

Laboratory. The following table gives the range of values obtained from quarterly composites of biweekly 24 hour samples.

Chrysotile asbestos content of ambient
air samples collected by NAPCA
in 49 United States cities.

<u>Fiber range in nanograms/m³</u>	<u>No. of samples in range</u>
0.1- 0.9	61
1.0- 4.9	102
5.0- 9.9	12
10.0-19	9
20 -49	2
50+	1
Total samples	187

Results were also obtained from a series of single 8 hour samples collected in New York City by the Department of Air Resources at 12 sites of their sampling network.

Chrysotile content of ambient air
in New York City by borough

<u>Sampling Locations</u>	<u>Number of Samples</u>	<u>Asbestos air level in 10⁻⁹ grams/m³</u>	
		<u>Range</u>	<u>Average</u>
Manhattan	7	8-65	30
Brooklyn	3	6-39	19
Bronx	4	2-25	12
Queens	4	3-18	9
Staten Island	4	5-14	8

Sampling about construction sites where extensive spraying of asbestos-containing fireproofing material was taking place shows this procedure to contribute significantly to asbestos air pollution. In some instances chrysotile asbestos levels approximately 100 times "background" were observed.

Chrysotile asbestos concentrations
near spray fireproofing sites

<u>Sampling Location</u>	<u>Number of Samples</u>	<u>Asbestos Air level in 10⁻⁹ g/m³</u>	
		<u>Range</u>	<u>Average</u>
1/8-1/4 mile	11	9 - 375	60
1/4-1/2 mile	6	8 - 54	25
1/2- 1 mile	5	3.5 - 36	18

Asbestos Lung Burdens

Examination of human tissues may provide information as to the intensity of fiber exposure; fiber type (involving mixed exposure); fiber distribution; and fiber alteration in vivo.

The amount of tissue examined in the search for asbestos fibers is related to the degree of exposure (occupationally exposed vs. the "general population," or "non-exposed") and the materials available for study. Little material is required for the identification of fibers in tissue from individuals with "heavy" asbestos exposure. Here, histologic sections are quite adequate. However, in cases where small amounts of asbestos are likely to be encountered, bulk tissue will significantly increase fiber yield, greatly reduce time of fiber search, and yield results with increased statistical validity.

Histologic sections may be prepared for fiber analysis by a number of methods. The technique selected is based upon the type of instrumentation which will be used in fiber localization and identification. The following technique is now used routinely in the preparation of tissues for examination with electron beam instruments; it is called the carbon-extraction technique (Pooley, 1972; Langer, et al, 1972b). The preparation involves:

1. the ashing of a 5-8 micron thick, unstained, histologic section mounted on a glass slide;
2. impregnating the relict tissue in a water-soluble plastic (polyvinylalcohol);
3. "peeling" the hardened plastic, and the incorporated ashed tissue, from the slide;
4. inverting the relict tissue and depositing a thick carbon coat onto the inverted surface;
5. dissolving the plastic from the carbon sheet (which now includes the relict tissue and the inorganic particles), and;
6. placing the carbon film onto appropriate substrates for examination in an electron beam instrument (EM copper locator grids are best for this purpose).

The bulk tissue technique is the KOH digestion method as outlined in Langer, et al (1971)

1. Dried lung tissue is digested in a 5% KOH solution while being heated at 90°C for a 4-hour period;
2. Several cycles of washing and centrifugation of the residue are required for the complete removal of digested materials and the KOH;

3. The residues are then dispersed in triple-distilled water by sonification and a small amount pipetted onto an appropriate electron microscope substrate.
4. After drying, the grid is scanned in a transmission electron microscope at a magnification of 42,000 X. The scan is made across the diameter of the field and the fiber density converted into mass.

The major advantage in using such a method is the concentration of particles from masses of tissue greatly in excess from what one would normally encounter in a histologic slide. The major disadvantages are the time required for a single specimen scan and the instrument commitment to such an analysis.

Some estimates of lung burden have been made. In one study of lung residues obtained from 28 people who died in New York City we estimated that their lungs contained chrysotile concentrations on the order of micrograms to tenths of milligrams quantities (several hundreds of millions of fibrils). However, that study produced conservative estimates on the basis of technique of preparation (sample loss) and enumeration (direct on EM screen). In another study of 100 additional cases from the "general population," a more controlled procedure produced lung burden estimates which exceed several 10's of milligrams. We have compared these values with those obtained in the analysis of tissues from workmen exposed to asbestos occupationally. Here the number of fibers per lung is on the order of hundreds of billions, and the calculated mass may be as high as 5 gms/lung. Indirect occupational exposure to fiber results in lung burdens lying between the general population and occupational exposure levels.

Some observations of importance are:

1. Histologic sections are adequate for particle evaluation in cases of intense exposure; however, bulk tissues give best results in cases from the general population.
2. Exposure intensities may be qualitatively evaluated in unknowns.
3. Sub-light microscopic fibers far exceed those seen by light microscopy in number in all cases and tissues studied thus far.
4. Asbestos bodies, objects visible by light microscopy and often used as an index of asbestos exposure, only partially and only in some occupational cases reflect the lung burden of asbestos.
5. Chrysotile asbestos is the most common sub-light microscopic fiber in human tissues, most often occurring in the fibril form.

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Problems and Perspectives

The shipyard mesothelioma question epitomizes the spectrum of difficulties now posed by the asbestos problem.

Background: Scientists have been sensitized to look for prior asbestos exposure, however brief, whenever mesothelioma is seen and, conversely, to watch for the occurrence of mesothelioma whenever an individual has had asbestos exposure. This sensitization perhaps explains the increasing uneasiness with which recent British publications have been received in this country. Starting in 1968, a series of papers has appeared reporting numerous mesotheliomas among individuals currently or previously employed in British shipyards. It is noteworthy that few of these people had been asbestos workers; they had merely been employed in the same yards (as carpenters, electricians, boiler-makers, riggers, pipefitters, caulkers, etc.) in which a relatively small number of other men (generally insulators or "laggers") had been working with asbestos. Their shipyard employment had, in most instances, started thirty or so years before the onset of mesothelioma.

These British data are of interest to us because their shipbuilding and shiprepairing industry was rejuvenated about five years before ours; 1935 to our 1939-1940, and their mesothelioma experience could presage similar disease in this country.

U.S. shipyard employment 1940-1945: Between the two world wars, approximately 75,000 men and women were employed in our shipyards at any one time. The vast expansion of the industry in World War II led to rapid growth of the workforce, which reached a maximum of 1,750,000 in the fall of 1943. Altogether, 4,500,000 men and women worked in our shipyards at some time 1940-1945. Given their age distribution in those years, about 3,000,000 are alive. Needless to say, few of these WW II shipyard workers are currently employed in this occupation (which numbers 225,000). They are working at a host of other trades or professions and many only dimly remember the shipyard interludes in their lives, thirty years ago.

Shipyard mesotheliomas: As in Britain, mesotheliomas are now being seen in this country in individuals who, in WW II, were employed in one or another capacity in shipyards -- men and women who had worked for six weeks, six months, two years. When lung tissue is examined, asbestos fibers and fibrils are readily found (by electron microscopy), in numbers considerably larger than the relatively scant contamination found among urban dwellers generally. Apparently, the mineral fibers inhaled 30 years ago have remained intact, in most instances, at least. The individual's exposure may have been six weeks -- that of the lung parenchyma 30 years.

The mesotheliomas being seen are both pleural and peritoneal, with a preponderance so far of the former. As a rule, there have been no X-ray changes of concomitant asbestosis -- it would seem that asbestos exposure insufficient to result in radiologically evident asbestosis

may still be enough to induce mesothelioma. Cases have been seen in former shipyard electricians, tinsmiths, engineers, riggers, boiler-makers, carpenters, laborers, etc. Parenthetically, the U.S. Navy accepts responsibility (in terms of compensation) for cases of mesothelioma among individuals who had worked in its yards in WW II, provided there has been no subsequent asbestos exposure, deeming itself the "last employer." These are random cases and it is not known how many are occurring, nor what proportion of the 3,000,000 former shipyard workers will develop mesothelioma. 7% of shipyard insulation workers die of this disease; it is highly unlikely that those indirectly exposed will reach this level, although it is conceivable. Those that occur will be seen over the next twenty years.

We have no way at the moment of predicting which individuals will develop mesothelioma, nor have we means of "early" diagnosis (at a time when the tumor is presumably still localized). Therapy has been palliative; cure eludes us.

What is to be done? Many groups are concerned with approaches to this asbestos problem, as to others; labor unions, industry, NIOSH, EPA, DOL, for example, are concerned with development of engineering controls, administrative standards and clinical surveillance. Scientists at NIH and elsewhere can augment and extend these efforts, utilizing a range of disciplines, from epidemiology to cell biology.

1. Can we inactivate the fibers presently in the lungs of shipyard workers? Can we "deluse" their asbestos lung burden before disease supervenes? There are some leads in this regard.
2. Can we develop serological or other means of predictive value? Early diagnosis?
3. Develop understanding of pathogenetic mechanisms, at the interface between "mineral matter and the living world."
4. Successful treatment of mesothelioma; worthy task for the National Cancer Plan.

Progress in these areas will be of value across the whole spectrum of asbestos disease, from occupational groups to environmental exposure, from the asbestos worker to the urban dweller with, currently, asbestos lung contamination. In addition, it is likely that biological concepts of fundamental value will be added to scientific understanding.

ASBESTOS FIBERS IN BEVERAGES

I. GIN

Henry J. Wehman and Barbara A. Plantholt

in press, with Bulletin of Environmental Contamination and
Toxicology. 1973.

INTRODUCTION

The purpose of this study is to collect survey data on the presence of asbestos particles in commercially retailed beverages. This particular report is restricted to electron microscopic analyses of gin samples from four manufacturers.

MATERIALS AND METHODS

The general procedure of NICHOLSON, et al. (1972) was followed with modifications as described below. Samples of gin sold under four different labels were purchased as "miniatures" (0.1 pints) from retail outlets in Baltimore County, Maryland. The samples were prepared for analysis by filtering 10 ml of each sample through Millipore membrane filters (AA, pore size 0.8μ , diameter 13 mm) in a Swinney hypodermic apparatus. The protocol for each sample was: filtration of 10 ml of deionized water through one filter, followed by filtration of 10 ml of sample through another filter, using the same syringe and Swinney adapter. All filtrations were done in a filtered-air hood with a laminar outflow pressure of 0.35 inches H₂O.

A total of 28 control and unknown samples were filtered: 14 control samples, 9 gin samples--3 from Company A, 1 from Company B, 3 from Company C, 2 from Company D--and 5 samples of water taken from the water supply of Company C.

Samples were prepared for electron microscopy by allowing the Millipore filters to dry on precleaned microscope slides in covered glass Petri dishes. The filters were subsequently ashed in the same vessels in an ashing oven at 500° C for 30 min. Slides bearing the ashed residue were covered with approximately 0.5% Formvar solution, which was allowed to dry. All operations after ashing were done in the filtered-air hood. When the Formvar film had dried, it was stripped from the glass slide by floating it onto the surface of Millipore-filtered water. The ashed residue adhered to the underside of the film, and was removed from the slide as the film was removed. 300-mesh copper grids (3.05 mm diameter) were deposited on the upper side of the film in areas overlying the ashed residue. The Formvar technique described here is

routinely used in other EM applications where it is desirable to have a low contrast support film for the specimen to be examined.

The grids were examined in an RCA EMU 3-G electron microscope as follows. Samples of gins, supply water, and control water ("blanks") were assigned code numbers by one investigator. A second investigator was instructed to scan each of three grids from each coded sample at low magnification (2200 X) to ascertain any regions of particle or fiber concentration. Next, the region of greatest particle concentration was to be scanned at 9600 X over 4 contiguous grid squares ($12,100 \mu^2$). Photographs were taken of any fiber observed in this area. If a grid appeared to be wholly negative, then 25 contiguous grid squares (each $55 \times 55 \mu$) were scanned to confirm this appearance. The "blind" investigator recorded semi-quantitative findings for each sample during scanning as F, RF, VRP, N--fibers, rare fibers, very rare fibers, negative.

Each micrograph was scored for "asbestos fibrils" according to these predetermined criteria: (a) exposed to 30 minutes' ashing at 500°C (true of all fibrils); (b) 150-400 A diameter, and (c) where at least one fibril on the same grid displayed the internal "capillary" or microtubular morphology described by previous investigators for chrysotile asbestos (LANGER, et al., 1971; BOOLEY, 1972). Each micrograph displaying material which did not meet all of the above criteria was recorded as "non-asbestos contamination."

As estimated maximum number of fibrils in each whole 10-ml sample was calculated by multiplying the number of fibrils observed in 4 grid squares by the factor (10.9×10^3). This factor is based on the assumption of a homogeneous distribution of fibrils throughout the sample, and it is derived from the areas of 4 grid squares, of the total grid, and of the total Millipore filter, as indicated in Table I.

TABLE I

Calculation of Factor for Estimated Total Number of Particles per 10 ml.

- (A) open area of 4 grid squares, 300 mesh = $55 \times 55 = 12,100 \mu^2$
- (B) diameter of grid = 3.05 mm = 3,050 μ
- (C) area of grid = $\pi \times 1525 \times 1525 = 7,302,462.5 \mu^2$
- (D) (C)/(A) = 603.51
- (E) area of grid = $\pi \times 1.525 \times 1.525 = 7.32 \text{ mm}^2$
- (F) area of Millipore Filter = $\pi \times 6.5 \times 6.5 = 132.67 \text{ mm}^2$
- (G) (F)/(E) = 18.12
- (H) (D) $\times$ (G) = 10,936 = conversion factor 10.9×10^3

RESULTS

The data obtained from each of the 28 samples tested, including blanks, is compiled in Table II. All gin samples from Companies A, B, and D were completely free of asbestos contamination. Asbestos was found in two of the 14 control samples; in both cases, the samples following these controls were negative. It should be noted that each odd-numbered sample is a control for the sample number immediately following it only. That is, the same syringe and Spinney adapter apparatus used for each even-numbered sample is first washed with distilled water; the filter through which this water is filtered is assigned the preceding odd number. Such "blanks," usually not included in published reports, are given here for the sake of completeness.

One of five water supply samples was positive for asbestos. The three samples of gin from Company C had significantly more asbestos fibrils than the samples from any other source.

Examples of the fibrillar morphology observed are illustrated in Figs. 1-3. Fibrils were almost always individual or in very small groups; this is most likely because of the instability of macrofibers of chrysotile asbestos in solutions of less than pH 10.0 (NAI and FAULS, 1962). The dissolution of native chrysotile into unit fibrils was not discouraged by our technique, however, since the individual fibrils allow better resolution of their internal morphology, and thus allow for more positive identification of asbestos in electron micrographs.

DISCUSSION

Increasing evidence of environmental asbestos contamination from other than airborne sources, or affecting organs other than the lung, is currently gaining attention as a possible hazard to health (RUFFS and LEBERSON, 1966; O'BRIEN and PONTREFACT, 1971; MERLISS, 1971; NICHOLSON, et al., 1972; SELIKOFF, et al., 1968; SELIKOFF, et al., 1972). Hence there is a need for independent investigators to find out where such contamination resides, and at the same time to develop a reliable survey method to monitor commercial substances. This method cannot be so exhaustive as to require the large numbers of tests of a basic search protocol (e.g., 1968 to 1971, as reported by NICHOLSON, et al., 1972); but on the other hand, it must yield distinguishable results which are clearly indicative of asbestos contamination. In the practical sphere, an adequate survey method might be used by responsible government agencies to alert the responsible companies to undertake more thorough research into this aspect of their quality control procedures. The method described in this report, which is

basically an application of those employed by previous investigators, adequately fulfills these two prerequisites. By using a blank control for each sample, unexplained contamination as found in #27 invalidates one sample only.

In the present instance, the type of asbestos observed is almost certainly chrysotile. The length distribution for chrysotile as determined for U.I.C.C. Standard Reference Asbestos Samples shows 83.8% of the fibrils observed to be less than 2 microns in length (RANDALL, 1972). In addition, the internal capillary substructure referred to earlier is considered to be very good evidence of the presence of chrysotile (NICHOLSON, et al., 1972).

Since the method of scanning is biased toward the finding of fibrils, the projected numbers of fibrils for each 10 ml sample represent a probable maximum. Thus Sample #14, for example, could be said "to contain not more than 23,980 fibrils per cubic centimeter." Therefore the method used in this investigation is recommended for determining whether asbestos has been added to liquids during the course of their manufacture.

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TABLE II

Orig. No.	Code No.	Semi- quant.	FIBRILS, numbers of asbestos.	PRINTS, numbers, non-asb.	Sample	Projected fibrils ($\times 10^3$) per 10 ml.
1	WS	WS			contr.	
2	24	N	0	0	gin A	
3	8	N	0	0	contr.	
4	9	RF	0	2	gin A	
5	1	RF	2	0	contr.	21.8
6	15	N	0	0	gin A	
7	WS	WS			contr.	
8	5	N	0	0	gin B	
9	4	RF	0	1	contr.	
10	11	F	12	1	gin C	130.8
11	WS	WS			contr.	
12	25	F	12	3	gin C	130.8
13	13	RF	0	4	contr.	
14	23	F	22	0	gin C	239.8
15	14	N	0	0	contr.	
16	19	N	0	0	gin D	
17	2	N	0	0	contr.	
18	18	N	0	0	gin D	
19	16	VRP	0	1	contr.	
20	17	VER	3	0	water C	32.7
21	22	N	0	0	contr.	
22	21	N	0	0	water C	
23	7	N	0	0	contr.	
24	10	N	0	0	water C	
25	20	RF	0	3	contr.	
26	3	N	0	0	water C	
27	6	RF	8	0	contr.	87.2
28	12	N	0	0	water C	

Original number indicates order of filtration and ashing; code number indicates order of analysis in RF. "VRP" = "won't strip," i.e., Formvar film could not be stripped from slide after ashing. Other abbreviations given in text.

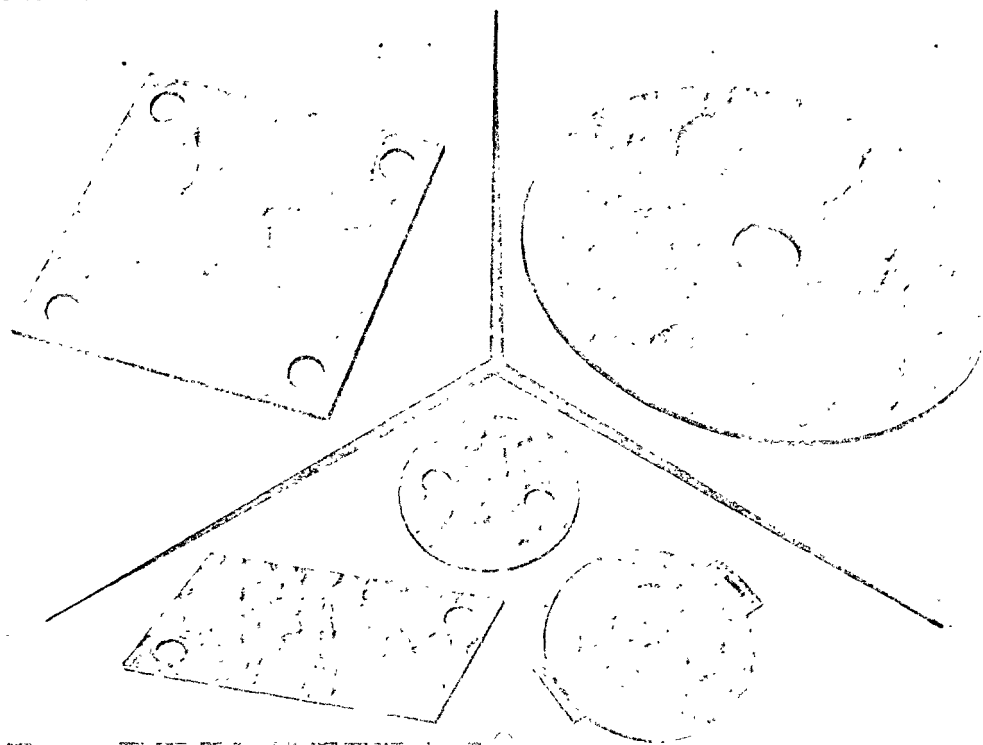


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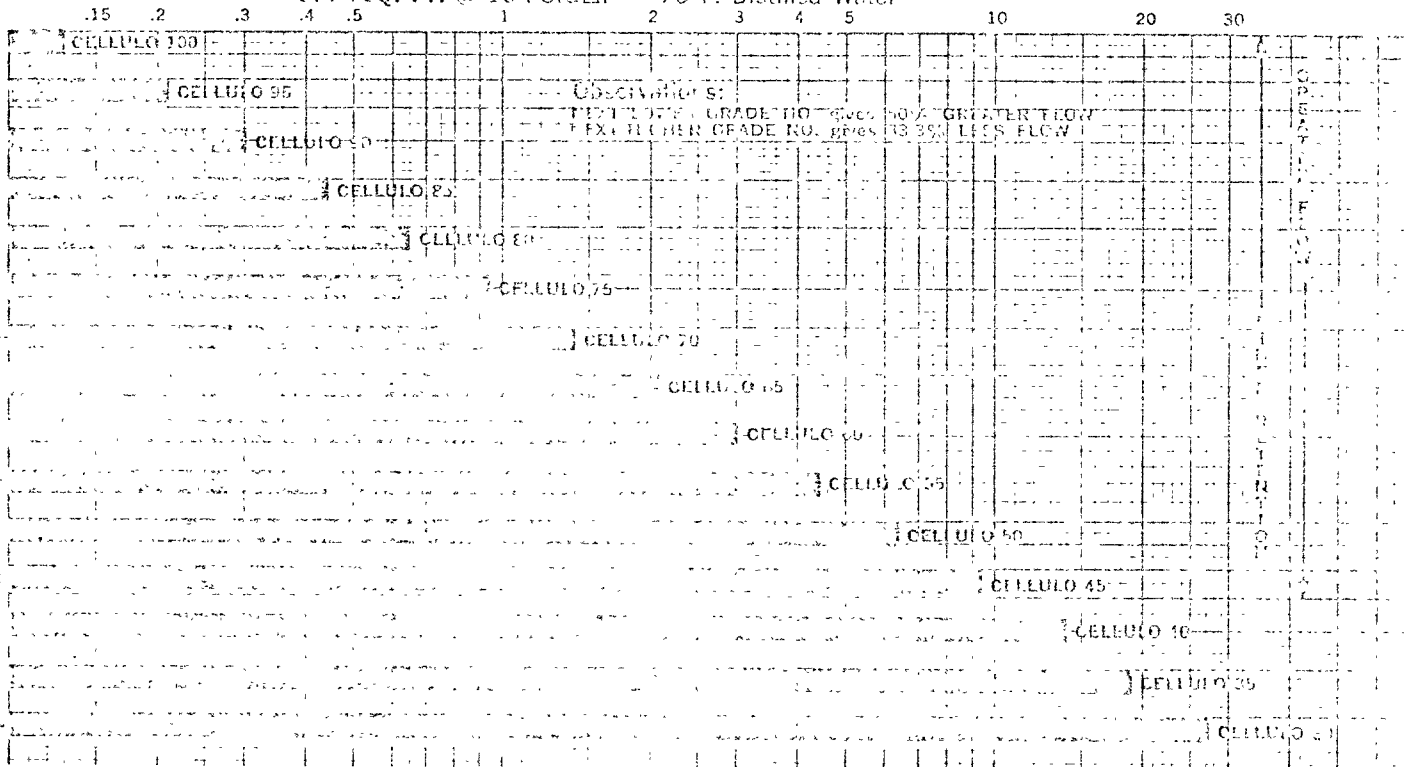
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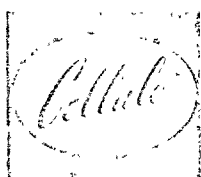
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Page 2
March 15, 1973

8 psi, and 90 stacked membranes would give a flow rate of almost 150 gallons per minute [see page 6, Specifications and Physical Properties; (this is for pure deionized water--give with particulation, generally have lower flow rates); Back-Flush Media Supports; 7-14; 7-15; 7-16; and Price List, page 3 and page 6 (marked in red). In a backwash configuration, the membrane cassette should have a very long life.

2. Nuclepore membrane cartridges have 9 square feet (for 10" cartridge) and 18 square feet (for 20" cartridge) of membrane enclosed by a pre-filter especially tailored to the membrane pore size. We have found that our cartridges have significantly longer service life than other cartridges available. For example, a 10" cartridge (9 sq. ft.) could therefore handle about 50 gallons per minute. These cartridges should have a very long life at low flow rates and in relatively particulate free applications. (See 1973 Handbook; page 11, Specifications and Physical Properties; and page 7 Price List, marked in black).

In both cases, the system is autoclavable in situ although this is probably not of importance given the high temperature and pressure involved.

I have enclosed a sample pack of our 0.4 micron rating, 47mm diameter, 28" length, (lot no. 2873), and (under separate cover) 1 liter of our 0.4 micron Ultra-Lok 47mm filter holder so you can test both polycarbonate for compatibility with your product. If you do not have a scanning electron microscope available, we would be pleased to test your product for particulation content and to provide a small Nuclepore cartridge.

Dr. S.J. Adame
Page 3
March 15, 1973

If you require additional information please contact
me at any time.

Very truly yours,

Harold W. Bailey,
President

HWB:rp

cc: Mr. Castleman

cc: Circulate: HUS, MCP, SCP, HAA

Le Journal de Microscopie Électronique est financé par les fonds de la Société Française de Microscopie Électronique avec le concours du Centre National de la Recherche Scientifique.

Le Journal de Microscopie Électronique paraît en 1970 huit numéros et publie des travaux originaux portant sur la microscopie et ses applications (méthode classique, électronique, optique, X, etc.); applications à la biologie, à la physique, à la métallurgie, etc.). Le journal accepte des articles en anglais et en allemand.

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1971, Vol. 10-12, 9 numéros

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THE USE OF NUCLEOPORE FILTERS IN LIGHT AND ELECTRON MICROSCOPY OF AEROSOLS

Evelyn R. FRANK, K.R. SPURNY*, D.C. SHEEDLEY and James P. LOZGA,
*Laboratory of Atmospheric Sciences, National Center for Atmospheric
Research**, Boulder, Colorado, U.S.A.*

INTRODUCTION

Studies of radiation damage to solids at the laboratories of the General Electric Company (1-4) led to the development of a new type of microporous filter material which has been trademarked Nucleopore. It is a 10- μ m thick polycarbonate film in which a chemical etching process has been worked out to leave cylindrical, highly uniform pores (Pl. 1, Fig. a). We have previously shown (5, 6) that the flow characteristics are similar to those of other membrane filters of similar pore size, and that the claims of pore uniformity are indeed true (Figure 1).

The filter material has the expected solubility in chloroform, ethyl acetate, dichloride, and strong bases, but is resistant to most alcohols, organic hydrocarbons, and dilute acids. Temperatures to 110°C are allowed. The film between the pores is transparent and very smooth, with a thickness of about 10 μ m. It has considerable birefringence, with refractive indices of 1.523 and 1.585, which somewhat hampers its use in polarized light microscopy.

* Visitor, Atmospheric Chemistry Program, NCAR, 1964-1967. Present affiliation: Czechoslovak Academy of Sciences, Institute of Physical Chemistry, Prague.

** The National Center for Atmospheric Research is sponsored by the National Science Foundation.

305 West Beltsville Street
Baltimore, Maryland 21201
July 7, 1972

Dr. John M. Courdy
Assistant Director for Medical
Affairs
Division of Otolaryngology and
Technology
Office of Product Technology
Food and Drug Administration
Washington, D.C. 20204

Dear Dr. Courdy:

I am writing to you to petition the Food and
Drug Administration to perform analyses of beverages,
etc. for contamination by asbestos used in

filters in food and drug processing. ^{should also be} ~~for regulatory~~ ^{in the}

As you are no doubt aware, the Delaney amendment
to the Federal Food, Drug, and Cosmetic Act
(Sec. 409[348] Action on Petition (3)(A)) provides "that
no additive shall be deemed safe if it is found to
induce cancer when ingested by man or animal."
Asbestos filters are commonly used in many food
and drug processing industries simply because

- 2 -

asbestos is a durable, cheap, all-purpose (acid, base, and heat resistant) filter medium. These plants began using asbestos before it was established that asbestos is carcinogenic, in many cases, and are most certainly unaware that a hazard is involved. In most cases, a number of other filter media are on the market which would be acceptable as substitutes at no loss in efficiency or increase in cost.

I reiterate that the safe threshold for exposure to asbestos is not known, and in this case the population at risk is the entire population of the United States (see "Typical Applications" an enclosure). Furthermore, it is against the law to add measurable amounts of known carcinogens to foodstuffs.

I suggest that electron microscope methods be employed on products from plants known to be using asbestos filters, as less powerful analytical tools may fail to turn up these minute fibers. The experts in this area of analysis are at the Mount Sinai Environmental Sciences Laboratory, 5th Avenue and 100th Street, New York 10029 (Dr. Arthur Langer).

Sincerely,

Barry C. Hoffman

cc: Representative Paul Sarbanes

Sen. J. Chafee, Maine

Sen. J. Chafee, Maine



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

July 12, 1972

Barry D. Castleman, M.D.
305 West Biddle Street
Baltimore, Maryland 21201

Dear Dr. Castleman:

For the past year the Food and Drug Administration has been exploring methods for identifying asbestos fibers in foods and drugs. During this time a number of products have been analyzed for this contaminant. As an incidental result of this activity we believe the use of asbestos filters is being discontinued.

In spite of the best efforts of Dr. Langer, experts from the National Institute of Occupational Safety and Health and others, there are problems which have not been solved.

Briefly, the problem is that methods which identify asbestos do not really shed any light on the number of fibers present. Methods of counting fibers, either optical or electron microscopy, do not definitively identify them as asbestos and do not give any idea as to the actual number present in W/W percentage. Since asbestos is present in the air in most large cities, it would be impractical to set a zero tolerance for fibers without introducing changes in the manufacturing environment and in our laboratories which are quite impossible at this time.

We are currently using all available methods for asbestos analysis but it is a slow process and we are still unable to correlate weight of asbestos and fiber content. Finally, no current method of analysis is accurate below 1%. Thus, we would not be able to enforce a tolerance below this level.

Sincerely yours,

John M. Gowdy
John M. Gowdy, M.D.
Assistant Director for Medical Review
Division of Colors & Cosmetics Technology
Office of Product Technology

under an asbestos
 $10^{-9} \mu\text{g}/\text{m}^3$



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

OCT 16 1972

Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Mathias:

This is in further reply to your August 18 request for comment on a letter from Mr. Barry Castleman, Baltimore, Maryland, petitioning the Food and Drug Administration (FDA) to analyze beverages, etc., for asbestos fibers used in filters in food and drug processing plants.

The Food and Drug Administration has such an investigation in progress. If these investigations reveal the presence of hazardous materials in food as a result of the use of asbestos filters or any other food contact material, all necessary measures provided for in the law will be undertaken to protect the public's health.

Our agency has been aware of the electron microscope methods used at the Mount Sinai Environmental Sciences Laboratory, to which Mr. Castleman made reference. We have collaborated with them in examining samples of talc. The Food and Drug Administration has an on-going contract with this group at the present time.

In further coping with the problem of eliminating asbestos-form particles from our food supply, FDA published a proposed regulation in the August 12, 1972 Federal Register which states in part that "any food or food packaging material containing talc that is not free of asbestos-form particles shall be deemed to be adulterated in violation of Section 402(c)(1) of the Act," (Federal Food, Drug, and Cosmetic Act).

If we can be of further assistance, please let us know.

Sincerely yours,

2 Enclosures

Gerald E. Meyer, Director
Office of Legislative Services

Constituent's ltr
Repr FR 8/12/72

305 West Biddle Street
Baltimore, Maryland 21201
October 24, 1972

Mr. Gerald F. Meyer, Director
Office of Legislative Services
Department of Health Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Meyer:

I am in receipt of a letter you sent to Senator Mathias stating that FDA has an investigation in progress concerning asbestos filters used in processing foods and drugs. I would appreciate it very much if you would send me a description of the scope and methods of this study, including the date the study began and the planned completion date.

I am glad to hear that FDA is taking a look at this problem, Mr. Meyer.

Sincerely,

Barry J. Castleman

cc: Senator Charles McC. Mathias
Dir. Michael S. Rosenberg, Center for Science
in the Public Interest

305 West Biddle Street
Baltimore, Maryland 21201
December 5, 1972

Hon. Charles McC. Mathias, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Mathias:

Since February of this year I have been corresponding with Dr. John Cowdy of the Food and Drug Administration's Office of Product Technology concerning the presence of asbestos in foods, drugs, beverages, and cosmetics. Last July 7, I petitioned the FDA through Dr. Cowdy to conduct analyses for asbestos in beverages which might be entrained in filtration using asbestos filters. In a letter dated July 12, 1972 he said that, "a number of products have been analyzed for this contaminant. As an incidental result of this activity we believe the use of asbestos filters is being discontinued as no current method of analysis is accurate below 1%. Thus, we would not be able to enforce a tolerance below this level."

In September of 1972, I went on a tour of one brewery and one distillery in my county, as a public health official. I found that each of these plants was using a suspect filter medium, and subsequent inquiries to manufacturers bore out my suspicions. Analysis by the state electron microscope laboratory was positive for asbestos fibers in both products, whereas the analysis was negative for pre-filter beer and metropolitan water samples. Our preliminary findings were reported to my Bureau Director, who told me he was glad he didn't drink Carling Beer. As I doubt he submitted the report to the FDA, I am

now doing so via our office, in my capacity as private citizen. Perhaps the most important aspect of the report is that the brewery's chief engineer did not know that the material was hazardous, and he had replaced it immediately following my initial visit. A plant tour at the time I informed him of our findings revealed that a non-asbestos replacement material occupied the place where the asbestos had been kept. In spite of the fact that I am a skeptical control agency official, I believe that this was a genuine act of voluntary compliance. There is every reason to believe that similar substitutes could be employed by all other beer companies using asbestos in filtration. No threats or extensive analytical programs would be necessary, just a few form letters, and plant inspections.

Last summer I sent a copy of my petition letter to you after receiving the frustrating reply from Dr. Condy. You passed it on to Mr. Gerald F. Meyer, of the Office of Legislative Services of the FDA. He replied on October 16 that the FDA had such an investigation "in progress." He promised that measures provided by law would be taken if hazardous materials are found in food as a result of use of asbestos filters. On October 24 I wrote to him requesting a description of the scope and methods of FDA's study, including starting and completion dates. So far I have received no reply.

The results of the state election microscope Laboratory study on a larger number of samples and controls will not be available before January.

Senator Mathias, I am writing now to inform you

that unnecessary and potentially hazardous use of asbestos filter media is apparently a widespread practice in brewing and distilling industries. All that is necessary to remove this problem is for the appropriate governmental control agency to let it be known that this is quite likely an illegal and dangerous practice, and an electron microscope analysis of all brands is being embarked upon. And then perform the analyses within a reasonable time; and prosecute any offenders found.

I mention in closing that Selikoff, the leading U.S. authority on health effects of asbestos, concluded in papers delivered October 4, 1972 that stomach cancer is an occupational hazard of (asbestos) insulation workers. Other hazards of asbestos workers include lung cancer, malignant mesothelioma of the pleura and peritoneum, and asbestosis, so it is not surprising that it took awhile to detect the stomach cancer risk. Through the Center for Science in the Public Interest I am collaborating on a comprehensive booklet on asbestos hazards to workers and the public, and what little is being done about it.

Needless to say, I would be glad to speak with you or members of your staff about these problems at your convenience.

Sincerely,

Barry Clinton

BALTIMORE COUNTY, MARYLAND

INTER-OFFICE CORRESPONDENCE

TO Thomas H. Devlin

Date September 28, 1972

FROM Barry Castleman and Valjean Gambill

SUBJECT ASBESTOS FILTERS IN BEVERAGE PROCESSING
PRELIMINARY REPORT

INTRODUCTION

We are performing a survey to see where asbestos filters are used in processing beverages (soda, beer and whiskey). Where such filters are identifiable, we want to assure that appropriate worker protection is in force and ascertain whether the fibers are showing up in the finished product. To determine the latter, the electron microscope laboratory at Rosewood State Hospital offered to perform electron microscope analyses on samples of incoming water and plant products.

Our reason for concern is that asbestos has been identified by numerous studies as a potent cancer-causing agent. In a mortality study of insulation workers, Selikoff et al. (Mt. Sinai School of Medicine, New York City) found 41 cases of gastrointestinal cancer where only 12 would be "expected" based on U.S. Mortality figures. A similar excess has been found in a study of insulation workers in Belfast.

The Food, Drug and Cosmetic Act states, "That no (food) additive shall be deemed safe if it is found to induce cancer when ingested by man or animal." On August 1, 1972, the Food and Drug Administration proposed to ban all talcs for use in food processing which contain asbestos-like mineral fibers.

We are alarmed by the careless use of asbestos in thousands of products, many of which give rise to hazards to an unsuspecting public. In the case of beverage processing, the unique properties of asbestos - heat, acid, and alkali resistance - are not called for, and substitutes can readily be found.

PRELIMINARY FINDINGS

None of the several soda manufacturers contacted were found to use asbestos-containing filters.

The Carling Brewery was found to use a powder called DIASBESTOS in the polishing (final) filter in beer processing.

The Calvert Distillery was found to use filter mats from the Seitz-Asbestos Works in West Germany on all products. However, in most cases this was followed by a cotton filter and a final charcoal filter.

Grefco, Inc. (in Los Angeles), which manufactures DIASBESTOS, did not respond to our request for a breakdown on the composition of this material.

SWK Machines, U. S. distributor for Seitz, informed us that the filters used by Calvert are 2/3 cotton and 1/3 asbestos.

Preliminary analyses of samples were performed by Dr. Henry Wehman using standard electron microscope techniques (0.8 micron millipore filtration, high temperature ashing, low power scanning, examination of representative fields with E.M.).

Numbered samples of Carling beer taken before and after the polishing filter were examined, the examiner did not know anything about the samples. The post-filter sample had asbestos fibers present, the pre-filter sample did not.

A sample of Calvert gin drawn from a miniature contained asbestos fibers. As a control, samples of metropolitan water (from which the gin is made) were analyzed and found free of asbestos.

These preliminary results were made known to the companies on September 21, 1972, by which time Carling had replaced DIASBESTOS with a cotton type of filter medium. Calvert was advised to seek a non-asbestos replacement for the Seitz filters.

PRESENT STATUS

A number of samples of water, beer and Calvert products were prepared for electron microscope analysis in a larger study which will have built-in tests for consistency of technique. Several other beers brewed in this area will also be analyzed. The results should be available in November, 1972.

REFERENCES

1. Selikoff, I. J., E.C. Hammond, R. Seloman, "Cancer Risk of Insulation Workers in the United States", presented at the meeting of the Working Group to Assess Biological Effects of Asbestos, International Agency for Research on Cancer, Lyon, France, October 4, 1972.
2. Elmes, P.C., and M.J.C. Simpson, "Insulation Workers in Belfast 3. Mortality 1940-1966", Brit. J. Industr. Med., 28, 226, (1971).
3. Federal Food, Drug and Cosmetic Act, Sect. 409 (348), (c)(3) (A).
4. "Proposal Regarding Regulation of Prior-Sanctioned Food Ingredients", Federal Register, August 1, 1972.

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United States Senate

COMMITTEE ON THE JUDICIARY
 WASHINGTON, D.C. 20510

JOHN H. BOLLOMAN III
 CHIEF COUNSEL AND STAFF DIRECTOR

December 11, 1972

Mr. Barry D. Castleman
 305 West Biddle Street
 Baltimore, Maryland 21201

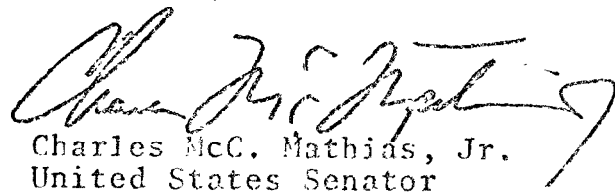
Dear Mr. Castleman:

Thank you very much for writing me again on the problem of asbestos filters used in processing foods and drugs. Your diligence in pursuing this matter is greatly appreciated, as is your offer to discuss the problem further with me and my staff.

I have once again contacted officials at the Food and Drug Administration to see why you have not heard from Mr. Meyer and I will be back in touch with you once I have heard from them.

With best wishes.

Sincerely,


 Charles McC. Mathias, Jr.
 United States Senator

CM:MWC



DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

January 2, 1973

Mr. Barry I. Castleman
305 West Biddle Street
Baltimore, Maryland 21201

Dear Mr. Castleman:

This is in reply to your letter of October 24, 1972 requesting information on investigations of asbestos filters.

The Food and Drug Administration has requested several firms from the edible oil industry and the beverage industry (both non-alcoholic and alcoholic) and a representative of the asbestos manufacturing firms to attend a meeting January 4, 1973 to discuss the problem of asbestos, including the technological aspects of the use of any types or forms of asbestos in food processing applications.

If such materials are being used, we have requested that they furnish details of their use including data as to the amount of asbestos fibers present in their products and steps taken to assure the absence of asbestos in the final consumer product. They should also consider what they could use as a replacement in case it became necessary to eliminate all forms of asbestos from food and beverage processing industries.

Methodology is also being studied by Dr. Lewin, of New York University who is under contract with FDA, and Dr. Selikoff, of Mt. Sinai Hospital. While Dr. Selikoff is not under contract there has been considerable contact with him. The most promising methodology appears to be X-ray Diffraction plus Optical Microscopy. However, many problems remain on applying this methodology to the regulations of asbestos. Types of asbestos, how to report the fibers and levels of detection are some of the things to be considered plus collaboration of methodology.

Enclosure:
cy ltr sent to
Senator Mathias

Sincerely yours,

Pat T. Adamo
Assistant to the Director
Division of Regulatory Guidance
Office of Compliance
Bureau of Foods

305 West Biddle Street
Baltimore, Maryland 21201

January 5, 1973

Hon. Senator Charles Mathias
United States Senate
Washington, DC

Dear Senator Mathias:

I have just received the reply from FDA to our letters about asbestos fillers in food and beverage processing. Unfortunately the January 4 meeting they informed me about had already been held by the time I received notice, so there was no opportunity to ask that they allow a representative of the public interest to sit in.

One thing I would like to get from FDA is a listing of "... use of any types or forms of asbestos in food processing applications". It would be impossible for me or anyone outside the industry to compile such a list, without spending an enormous amount of time and using expensive instrumentation. As consumers we put a number of these suspect products through our digestive systems, and should be able to find out about the risky items whether they subsequently turn out to be prosecuted as legal infractions or not.

-15-
I would be grateful for anything you can procure from FDA's inventory of asbestos uses, especially with the additions from their meeting with food and asbestos industry representatives yesterday.

I won't go into technical criticisms of the analytical techniques named, except to say that I know of examples of both being used to report no detectable asbestos when asbestos was in fact there. Perhaps they are wary of what they would find by using electron microscope and electron microprobe techniques.

This circus of meetings and "many problems remain in applying this methodology" is just the old runaround. The food industry is potential for voluntary compliance (substitution by non-asbestos flour) if requested, and the simplicity of demonstrating the presence of this carcinogenic food additive have been demonstrated in the Baltimore County preliminary study. I hope we can get the Food and Drug Administration to take a more direct approach to protect the public's health.

Sincerely yours,

Barry J. Castleman

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JOHN H. HOLLOMAN III
CHIEF COUNSEL AND STAFF DIRECTOR

United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, D.C. 20510

January 17, 1973

Mr. Barry D. Castleman
305 West Biddle Street
Baltimore, Maryland 21201

Dear Mr. Castleman:

I was dismayed to learn that the response you received from the Food and Drug Administration concerning asbestos filters arrived too late for you to attend the Administration's planned meeting.

I have taken the liberty of contacting officials at the Food and Drug Administration once again on your behalf to express your views; as soon as I receive their reply, I will be back in touch with you.

With best wishes.

Sincerely,


Charles McC. Mathias, Jr.
United States Senator

CM:mwc



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

FEB 26 1973

Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, D. C. 20510

Dear Senator Mathias:

This replies to your request of January 17, 1973, addressed to Dr. Virgil O. Hedrick of our Bureau of Foods, for comment on a letter from Mr. Harry Castleman, Baltimore, Maryland, on the use of asbestos filters in the food industry.

We have not compiled any listing such as requested by Mr. Castleman of the types of asbestos filters which may be used in the food industry.

Asbestos is used in many facets of the food and beverage industry as filtering aids. In most food industries, polish or final filters are used, after the asbestos filter. These are made up of rayon and paper, millipore type filters, or for clarification alone filter.

Industry has advised us that they have little data available on how much asbestos is removed during processing of asbestos filters are used. Although studies indicate that beer passing through asbestos filters contains no more asbestos than the water used to make the beer, the methodology is still not validated adequately.

The study by the Canadian Food and Drug Directorate using electron microscopy has been cited by several researchers in the United States, but they have not been able to duplicate the results. One of the experts of methodology feel that electron microscopy is not reliable and is very difficult to use as a control tool.

As Mr. Castleman can appreciate, it would be useless to regulate the levels of asbestos in food if adequate methodology is not available to determine any violations that may occur.

X-ray diffraction plus electron microscopy may be the most reliable method for solids. However, sufficient work has not been done on solids to come out with an official (collaborated) method at this time. Work on beverages has not been as successful. No validation data have been obtained by analysts working on liquid foods.

Page 2 - Honorable Charles McC. Mathias, Jr.

We would appreciate any help we can get in obtaining workable methodology. Perhaps Mr. Castleman would care to volunteer data he may have available on methodology techniques. Mr. Castleman may be assured that work is continuing in trying to perfect reliable methodology.

If we can be of further assistance, please let us know.

Sincerely yours,

Gerald F. Meyer, Director
Office of Legislative Services

Enclosure
Constituent's ltr

BALTIMORE COUNTY, MARYLAND

INTER-OFFICE CORRESPONDENCE

TO William L. Phillips

Date January 23, 1973

FROM Technical Services Section

SUBJECT Asbestos Filter Study

I have just spoken with Mr. Dick Varier of Grefco, Incorporated, co. carbon filter media used in the making of beer. Mr. Varier is about to present findings on alternate filter media to the beer manufacturers in the Baltimore area and was calling to find out what regulations applied.

You will remember that I conducted an investigation with Veljean Campbell of Food Control Division last September and we found asbestos-containing filter media in use at Carling Brewery and Claret Distillery, and preliminary chemical-analytic analyses indicated contamination of the fibers in the final product.

Mr. Varier informed me that four breweries were using Grefco's DEMONSTRATION of the use of our study. Since these all four have worked on switching to a cellulose substitute which is also made by Grefco, and which is apparently satisfactory in terms of product quality. In fact, our County Insurance Board is a serious idea since many brewers to convert to the cellulose substitute in order to preempt governmental regulation and other problems.

He will be arriving in Baltimore late in February and as soon as Mr. Varier has the details he will send an invitation. In response to his question as to what the "regulations" involved were two clauses of the Federal Food, Drug and Cosmetic Act prohibiting addition of (1) poisonous or deleterious substances and (2) substances which are known causes to foods. He agreed that it is prudent not to use asbestos where safe substitutes are readily available.

BC

Barry Castleman

BC/cc

cc: Veljean Campbell, Food Control Division

ENVIRONMENTAL
DEFENSE
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1712

~~1810~~ N STREET, N.W., WASHINGTON, D.C. 20036/202 833-1485

December 14, 1972

D. Henry Simmons,
Director
Bureau of Drugs
Park Lawn Building
5600 Fishers Lane
Rockville, Maryland

Dear Dr. Simmons:

I am sure you are aware that asbestos fibers have been reported to be present in some parenteral drug preparations (Nicholson et al. Science 177 (1972) 171).

We would like to know whether in response to this report, the companies concerned have modified their production methods in such a way as to exclude this carcinogen from all injection fluids. If by chance they have not, will FDA take action to assure that they do?

We would appreciate it if you would provide us with the answers to these questions, or advise us where they can be obtained.

Sincerely,

Lucile Adamson, Ph.D.
Staff Scientist

LA:mh

Scott Lang
Washington Counsel

1712

xx

April 11, 1973

Henry Simmons,
Director
Bureau of Drugs
Park Lawn Building
5600 Fishers Lane
Rockville, Maryland

Attention: Mrs. Paisgrove

Dear Dr. Simmons:

On December 14, 1972 we sent you a letter inquiring whether FDA is taking action to insure the exclusion of asbestos from parenteral drugs, a copy of which is enclosed. As of this date - 4 months later - we have received no response.

The presence of asbestos in drugs was called to the attention of FDA approximately 2 years ago, or more. Therefore action by FDA on this matter is long overdue.

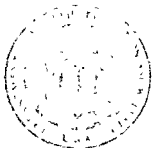
The questions contained in our original letter did not reflect idle curiosity. We would really like to know the answers to them. We believe that we have been sufficiently patient in waiting for a reply. Unless we receive a response to the re-submitted letter within one month from today, we will assume that FDA is taking no action concerning the problem mentioned, and we will act accordingly.

Sincerely,

Lucille P. Jansson, Ph.D.
Staff Scientist

Scott H. Lenz
Washington Council

Yf:ark



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

March 2, 1973

Dr. Lucile Adamson, Staff Scientist
Mr. Scott Lang, Washington Counsel
Environmental Defense Fund
1712 N Street, N.W.
Washington, D.C. 20036

Dear Dr. Adamson and Mr. Lang:

I regret the long delay in replying to your letter about asbestos in talc. Part of the delay was due to a heavy load of other responsibilities, and part was due to a hope that events might have proceeded to the point of resolution of the various questions involved. Even though this hope has not yet been realized, the lapse of time has been great enough to impel me to write as follows in response to your specific questions.

Your remarks on the health hazards of asbestos are of course well-founded; this has been of concern to us for some time. In August 1971 I organized a discussion session at FDA on asbestos in talc, which was attended by almost fifty representatives of industry, universities, and government. A major topic at the meeting was the analytical methodology for detecting small amounts of asbestos in talc. This was recognized as a difficult problem which is best attacked by a battery of four methods (optical microscopy, X-ray diffraction, electron microscopy, and electron diffraction) and possibly a fifth method, elemental analysis by electron microprobe. However, it was noted that the combined use of all the methods would be almost prohibitively expensive.

One of those in attendance at the meeting was Prof. Seymour Z. Lewin of New York University, a recognized expert on mineralogical chemistry and analysis. Some time after the meeting, I asked Dr. Lewin to undertake the analysis of samples of commercial talcum powder products for asbestos (particularly the chrysotile and tremolite varieties) by means of the X-ray diffraction technique primarily, with additional work by optical microscopy as needed. He carried out most of this work during 1972; to date he has examined 195 samples of talcum powders plus some miscellaneous samples for others at FDA.

Dr. Lewin has given us reports on his results from time to time, but we do not yet have a truly final report from him. Until we receive it, we cannot publicize the incomplete information in our possession. Dr. Lewin has written that the final report will be ready "within a few weeks" but he is a very busy man and our past experience suggests that it may not arrive until a few months from now.

Page 2 - Dr. Lucile Adamsen and Mr. Scott Lang

I hold a high regard for Dr. Lewin and the scientific quality of his work; of course, it is always necessary to maintain a critical attitude towards the results obtained by sophisticated analytical techniques. This has been particularly true in the present case, where the small amounts of asbestos involved, and the presence of transitional and altered mineralogical species, led to ambiguities in the data. In his eagerness to protect the public interest to the fullest extent, Dr. Lewin in certain cases interpreted borderline results as showing the presence of asbestos, in his earlier reports, but he later used a more conservative interpretation. He has spent a lot of time and energy in creative scientific work aimed at resolving the ambiguities (for which the public and FDA owe him a debt of gratitude) and he has succeeded for the most part. As you may know, some discussion of Dr. Lewin's earlier interpretation of the data was included in an article on asbestos in the Wall Street Journal of February 26, 1973.

Inasmuch as Dr. Lewin's results are judged acceptable, subject to the above comments, we have not undertaken a repeat survey. Because of the possibility that optical microscopy alone may constitute an acceptable technique for the detection of asbestos in talc (and is more generally available than X-ray diffraction) we are currently making a comparison between Dr. Lewin's results on selected samples and the results obtained by in-house FDA microscopists. After this comparison work is completed, a decision will be made as to the preferred procedure for detection of asbestos in talc. Details of the analytical procedure are needed for the official statement which FDA plans to issue on asbestos contamination of talc.

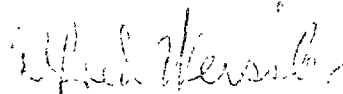
One more point should be noted, that FDA activities have already led to a substantial upgrading of the quality of talc used in cosmetic products. This is evident both from the results obtained by Dr. Lewin upon re-analyses of a given product where repeat purchases were made at retail over a period of time, and also from discussions with a principal supplier of talc who indicates that he now sells only asbestos-free grades of talc to the cosmetics industry.

With reference to your last question, FDA has undertaken extensive literature surveys on the carcinogenicity of asbestos and of talc, but the results thus far do not establish that talc itself is carcinogenic. We also have had discussions with members of the National Cancer Institute, where work is currently underway on carcinogenesis by fibers and minerals as well as other chemicals. As you probably realize, the mission and facilities of the National Cancer Institute are more appropriate than those of FDA for resolving the question of the possible carcinogenicity of pure talc; also, a period of many years will be needed to obtain the answer.

Page 3 - Dr. Lucile Adamson and Mr. Scott Lang

I trust that the above information satisfies your needs, and again express regret for the delay.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Alfred Weissler".

Alfred Weissler, Ph.D.

Acting Director

Division of Colors and Cosmetics Technology

Office of Product Technology