



MOUNT SINAI SCHOOL OF MEDICINE
of The City University of New York
FIFTH AVENUE AND 100TH STREET • NEW YORK, N.Y. 10029



Department of Community Medicine

May 9, 1972

Mr. John Tuit
Columbia Filter Company, Inc.
199 Seventh Avenue
Hawthorne, New Jersey 07507

Dear Mr. Tuit:

I am sorry that you have not yet received an answer to your letter of March 15. I had asked some of our laboratory staff to answer your specific questions; something may have gone awry. I will bring this once more to their attention.

Pending their response, I will add several comments of my own. First, the chrysotile fibers do not have a strong negative charge; this was a transcription error and was corrected in the manuscript some time ago. They have a positive charge.

Second, we have no knowledge of the source of other foreign fibers and particles, which were present in the drugs tested. These have not been identified and, failing such identification, their properties have not been explored. I believe this subject is of some importance and agree with the suggestion I infer, that investigation of such particles is in order. It would be. I accept, too, that it would be useful to investigate chemical contamination from synthetic membrane filter media. As you know, this area is one in which some research is being done, primarily insofar as tubing or containers are concerned, with plasticizers and stabilizers the objects of such study. I don't know whether filter material is also under scrutiny. Do you know whether they are? I have reviewed the question of phthalates with colleagues working in the field and find that trace amounts are not unusual in blood samples taken in some areas, although the source and significance of these findings are unstudied. I can't agree that it is important to investigate whether asbestos in parenteral drugs can cause cancer in humans; *pari passu* with administration of parenterals so contaminated. It would seem prudent to avoid such drugs.

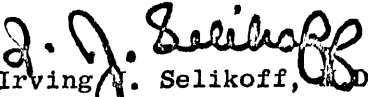
Mr. John Tuit

May 9, 1972

It is conceivable that asbestos filters could be used, because of their unique and valuable properties, provided further treatment of the filtrate would remove those fibrils that are added. This is a technical matter, however, and I am sure that you know much more about it than we do.

Finally, I don't believe that the paper claimed that we had evidence that asbestos contamination at levels mentioned constitute a threat to health. Indeed, I thought we made clear that cancers associated with asbestos in humans have so far been observed only in other circumstances, presumably at levels considerably higher than those associated with parenteral drug contamination. Indeed, we cannot even guarantee that the asbestos we have found in the particular drug samples tested by us came from asbestos filters in the production lines concerned; it is conceivable that contamination occurred at some point after filtration. However, we have ascertained that asbestos can be found in the filtrate of at least some production lines. We would be interested in such evidence as you might have that the filters made by your company do not shed fibers or fibrils to contaminate the filtrate.

Sincerely yours,


Irving J. Selikoff, Ph.D.
Professor

IJS:sa

cc: W.J. Nicholson, Ph.D.

C. Maggiore, Ph.D.

March 15, 1972

Irving J. Selikoff, M. D.
750 Broadway
Paterson, New Jersey

Dear Dr. Selikoff:

As manufacturers of asbestos-cellulose filter pads, we are interested in more details regarding your paper, "Asbestos in Parenteral Drugs."

The first item is your mention of the asbestos fibers, as used in the pharmaceutical industry, having a strong negative charge. Are you certain about this?

Further, we note that your preparation procedures were carried out with a laminar flow filtered air hood. Please advise us of the make and style unit employed, as well as the make and type of final filter used.

In your findings, you refer in passing to other foreign fibers and particles which were present in the drugs tested. To what do you attribute this, and what problems might they cause?

At this point, we do not believe that your paper presents conclusive proof that liquids may become contaminated with asbestos during filtration, or that such possible contamination at the levels mentioned constitute a threat to health.

Have you investigated the alternatives? It would be interesting to investigate the possibility of absorption of chemical contamination, such as plasticizers, from the synthetic membrane filter media also widely used. This potential may exist, and is pointed out by the recent disclosure of a situation where IV solutions have been found to absorb plasticizers from their synthetic containers, with possible harmful results.

It appears that we are at a point where asbestos media is guilty of contamination of pharmaceuticals by inference and conjecture, rather than by proof. Rather than not knowing if

Irving J. Selikoff, M. D.

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asbestos in injectables can cause cancer in humans, which is your stated preference, I think that it is important to investigate the matter thoroughly to a definitive conclusion. To prefer ignorance in this matter detracts from the credibility of your work.

If asbestos media is truly a factor in contamination of pharmaceuticals, with resultant disease, we could be the staunchest advocate of the search for a superior substitute.

We look forward to receipt of your comments, and would welcome the opportunity to meet with you to discuss the matter in detail.

Very truly yours,

COLUMBIA FILTER CO., INC.

John Tuit,
President

JT/pm



ORTHO DIAGNOSTICS

Raritan, New Jersey 08869

January 9, 1973

As we have discussed previously, we use asbestos-cellulose filter pads for processing and for final filtration of many of our biological products.

For example, asbestos filter pads have been used by most manufacturers for immune serum globulins and for normal serum albumin. These products have been used for over 30 years.

In our use of the filter pads, we use parchment backing paper and also wash the pads and press beforehand. By these means we prevent fibre particles from being in the final product.

Asbestos-cellulose filter pads are, at the present, the best means of making several of our products.

Sincerely,

Leo Zuckerman
Manufacturing Director
Biochemical Production

LZ:ps

RECEIVED

JAN 14 1973

SUMMARY OF ASBESTOS FIBER CONTENT IN COMMERCIAL BEERS

<u>Brand</u>	<u>Filtration</u>	<u>Fiber Content (μg/gal.)*</u>
SCHLITZ (regular) Sample 1	(Primary - diatomite only	0.23
SCHLITZ (regular) Sample 2	(Polish - asbestos-cellulose precoat + diatomite body feel	2.50
SCHLITZ draft	Same as regular + Millipore	2.50
RHEINGOLD extra dry	(Primary - diatomite only (Polish - asbestos-diatomite precoat + diatomite body feel	0.61
SCHMITZ	Same as Schlitz regular	1.39
NARRAGANSET	(Primary - diatomite only (Polish - diatomite only	1.14
OLD BOHEMIAN	(Primary - two stage diatomite (No polish	3.07
KAIERS	(Primary - diatomite only (Polish - diatomite only	0.24
PIELS regular	?	3.96
PIELS draft	?	0.74

*1 μ g/gal. = 1 gram in 1,000,000 gallons = 1 ounce in 2,840,000,000 gal.

All values determined by electron microscope observation. No fibers were visible in any of the samples under optical microscopic observation at 450X magnification.

J. P. LEINEWEBER
10-15-68