NHL was a new finding.) A recent study by this team of investigators has also demonstrated bone marrow toxicity among workers resulting from benzene exposure levels below 1 ppm—the current occupational limit in the United States.⁴¹ The latter finding of blood abnormalities resulting from benzene exposures below 1 ppm confirmed the results of an earlier study.⁴²

The findings reported by Hayes et al.,⁴⁰ however, have been challenged by Wong and Budinsky, et al.^{43,44} These investigators are of the opinion that only high-level exposures to benzene can cause blood diseases, including leukemia. They also opine that the NCI/CAPM study⁴⁰ suffers from errors in benzene exposure estimation and that these errors may be responsible for low-level benzene exposure's demonstrating adverse effects on the hematopoietic system, as observed in the NCI/CAPM study. Hayes et al. have responded that the critics had misinterpreted earlier literature reports on benzene's adverse effects on leukocyte counts from low-level benzene exposures, and had failed to consider more recent literature (up to 1996) indicating that there was no evidence of a threshold below which benzene does not cause hematotoxicity.⁴⁵ They also provided evidence indicating that Wong and Budinsky et al.^{43,44} had made incorrect assumptions about the NCI/CAPM exposure estimation procedures used in the NCI/CAPM dose-response analyses. Hayes et al.⁴⁵ concluded that their earlier findings⁴⁰ provided new information regarding low-level benzene exposure and leukemia, and also that benzene may cause other lymphohematopoietic cancers.

Appearance of Bias in Future Industry-funded Benzene Research. Recently, in what appears to be an effort to

†This claim was false. From my experience of having worked at NIOSH, all publications are required to pass extensive internal peer review before they can be submitted to a journal for publication. Furthermore, R. Rinsky also acknowledged that the study had undergone internal NIOSH peer review prior to any discussion with the press (personal communication).

counter the findings from the NCI/CAPM study, the API has collected \$27 million from member companies to fund research in Shanghai, China.⁴⁶ In an effort to solicit money for the study, prior to its commencement, the API presented to its member companies what appears to have been a PowerPoint presentation of the “expected results” of the “Shanghai study.” According to the presentation, the research results are expected to “affect” significant issues of global financial concern to the petroleum industry, such as requirements to reformulate gasoline, requirements to clean up petroleum-contaminated soil and water, requirements to reduce benzene exposures from refineries and marketing facilities, and litigation costs for individuals contracting leukemia and other hematopoietic diseases.⁴⁶

The PowerPoint presentation apparently sent to Craig Parker, Manager of Toxicology and Product Safety, Marathon Oil Corporation, states that the planned research results will enhance industry’s ability to achieve the above-mentioned objectives, as the findings of the “Shanghai study” are expected to:

- a) provide strong scientific support for the lack of a risk of leukemia or other hematological disease at current ambient benzene concentrations to the general population;
- b) establish that adherence to current occupational exposure limits (in the range of 1–5 ppm) do not create a significant risk to workers exposed to benzene;
- c) refute the allegation that Non-Hodgkin’s lymphoma can be induced by benzene.

The drawing of such conclusions prior to the commencement of the study provides evidence of potential bias in the outcome of the study. Others also have expressed concern about bias in this study.⁴⁶ If the findings of the study turn out to be similar to those expressed prior to the commencement of the study, they will be difficult to accept unless a research organization that does not have an invested interest in the outcome is given the responsibility to complete the study. The validity of research findings related to additional issues of benzene toxicity also may be questioned. Therefore, in order for the findings to merit scientific credibility, it may be most beneficial for the API and for occupational health in general to turn the research activities for the Shanghai study over to the NIOSH or to the NCI. Letters have been sent previously to member organizations of the API requesting the transfer of the research to an independent body in order to remove “any built-in bias” in the study results.⁴⁷ The NCI has been conducting research in China for more than 15 years and clearly has experience in working with Chinese investigators. The NCI also has experience in dealing with methodological issues that may arise during the conduct of the study.

CONCLUSIONS

My past employment in governmental research and regulatory agencies allowed me to interact with industry’s representatives and its researchers for 27 years. As a result of this experience, it is my belief that industry’s research findings are sometimes suppressed when the results are not in the interest of the industries funding the studies. Furthermore, in the two examples of cytogenetic data being withheld from OSHA, and the from public in general, both senior investigators, who were employed by industry or by an industry-funded research facility, resigned from their toxicology positions because of disputes with upper-level management about the way in which their reports were being handled internally. These observations also imply that industry researchers with the integrity to stand up to corporate management regarding the adverse effects of products on workers may lose their jobs.

Research on benzene currently being carried out in China through funding by the American Petroleum Institute suggests a bias in future study results. This potential bias is indicated by a priori conclusions about the study results that were developed by those involved in the solicitation of funding for the research. It is recommended that the “Shanghai study” be turned over to the NIOSH or to the NCI for its completion. To do otherwise may result in the findings having little scientific credibility.

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