PLAINTIFF'S EXHIBIT

CAP-1278

A/C Pipe
Producers Association

Internal Correspondence

TO Public Affairs Committee
International Affairs Committee

FROM J. F. Welch
J. F. Welch, Director, Public Affairs

DATE October 22, 1981

SUBJECT AACPP Comments on "The Use of Asbestos Cement Pipe for Public Water Supply and the Incidence of Cancer in Selected Communities in Utah, 1967-1976."

REF: JCJ correspondence, same title, September 8, 1981.

ACTION REQUIRED: Review for information

Enclosed are Staff's comments to the manuscript "The Use of Asbestos Cement Pipe for Public Water Supply and the Incidence of Cancer in Selected Communities in Utah, 1967-1976" submitted for publication in the Journal of the American Water Works Association. It was recommended that the article not be published.

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

JFW/ajb

Enclosure

cc: A. Kahn, Esq.
N. Rahn, Esq.
N. Battle
B. Commins
K. Robock (Asbestos Institute)

copies to:

Public Affairs Committee	International Affairs Committee
H. Olson	R. Dorner
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COMMENTS ON THE MANUSCRIPT "THE USE OF ASBESTOS-CEMENT PIPE FOR PUBLIC WATER SUPPLY AND THE INCIDENCE OF CANCER IN SELECTED COMMUNITIES IN UTAH, 1967-1976"

Before beginning the detailed review of the manuscript, a few remarks about epidemiologic studies such as this are in order. Assuming that a study is well conducted, a number of inferences can be drawn from epidemiologic studies. These range from firm to speculative. If the study is not well conducted, it can be very difficult to make even speculative inferences much less draw conclusions about cause and effect relationships.

In the hierarchy of research designs for epidemiologic studies, the manuscript describes an ecologic study, one of the weakest methods of studying a phenomenon. Ecologic units (in this case, municipalities) are characterized (asbestos cement vs. non-asbestos cement) and possible relationships between these characteristics and cancer incidence are suggested by comparing incidence rates among ecologic units. This type of study must be interpreted with great caution and used only to generate hypotheses since the exposure information is so far removed from its potential effect.[1]

The study design described in the manuscript is even weaker than that of a conventional ecologic study. This is because the basic hypothesis (" ... that there is a positive association between the use of asbestos cement piping (exposure to asbestos in drinking water) ... and the incidence of gastrointestinal and kidney cancer") is not

[1] Direct testimony of Michel A. Ibrahim, M.D., PhD., Professor and Chairman, Department of Epidemiology, University of North Carolina School of Public Health, The Dow Chemical Company, et al before the Environmental Protection Agency, Docket Number 415, et al.

supported by a single piece of exposure data. The author assumes that if the distribution system contains A/C pipe then asbestos is present in the drinking water. Without knowing definitively that asbestos is or is not present in the drinking water of systems containing A/C pipe (or even those not containing A/C pipe) the results of this study are virtually meaningless. How can any meaningful inferences by drawn about "effect" when it has not been shown that "cause" (exposure) exists in the first place? Clearly they cannot. By example, the author purports to find an increase in kidney cancer in males in communities using A/C pipe. In the absence of asbestos fiber counts, it could be theorized legitimately that this increase is the result of a contaminant from the rubber rings in the system or perhaps a contaminant from the lubricant used to assemble the pipe or the other piping material(s) in the system. The author does not draw these conclusions but they would be just as valid as the "conclusions" made about asbestos in drinking water and cancer incidence.

This reviewer has been aware of the findings of this study for more than three years. The fact that it appears to have been submitted and rejected for publication in peer reviewed medical journals suggests that its scientific foundations are badly wanting. It is not recommended that the AWWA Journal publish such rudimentary studies unless they have been reviewed and approved by medical scientists, preferably epidemiologists. Specific comments on the abstract follow:

Abstract

Paragraph 1 demonstrates that the author does not understand the limited power of the ecologic study. Most epidemiologists agree that ecologic studies are suitable only for hypotheses generation. Not until one reaches cross sectional, case control or cohort studies can hypotheses be tested with a high degree of reliability. In sentence 1, the

phrase "tested the hypothesis" therefore seems inappropriate.

Paragraph 2 lists without explanation the increased cancer incidence rates found in the study. Such data should not be presented in the abstract without at least a brief explanation as to its statistical significance and its relationship to the study hypotheses and conclusions. For example, one might conclude from reading the abstract alone that leukemia in women results from consuming drinking water conveyed through A/C pipe. This, of course, is not a conclusion of the study but it underlines the fact that the abstract needs substantial clarification.

In Paragraph 4, the author states "the results of the study were considered non-conclusive." The facts are that the evidence, however poorly developed, provide no consistent evidence that A/C pipe was linked to cancer. The author himself concludes (Page 14, para. 3) that the study " ... found no association of gastrointestinal, peritoneal, or kidney neoplasms with asbestos."

Introduction

A/C pipe is not the predominant use of asbestos in the United States; flooring products consume greater total quantities.

In Paragraph 2, sentence 1, it would be more accurate to state that early descriptions of asbestos related lung disease <u>included</u> reports of lung cancer and mesothelioma. In sentence 2, the author does not support by reference the claim that asbestosis or mesothelioma may be caused by "environmental exposure." Asbestosis results from chronic occupational or para-occupational exposures to high levels of airborne asbestos and, to the best of this reviewer's knowledge, never has been related to

low-level environmental exposure. Mesothelioma also has not been related to environmental exposures to asbestos.

In Paragraph 3, the author provides only one slice of the total pie of evidence on GI cancers in asbestos workers. The resulting impression is that all workers occupationally exposed to airborne asbestos manifest the diseases cited. This is not the case. Several cohorts (Selikoff-1979, Newhouse and Rubino-1979, Meurman-1974, Peto-1977 and Weill-1979) found no increased incidence of GI cancer and in some cases no peritoneal mesothelioma in similarly exposed worker groups. In sentence 3, the author mixes apples and oranges by referencing penetration of the gastrointestinal mucosa. Mucociliary clearance is a human phenomenon. Reference (15) refers to an animal study in which asbestos fibers were perfused through an excised portion of the duodenum of rats. It was not a human study as the sentence suggests.

In Paragraph 4, the word "culinary" should be deleted in sentence 1.

On Page 2, Paragraph 1, sentence 2 does not describe all sources of asbestos in water systems. In addition to the possibility of fibers being released (not "leached"), contamination by asbestos containing soils, residues from installation practices and other asbestos containing materials in the water supply and distribution system may contribute fiber to drinking water. In sentence 3, the reference to (23) as a "recent investigation" shows that the manuscript is badly outdated. This 1978 study was superceded by a 1980 study (Meigs, et al). Moreover, there is no mention of the two epidemiology studies (Mason-1974 and Levy-1976) conducted in Duluth and the 1977 Wigle study, "Cancer Mortality in Relation to Municipal Water Supplies in the Asbestos Mining Areas of Canada." All those studies found no association between asbestos in drinking water and disease.

In Paragraph 2, it would be more accurate to state that Cook has claimed to show, rather than shown, that ingested asbestos is excreted in human urine. To the best of this reviewer's knowledge, this study has never been replicated in humans, even using the high asbestos content waters of the Pacific Northwest. Further, it is questionable whether the word "absorbed" truly describes the physiological process operative in the Cook study. If one accepts his theory, it seems more likely that asbestos penetrated the gut rather than was absorbed like water and nutrients. In sentence 2, the word "insulator" should be replaced with "insulation". In sentence 3, Reference (26) had very little to do with "the use of asbestos cement pipe," and largely involved exposures to naturally occurring asbestos in drinking water.

In Paragraph 3, sentence 2 should be rewritten as follows: This study sought to determine if this ingestion may increase the risk of asbestos-induced cancer, ..."

Methods

This section demonstrates the serious scientific flaws of this study. In Paragraph 2, the author states "Very little information was available ... on exact distances, but they confirm that asbestos cement pipe was the primary pipe used in main distribution lines." On the basis of this "very little information" the author, without defining his criteria, determines that A/C pipe was the "predominant," type of piping used in the system. Is "predominant" greater than 50%, 75% or 90%? Depending on the definition of "predominant," the amount of other piping materials in the systems studied could vary from 50% to 10%. If the figure was 50% how then did the author know that his results did not relate to <u>other</u> pipe in the system? It should be obvious that such an arbitrary

and biased selection process, particularly in the absence of asbestos measurements, can lead only to the most speculative of conclusions.

On Page 4, Paragraph 1 again emphasizes the inherent problems in conducting an ecologic study. Such a study cannot correct for the confounding variable of population mobility which in turn may have a significant impact on cancer incidence rates. The criterion of a "less than 200 percent increase in population from 1960 to 1975" is only a surrogate control for population mobility. Moreover, no attempt is made in the study to account for ethnicity, exposures to occupational carcinogens, dietary habits, smoking habits, and alcohol consumption although these may be important contributors to differential cancer rates. This is very, very weak science.

On Page 4, Paragraph 2, the author assumes that the control group i.e., those without any A/C pipe, do not have asbestos in their drinking water. Such an assumption must be based on actual exposure conditions; without asbestos in water measurements, it is no more than an assumption.

On Page 4, last Paragraph, the phrase "cancer of" should be deleted.

On Page 5, Paragraph 1, line 1, the word "statistically" should be inserted before the phrase "significant trends."

On page 5, Paragraph 2, the author selects three control sites but gives no explanation as to why these sites were chosen. The answer is that these diseases have no established link with asbestos exposure. The manuscript should state as much.

Results

The results are poorly organized and presented. For example, the author inserts a control site statistic in between the specific cancer sites chosen for the research. Data on only one control site (leukemia) are presented. What were the studies findings with respect to the other two control sites (melanoma and lymphoma)? It would be more desirable to first present the results of the sites chosen for research, then present results on the control sites and finally, compare the findings.

On Page 7, Paragraph 1, such phrases as "significantly increased" should be followed with p values to show the strength of the statistical significance.

Discussion

The Discussion falls prey to the same shortcomings of the Introduction and Results sections. The impression conveyed by reading the Discussion is that the author attempted, unsuccessfully so, to buttress the power of his study by drawing on data from other research. What results is a disjointed and weakly reasoned explanation of the study.

In Paragraph 1, sentence 2, the author shows a surprising unfamilarity with a possible exposure scenarios for asbestos. In observing that Utah is "unique" because it "has no major asbestos industry (e.g., shipyard employment, asbestos factories)," the author too easily dismisses the possibility of asbestos exposures which may have resulted from the once wide spread use of asbestos in insulation products. The author again claims that "there are no known naturally occurring asbestos fibers in the water supplies." As previously stated, the absence of actual asbestos in water counts remains a

serious methodological flaw to this study. Thus, there is no reason to believe that this study is not subject to the shortcomings of "previous studies" which may have been confounded by occupational exposures or naturally occurring asbestos in drinking water. In sentence 7, the author inexplicably raises and dismisses the possibility of the Groton Shipyard influencing the Connecticut epidemiology study (23). If the results were in fact negative, why even mention the fact that they "could have been influenced by occupational exposure?"

On Page 10, Paragraph 1,line 3, the phrase "also further" should be rewritten to be less redundant. Defining the results of this study as "nonconclusive" (sentence 2) is misleading. The results provide no consistent evidence that A/C pipe was linked to cancer or that no association was found. (As an aside, one questions whether the Journal should even be considering publication of studies which are "nonconclusive".) The final sentence in Paragraph 1 imparts far more relevance to the finding of increased incidence of kidney cancer than either the data or the author's own conclusions support. If the findings are "nonconclusive" why then state in the next sentence that the observance of increased kidney cancer is "disconcerting?" The absence of a similar increased risk in females, who some researchers believe are more likely to consume greater quantities of potable water, renders invalid any meaningful conclusions about ingested asbestos and kidney cancer. The author himself states on Page 11, Paragraph 4 and Page 12, Paragraph 1 that the increases in kidney cancer were due to "chance alone" or "older age groups." And the conclusion at Page 14, Paragraph 3, states that the study "found no association of ... kidney neoplasms with asbestos." It is incomprehensible how this finding can be labeled "disconcerting."

The results described on Page 10, Paragraph 2, also raise questions about the validity of the study because a disease not ever linked with asbestos is related

statistically to the study's theoretical asbestos exposure. Rather than offering a reasonable explanation for this anomaly, the author chases down a hypothetical cul-de-sac on how asbestos might induce leukemia. Reference to the Pontefract study (30) in sentence 6 without mention of the confounding factor of the tissue fixing solution being contaminanted by asbestos, is without scientific merit.

Paragraph 3 of Page 10 and Paragraph 1 and 2 of Page 11 are redundant of matters discussed in the Introduction.

On Page 13, Paragraph 2, this reviewer does not agree with the author's conclusion that "follow up of this study group is warranted." Unless asbestos exposure measurements are available, and until the methodology is refined to control confounding variables, repetition of this study would be meaningless. On Page 13, Paragraphs 2 and 3 are better suited to the Introduction than to the Discussion.

On Page 14, Paragraph 3, the author finally articulates an appropriate conclusion for his "nonconclusive" study i.e., "no association" was found. It is worth mentioning that this is remarkably straight forward and rather inconsistent with his earlier waffling about the "nonconclusive" nature of the study and the "disconcerting" finding of increased incidence of kidney cancer in men. It also should appear in the Abstract.