



A/C Pipe
Producers Association

PLAINTIFF'S EXHIBIT

CAP-1683

Internal Correspondence

TO Executive Committee
International Affairs Committee

FROM *J.F. Welch*
J.F. Welch, Vice President

DATE October 27, 1982

SUBJECT U.S. Environmental Protection Agency (EPA) - Summary Workshop on Ingested Asbestos

Ref: JFW correspondence, same title, September 2, 1982

Action Required: Review for information

On October 13-14, 1982 EPA held its "Summary Workshop on Ingested Asbestos" to review Agency-sponsored research on exposure to and potential health effects of ingested asbestos. There were approximately forty attendees, predominantly EPA officials and research contractors, a small number of water utilities and scientists from academia. Industry was represented by AACPP Staff and Dr. Mansour of the Asbest-Institutes fur Arbeits- und Umweltschutz e.V. Also present were Helen Pentrack and three other residents from Blairsville, Pennsylvania, the location of a lingering field problem and potential litigation. No media representatives were present.

Workshop proceedings will be published in Environmental Health Perspectives, probably in early 1983.

During his opening remarks, Jim Millette (Health Effects Research Laboratory - HERL) read a disclaimer (Attachment 1) stating that regulatory policy would not be discussed and should not be inferred from the presentations. The following is a synopsis of the presentations.

Session A - Toxicology

Review of Published Studies of Orally-Administered Asbestos - L. Condie (EPA - HERL)

Condie chronologically reviewed the published toxicology studies (Attachment 2), commenting, "Ingested asbestos has been fairly well investigated and the vast majority of the studies are negative even though massive levels were administered." He discussed possible reasons for these negative findings, concluding that the studies "cast some doubt" on the hypothesis that ingested asbestos causes peritoneal mesothelioma or gastrointestinal cancers.

NIEHS Feeding Studies - Gene McConnell (NIEHS)

Dr. McConnell made an eloquent presentation on the long-term feeding studies of the National Institute of Environmental Health Sciences (NIEHS). The previously released results of the hamster studies, whose primary objective was to assess carcinogenesis of ingested asbestos, were reviewed. McConnell also issued preliminary findings on the rat studies.

The rat studies involved five thousand animals and were considered the

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definitive research for non-neoplastic effects from oral administration of asbestos. For both amosite and tremolite, treated animals exhibited no carcinogenic effect. Test animals also were examined for presence of non-neoplastic disease (inflammation, diverticulitis, ulcerations) but none was found.

For amosite-fed animals there was a statistically significant increase in C-cell tumors of the thyroid, but NIEHS considered this a spurious observation not related to administration. Incidence of monocytic leukemia also increased. However, this is an age-related tumor and the asbestos-fed rats survived longer. Thus, NIEHS concluded that the tumor's biological significance was not related to the administration of asbestos and the observation was discounted. The tremolite results were likewise negative.

McConnell reported that the survival (life span) of rats fed short-range and intermediate-range chrysotile and crocidolite had not been affected. Speaking privately to Staff, McConnell said his histopathologic review of the crocidolite and chrysotile treated animals showed no carcinogenic effect either. Histopathologic data will be peer reviewed in early 1983.

Lee McCabe (EPA), always playing the devil's advocate, asked McConnell whether NIEHS really gave it "its best shot" with the asbestos feeding studies. McConnell retorted, "I've never done a perfect study but the rat study is one of the cleanest I have ever dealt with." McConnell felt that some of the treated hamsters should have been sacrificed earlier to permit more extensive tissue examination.

During the question and answer period, Helen Pentrack asked McConnell whether the asbestos results might be like arsenic, which is a human carcinogen but does not induce cancers in laboratory animals. She also questioned whether the asbestos used in the studies was comparable to that in A/C water pipe. McConnell responded that the asbestos types did occur in A/C pipe and also were longer (and theoretically more dangerous) than asbestos normally found in drinking water. Possible explanations for the lack of carcinogenic effect were proposed by Phil Cook (EPA), but these were handily dismissed by McConnell.

Session B - Epidemiology

Asbestos in U.S. Water Supplies - James Millette (EPA - HERL)

No new data here. Millette reviewed the potential sources of asbestos in drinking water and what little additional research is being done. He mentioned the finding of levels of 4.5 million fibers per liter (MFL) of crocidolite in well water in New Jersey. He also said that the Effluent Guidelines Division would soon issue a report on asbestos discharges. Staff will follow up on this report.

Millette concluded that it does not appear that there are a large number of U.S. water supplies where asbestos concentrations exceed 1.0 MFL.

Review of Published Studies of Ingested Asbestos - G. Marsh (University of Pittsburgh School of Epidemiology)

This was a review of epidemiologic studies on asbestos in drinking water and cancer incidence. Its purpose was to determine what types of studies, if any, are needed for further investigation.

Nash hypothesized explanations for "internal and external consistencies" in the thirteen epidemiologic studies conducted on asbestos in drinking water. This was a very complex presentation, loaded with data potentially valuable in preparing comments to EPA's advance notice of proposed rulemaking that will request comments on asbestos in drinking water.

Nash summarized the methodological weaknesses of the epidemiologic studies as follows:

	<u>Weakness</u>	<u>Studies with Characteristics</u>
1	Ecologic study design (does not permit definitive conclusions to be drawn)	13
2	Insufficient latency period	4
3	Death certificate data	3
4	Duration and/or intensity of exposure	6
5	Uncontrolled confounding variables	6
6	Absent or incomplete data on dose response	8
7	Multiple comparisons problems	12
8	Insensitivity of summary statistics	10
9	Absence of historical asbestos exposure data	13
10	Use of at least one questionable statistical procedure	4

Nash concluded that future study was warranted. He recommended moving away from rather insensitive ecologic studies to case control studies that might more accurately determine risk levels.

Case Control Study in the Puget Sound Area - Lincoln Polissar (Hutchinson Cancer Research Center)

This study, yet unpublished, was a refinement of the census tract epidemiologic study conducted in the area. Polissar used data in low migration census tracts and isolated 400 eligible cases and 500-600 control cases; "years of exposure" categories were 0-9, 10-29 and 30 plus. Relative risks were calculated for individuals exposed for twenty years or more to Sultan River water (mean asbestos content: 206 MFL) and then compared to individuals with no exposure. Preliminary conclusions were:

1. Relative risks show considerable variation between sites
2. There are no good sex coincidence data, i.e. male/female cancer incidence does not agree
3. There were increased relative risks as high as 2.0 for cancer of the stomach and other sites

Polissar also commented on the power of the study, that is, its ability to detect increased disease incidence in the sites of interest. He said it was unlikely that this case control study could detect increased risks below a range of 4.0 to 6.0. In other words, the study was not sufficiently powerful to confirm the low relative risks observed. Thus, no significant increased risks were considered to be demonstrated.

Observations on Most Recent Data (1980) for Duluth - Eunice Sigurdson (Minnesota Department of Health)

As stated in her census tract study of cancer incidence in Duluth (published in 1981) Sigurdson recommended that more precise research be conducted. She concluded with no small measure of bitterness that EPA would not allocate funds for additional research in Duluth.

Effect of Population Density on the California Bay Area Study - Paul Conforti (University of California - Berkeley)

Conforti's reanalysis of the Kanarek et al studies concluded:

1. Correlation coefficients for population density and cancer incidence were negative in females for all sites and individual sites.
2. Some correlation coefficients for population density and cancer incidence in males were positive and some were negative.
3. For females, population density reanalysis reduces the significance of the cancer incidence data.
4. For males, population density reanalysis increases the significance of cancer incidence data.

Graphical Reanalysis of the California Bay Area Study - Michael Tarter (University of California - Berkeley)

Tarter reaffirmed Conforti's findings that population density does not appear to affect results of the Kanarek studies; the positive correlations still persist. However, he used sophisticated mathematical techniques and data image enhancement to make a startling finding. His reanalysis of San Francisco census tracts (where asbestos exposure levels are high) show a negative association between asbestos exposure and cancer incidence. He tagged this observation "the San Francisco effect" and cautioned that until it is fully understood, "one must be very careful about interpreting the Kanarek studies."

In discussions with Staff, Tarter underlined the fact that his findings were favorable to the A/C pipe industry's position. He left little doubt that he would be willing to publish his data if industry chose to fund publication.

Asbestos Cement Pipe and Cancer Mortality in Escambia County, Florida - James Millette (EPA - HERL)

Millette described EPA efforts to do a "quick and easy" study of the possible health effects of asbestos in drinking water on a small population in Florida. The study was neither quick nor easy and did not demonstrate any increased cancer mortality in exposed groups.

Escambia County includes the city of Pensacola, where a much publicized A/C pipe system was undergoing deterioration as a result of exposure to highly aggressive waters. The population was exposed to high levels of asbestos for approximately 25 years. Fiber counts ranged from 0.7 MFL to 32.7 MFL. The area, which included approximately 200,000 people, was subdivided into forty census tracts. Since there was no tumor registry, researchers reviewed death certificates for the period 1963 - 1976. High, low and no exposure categories were established based on available exposure data and observed cases. EPA concluded that there were no statistically significant differences in cancer mortality between the high exposure and no exposure population groups. The study is not particularly valuable as cancer mortality data were limited.

Comparing Epidemiology Studies of Ingested Asbestos for Criteria Documents - L. Erdrich (EPA - HERL)

In a rather theoretical presentation, Erdrich estimated the maximum number of excess cases of cancer that might occur in each epidemiologic study if EPA's water quality criteria for asbestos were valid. The criteria, calculated by Dr. Nicholson at the Mount Sinai School of Medicine, estimated that there would be one increased death per 100,000 persons exposed to 0.3 MFL. Her estimates follow:

Duluth	1
Connecticut	0.03 - 0.2
San Francisco Bay Area	6 - 15
Puget Sound Area	20
Florida	0.05 - 0.5
Quebec	6 - 15

Panel Presentations

Dr. Nicholson of Mount Sinai School of Medicine was absent; Millette substituted.

Dr. Jim Rowe (Office of Toxic Substances) gave an estimate of the contribution of diet and inhaled air to total ingestion exposure in humans. Using a number of very theoretical assumptions, Rowe estimated that a person might cumulatively ingest as much as 320 million fibers per year.

J. Wister Meigs, M.D. commented on his Connecticut studies which, in his words, showed "no plausible associations and no evidence of excess cancer risks in populations exposed to water delivered through A/C pipe." Meigs opined that the

whole matter of the risk of asbestos in drinking water should be reassessed in the context of drinking water exposures to other chemicals occurring naturally in water or released from coatings, pipe, etc. He urged EPA to think about the public's misconception of water as a pure substance rather than the "chemical product" that it is. He said that the public should be reassured that it is safe to consume water conveyed through A/C pipe if the water is properly stabilized. In his judgment this represented the best of all possible worlds because the consumer's health was safeguarded regardless of the outcome of any research on the subject.

Dr. Marty Kanarek responded by defending the San Francisco Bay Area studies. He said it was doubtful that his results were spurious because numerous researchers had analysed his data and could not make the results "go away." He did not comment on the Tarter findings of the "San Francisco effect." He felt that the statistical power, fiber amounts and fiber size in his studies were relevant and important to the issue. He recommended that case control studies be done in the San Francisco Bay Area.

Kanarek's co-worker, Dr. Robert Cooper, discussed the potentially confounding variables in the studies and reiterated that the study team "never said there was a cause and effect," only a statistical correlation between asbestos in drinking water and cancer. He concluded his remarks by saying the studies still left a "pretty muddy picture."

Dr. Polissar said that all the epidemiologic studies were subject to the important confounding variable of population mobility. He said that it was not important how long asbestos in drinking water had been around, but how long the people had been exposed to that asbestos. His analysis of the epidemiologic studies was that if there are risks, they are very, very small.

Session C - Asbestos Penetration of the Gastrointestinal (GI) Tract

Review of Published Studies on Gut Penetration - Phil Cook (EPA)

Cook merely reviewed the literature (Attachment 3), in particular his study that claims to document movement of asbestos through the gut wall.

Analysis of Urine from Residents Drinking Water Containing Asbestos in the Pacific Northwest - Ed Boatman (University of Seattle)

In contrast to Cook's claims of substantial gut penetration, Boatman characterized his results as inconclusive. He reviewed plausible physiological explanations for penetration and movement through the kidneys, but cast considerable doubt on the probability of such a series of events.

Accumulation of Ingested Asbestos Fibers in Rat Tissue over Time - James Millette (EPA - HERL)

Millette gave a very brief presentation on a study of asbestos bioaccumulation in rats. The studies were conducted by Epstein and Ickwell of the University of Illinois. The kidney cortex of the test animals was examined microscopically and although asbestos fibers were found, the levels were not dose or time related.

Leaching Effect of Stomach Acid in Water on Chrysotile Asbestos - K. Seshen
(University of Arizona)

The objective of this research was to determine whether there is a change in surface, physical and chemical properties of chrysotile when exposed to synthetic stomach acid. Although the simulated gastric juice contained no mucoproteins or glycoproteins, magnesium was leached from the fiber and the refractive index decreased, along with surface charge. Chrysotile asbestos appears to become more silica-like in its surface charge and this may have some effect on how the fiber reacts with cells. There also appears to be some evidence of fiber bundle breakdown.

Transmigration of Ingested Asbestos Fibers - E. Meek (Health and Welfare
Canada)

Staff obtained a complete report of Meek's research and will circulate it with a separate transmittal. Test animals were administered amosite in corn oil, (10,000 times the likely human exposure) with no evidence of macrophage or pathological effects. Meek also induced ulcers in test animals and then administered asbestos. She found no evidence of transmigration in spite of extensive gastrointestinal ulceration.

Session D - In Vitro Studies (Bernie Daniel - EPA - HERL)

Daniel provided a broad overview of in vitro studies of ingested asbestos. He said the evidence on the genotoxicity of asbestos is negative or very weak. With regard to other genotoxic parameters, he said that asbestos exhibited no mutagenic effects, had only a weak effect on mammalian cell transformation, a negative effect on DNA damage and repair, a negative to weak effect on sister chromatid exchange and an unknown effect on chromosomal abnormalities. Consistent with other thinking about asbestos, he said it was unlikely that asbestos initiated carcinogenesis, but was instead a promoter.

Session E - Methods

Methods of Reducing Asbestos in Water Supplies - Gary Logsdon (EPA - Municipal
Environmental Research Laboratory)

Logsdon summarized filtration methods to minimize asbestos in source water and stabilization/treatment techniques to minimize the corrosion of A/C water pipe. No new data was released; see Attachment 4.

Session F - Wrap Up

General Discussion on Whether Further Research is Needed - James Millette
(EPA - HERL)

Millette posed the question whether additional research is warranted but there was absolutely no audience response — none. It is likely that most of the attendees, who make their living from research grants, were forewarned that EPA will not fund new research on ingested asbestos. Nonetheless, the silence in the audience was overwhelming.

Comments from the Department of National Health and Welfare, Canada -
E. Meek

Meek described the importance of asbestos to the Canadian economy and reviewed the country's contributions to the medical literature. She recommended that case control or cohort studies be conducted on populations exposed to extremely high levels of asbestos in drinking water, such as those that occur in Sherbrooke or the San Francisco Bay Area. She concluded that the risk of disease from ingesting asbestos in drinking water probably is very small, but further research is necessary before firm conclusions can be drawn regarding the degree of risk.

Comments from the Office of Drinking Water - Joseph Cotruvo (EPA)

Cotruvo opened his remarks by saying that a conference like this allows Agency policy makers to review all the data available on controversial issues. He reviewed the long history of asbestos in drinking water research and restated the Agency's historical position that in the absence of firm data, it is reasonable and prudent to minimize exposures to asbestos. He said in his seven-year experience with EPA, he could not recall another drinking water issue where such extensive research had been conducted.

The policy options now available to EPA are:

1. To regulate
2. Not to regulate
3. Not to regulate but provide guidance to water utilities
4. Conclude that there is insufficient data to make a regulatory decision

He then reviewed the major study areas and drew his conclusions about the evidence. He concluded that the consensus on animal studies is that ingested asbestos is not toxic. The consensus of opinion on epidemiologic studies is not firm but conflicting, he said. However, he noted that the Puget Sound case control study did not demonstrate a statistically-significant risk in highly exposed populations. He said if there is a risk from ingested asbestos it has not been reproducibly demonstrated by epidemiologic studies. He also concluded that asbestos fibers do appear to penetrate the GI tract and move through the body.

He said EPA policy makers must now assemble these data and make a judgment on the matter. Consistent with AACPP knowledge, he said that an advance notice of proposed rulemaking would be issued within three months to address the question whether asbestos in drinking water should be regulated. A proposed rulemaking and a final policy statement probably would be issued in six months.

He commented that "EPA is on track to make a decision." He said of all environmental issues he had dealt with, EPA had a good body of evidence to assess the risks, if any, of ingested asbestos. He said regardless of the regulatory outcome, it made sense to minimize asbestos exposures either by filtering asbestos in source waters or stabilizing water so that it was not corrosive to A/C

pipe. He concluded by stating that extensive additional research would not add to the knowledge of the subject; a decision would be made on what evidence is currently available.

Staff Analysis

It appears that the concerns of the regulatory and medical communities about the potential health effects of asbestos in drinking water are fast drawing to a close. The evidence stands on face value and the industry's position, after nearly nine years of research, is vindicated. There simply is no reasonable basis for promulgating a maximum contaminant level for asbestos in drinking water or usage guidelines for A/C water pipe.

However, Cotruvo's concluding remarks strongly suggest that EPA probably will attempt to recommend non-legally binding guidance on asbestos levels in drinking water and quality of water conveyed through A/C pipe. Although this may be no more than a general statement, it is Staff's judgment that such a recommendation will perpetuate rather than terminate concerns about the safety of A/C water pipe. Skeptical public interest groups and malicious competitors may even say it was a "political sellout" by the Reagan Administration. The Agency has conducted sufficient research to make an affirmative finding on product safety. Future industry efforts should be directed towards achieving that objective. To ensure that it is achieved, Staff recommends that AACPP retain Kirkland & Ellis to prepare comments to the forthcoming advance notice of proposed rulemaking and, with AACPP Staff assistance, intervene with EPA officials to effect a favorable outcome.

If you have any questions, please do not hesitate to call.

JFW/ccw

Attachments

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ATTACHMENT 1

NOTE TO ATTENDEES

The Office of Drinking Water and other offices within the United States Environmental Protection Agency are in the process of analyzing data on all aspects of the asbestos in drinking water issue. It is not anticipated that this review will be completed before mid-1983. This October 13 and 14 meeting is being held to summarize the EPA sponsored research efforts in the area of ingested asbestos. Although the research described during this meeting has been funded wholly or in part by the United States Environmental Protection Agency through various contracts, grants, or in-house projects, it has not been subjected to the Agency's required peer and policy review and therefore does not necessarily reflect the views of the Agency and no official endorsement should be inferred. When, and if, it becomes appropriate for the Agency to make a specific determination concerning asbestos, that determination will be made formally with adequate opportunity for public review and comment of the proposed actions of the Agency. This meeting is being held to summarize scientific research. It is not intended that policy issues be discussed.

ATTACHMENT 2

TOXICOLOGY

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ATTACHMENT 3

SUMMARY OF EVIDENCE FOR/AGAINST FIBER PENETRATION

+/- Authors (date)	Species/#	Fiber Type	Fiber Dose Characterized	Tissue Analyzed	Tissue Preparation	Microscope Technique	Detection Limit	Controls pos/neg
+ Wyss (1953)	human/4	asbestos	no occ. exp.	urine	bulk	OM	?	-/-
+ Westlake et al. (1965)	rat/3	chrysotile	no	colon mes. nodes spleen	thin	TEM	qualitative	-/+
- Gross et al. (1974)	rat	chrysotile amosite crocidolite	UICC	multiple sites	thick and bulk	OM TEM	no	-/-
+ Cunningham and Pontabart (1973, 1977)	rat/10	chrysotile	size only	multiple sites	bulk	TEM	?	-/+
- Bolton and Davis (1976)	rat	chrysotile crocidolite amosite	UICC	GI	bulk	SEM	no	-/-
+ Storeygard and Brown (1977)	rat/5	amosite	UICC	jejunum epithelial segment surface		SEM	qualitative	-/+
- Auerbach et al. (1977)	human	asbestos bodies	no	lung	bulk	OM		-/-
+ Cook and Olson (1979)	human/16	amphibole	yes	urine	bulk	TEM	yes	+/+
+ Cook and Longrie (1981)	human/34	chrysotile	water- neg.	urine	bulk	TEM	yes	-/+
+ Hallenbeck (1978)	baboon/1	chrysotile	yes	tissues urine, blood	bulk	TEM	yes	-/-
+ Hallenbeck and Patel-Mandlik (1979)	baboon/1	chrysotile	UICC size	urine	bulk	TEM	yes	-/-
+ Carter and Taylor (1980)	human/53	amphibole - chrysotile -	yes no	liver, lung jejunum	bulk	TEM	yes	+/+
+ Sebastian et al. (1980)	rat/35	chrysotile (3) crocidolite	yes N/E/S	lymph fluid G.I.	bulk	TEM	?	/+
+ Bignon et al. (1981)	human/1	attapulgite	yes	urine	bulk	TEM		-/-
+ Denham et al. (1980)	rat/20	chrysotile	UICC	colon colon 20µm	thin bulk	TEM	no	-/+
- Hallenbeck et al. (1981)	baboon/2	chrysotile crocidolite	N/E/S size only	tissue blood, urine	bulk	TEM	yes	+/-

+ Patel-Mandlik and Millette (1980)	baboon/2 newborn	chrysotile	UICC site	kidney, cortex other tissues	bulk	TEM	yes	-/+
+ Batterman and Cook (1981)	fish/8	amphibole chrysotile	estimate	kidney, liver, muscle	bulk	TEM	yes	-/+
- Bolton et al (1982)	rat/39	chrysotile amosite crocidolite	UICC sites	various	bulk	SEM	??	-/+

ATTACHMENT 4

Asbestos in Water Publications
HERL Supported Research

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