Risk Estimate Vanishes from Benzene Report

Critics charge the National Cancer Institute with meddling after meeting with industry

In October 1981, a group of scientists meeting at the World Health Organization's cancer agency concluded that workers regularly exposed to small amounts of benzene might contract leukemia at three times the expected rate. The estimate would have had wide regulatory implications in the United States for the chemical industry and the 1 million workers currently exposed to benzene. But last month, when the International Agency for Research on Cancer (IARC) published a report on benzene based on the October meeting, the group's conclusion had vanished from print.

The deletion of the estimate has drawn harsh criticism from many scientists, labor leaders, and Representative David Obey (D–Wisc.). They charge that National Cancer Institute (NCI) officials, after meeting with chemical industry representatives, pressured the international cancer agency to back off from quantitative risk assessment. In apparent acquiescence to NCI, IARC withdrew its risk estimate of benzene. Critics allege that the actions taken by the cancer institute constitute undue interference in the affairs of a widely respected health agency. At the very least, IARC's handling of the deletion represents a serious procedural blunder, according to more moderate critics.

The risk estimate calculated by the advisory group was derived from an extrapolation of human data. It was significant because, for the first time, IARC was addressing the scientifically controversial area of quantitative risk assessment in its reports or monographs, as they are called. The documents are widely used by many countries as the basis for regulation of chemicals. Indeed, the publication of the risk estimate on benzene was important because it would have bolstered arguments in the United States to limit exposure to very low levels. In 1980, the U.S. Supreme Court rejected attempts by the Occupational Safety and Health Administration to regulate benzene below the current standard of 10 parts per million (ppm) in air, saying that the agency had not demonstrated significant risk. Labor leaders would have ammunition to reargue the need for benzene regulation, if a document were published bearing the imprimatur of IARC.

But the risk assessment failed to appear in the monograph. Last October, IARC published a draft of the benzene monograph shortly after its advisory group had met. In January, representatives from the Shell Oil Company, Exxon Corporation, and Chemical Manufacturers Association held a meeting with NCI official Richard Adamson to complain that the risk estimate in the IARC draft was faulty partly because it did not state the limitations of the data and suffered from "procedural flaws." According to an internal memo written by Curtis Smith of Shell Oil, they met with Adamson "to solicit his support. . . . Dr. Adamson understands the regulatory impact of risk assessment and does not believe that the IARC should be engaged in this activity."

Two months later, Adamson wrote a letter to IARC director Lorenzo Tomatis, admonishing him to refrain from quantitative risk assessment, although he did not specifically mention the benzene case. Adamson warned Tomatis that the area is fraught with scientific and societal difficulties. "I wish to make sure that no discredit comes to the NCI or IARC as a result of possibly going into the area of risk assessment. I know that it is an area that the regulatory agencies are heavily involved with, but it is an area that also involves national policy." Adamson added, ". . . I recommend that no change in policy be made as a result of a unilateral decision by you" and that the issue be addressed by the agency's governing council. In the same letter, Adamson said he did not foresee any difficulties in the renewal of NCI funding of IARC's monograph series. Adamson, who has been at NCI for almost 20 years, is director of the division of cancer cause and prevention. He controls the $1.5 million that the NCI contributes to IARC's $13-million annual budget. About $500,000 of the NCI money is allocated for the monograph program.

In July, when the benzene report was published, it was apparent that Tomatis had expunged the estimate. Specifically, he deleted a calculation predicting that exposure over a lifetime to 10 ppm of benzene daily might result in 17 excess leukemia deaths per 1000 workers. His action was highly unusual because changes in IARC's monographs are customarily cleared with the original discussion group before publication. But in this instance, members of the IARC group were not polled for a consensus.

Adamson denied that he placed any pressure on Tomatis to block publication of the benzene risk assessment. "I have no objection that the group did a risk assessment," he said in an interview. But he pointed out that he believes one of the studies which was important to the conclusions about risk is "debatable." Adamson said, "I don't know if it was scientifically sound to extrapolate down to 10 ppm. That question is best addressed by the working group, Tomatis and peer review."

Adamson notes that his letter to Tomatis did not mention benzene and only discussed risk assessment in general. IARC, however, at that time, was considering risk estimates for only two chemicals, benzene and a less common substance, benzidine. When asked why NCI did not raise objections at the October meeting to which the institute sent a representative, Adamson said that NCI generally maintains a "hands off" policy. The only reason he wrote the letter was to follow up a conversation in which Tomatis first raised the issue of risk assessment, Adamson claimed.

Tomatis said, however, that the letter "came from out of the blue." He remarked in a telephone interview from IARC headquarters in Lyons, France, "I was upset by its style. I was upset because he told me how to behave. I would not tell the director of NCI how to behave." But he said that Adamson's letter had "nothing to do with benzene." He insists that NCI did not force him to change the monograph. Tomatis said he pulled the 10 ppm risk assessment from the monograph because the data were inadequate to support the estimate. "I wanted it to be solid and defensible," Tomatis stated.

But other scientists believe that the benzene data are good enough to justify an estimate of risk. David Hoel, director of the division of biometry at the National Institute of Environmental Health Sciences and a key member of the working group that drafted the risk estimate, says, "I thought we were cautious. We felt we were on safe ground. I was surprised to see the changes." Hoel and other epidemiologists find it odd that

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Tomatis removed the 10 ppm extrapolation but retained a 100 ppm estimate that was also based on the same extrapolation. Hoel said that the inconsistency was "peculiar."

Tomatis said that he had reservations about the estimate once the draft was published. He then had an agency statistician contact the scientists who calculated the risk estimate. Hoel said that is true, but he told the statistician that if the 10 ppm calculation was dropped, then a paragraph should be added to explain the deletion. Hoel requested that a written draft of any changes be circulated among the working group members and another consensus reached.

Philip Landrigan, a member of the working group and director of the surveillance, hazard evaluations, and field studies at the National Institute for Occupational Health and Safety, fired off a telegram to Tomatis in July saying that he was "surprised and chagrined to see a critical portion of the benzene risk assessment altered. . . . I fail to understand why the working group was not consulted in regard to this important change. . . ." He said the deletion "goes against the text agreed upon by the group . . . and also appears to run completely counter to that stated policy of IARC" that working groups' conclusions are immutable.

Tomatis wired back, arguing that the section of the monograph in which the estimate initially appeared was the appendix and therefore not subject to the same procedural tradition as the actual monograph itself.

In retrospect, Tomatis said, the quantitative risk assessment should have been published separately from the monograph. He concluded he should also have sent a written confirmation of his changes to the scientists involved. But he said he is unsure what he would have done if they had objected to his actions. "I wish I could go back in history," he said with frustration.

The toughest critics of NCI and IARC in this matter point out that Tomatis is caught between a rock and a hard place because the agency is financially supported by the cancer institute. "Tomatis is a good man," but he "must have felt threatened by NCI," said Roy Albert, a member of the October working group and a professor at the Institute for Environmental Medicine at New York University. "I know for a fact that Tomatis was leary of quantitative risk assessment," and that he has legitimate scientific reasons. On the other hand, the circumstances leading up the deletion "look perfectly awful," Albert said.

At a National Cancer Advisory Board meeting in May, Tomatis reiterated that the institute had not pressured him to refrain from risk assessment. Board members seemed satisfied with his denial. But Sheldon Samuels, a board member and director of health, safety, and environment for the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), proposed that a board subcommittee investigate the matter further. He was voted down 11 to 2. (William E. Powers, chief of radiology at Detroit's Harper Grace Hospital, sided with Samuels.)

The problems with the benzene monograph apparently troubled the special review group at the cancer institute that evaluates funding proposals, including IARC requests. This group, comprised of scientists outside the cancer institute, told NCI, in effect, to mind its own business and stop meddling in the agency's affairs. According to a memo written by a cancer institute official who attended the meeting, the committee "believes that IARC should remain open to suggestions from NCI . . . , but it would be a mistake for NCI to use its financial leverage to influence unduly the selection of topics or the choice of individuals to participate in the reviews."

Obey, who is a member of the House Appropriations Committee that oversees the NCI budget, has promised to continue investigating the matter. He said in a recent statement that he finds it "difficult to believe that the extraordinary steps taken by IARC staff in altering the findings of a scientific panel without approval from that panel were not at least partially a result of pressure from the National Cancer Institute officials who control IARC funding."—MARJORIE SUN

U.N. Space Conference Ends in Compromise

But final agreement papers over some major disagreements between rich and poor countries

Moderation and compromise finally won the day at the 2nd United Nations Conference on the Exploration and Peaceful Uses of Outer Space (UNISPACE-2), which ended in Vienna, Austria, on 21 August, with the rich nations giving away few concessions to the poor.

The results left many representatives from the developing countries frustrated that their more radical demands for international regulation of space technology had not been met. In contrast, negotiators from the industrial nations were relieved that their refusal to make any major concessions did not seem to have created substantial obstacles either to their efforts to sell space technology for Third World needs, or to further U.N. conferences on global technical issues.

The spirit of compromise was revealed in what rapidly became one of the most controversial topics of the conference, namely how far a meeting formally devoted to the peaceful uses of space technology should go in condemning efforts to exploit its potential military applications.

From the opening session it was clear that this topic was not going to be ignored. In a strong and emotional statement, U.N. Secretary General Javier Perez de Cuellar claimed that the "increasing and rapidly escalating militarization of outer space" threatens not only to inhibit and reduce international cooperation, but "to divert urgently needed resources from programs of social and economic development." Recent military activities in space, he said, seem to contravene the spirit, if not the letter, of the U.N. outer space treaty of 1967, which states that space is considered the province of all mankind and should only be used for peaceful purposes.

Others—particularly the United States, with the support of the United Kingdom—made it clear that they did not consider the militarization of space to be a legitimate topic for a conference officially devoted to peaceful applications. James Beggs, the administrator of the National Aeronautics and Space Administration and the head of the U.S. delegation, emphasized at a press con-

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