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October 17, 1973

MEMORANDUM

To: Rod Cameron and the Executive Committee, Lucile Adamson, Bob Harris

From: Scott H. Lang

Re: Asbestos fibers in food and drugs

A. FDA Notice of Proposed Rulemaking

The FDA has finally proposed regulations on asbestos filters and talc containing asbestos, in response to the petition filed last June by EDF and the Center for Science in the Public Interest (CSPI). FDA published EDF's proposed regulations plus a set of its own proposed regulations in the September 28th Federal Register, a copy of which is enclosed.

EDF and CSPI had petitioned the agency for four separate regulations. If the FDA's counter-proposed regulations are adopted, which I think is the best we can hope for without a court suit, we will have been granted one of our requests almost entirely, two others partially, and the fourth will have been wholly denied. The scorecard looks essentially like this:

EDF & CSPI Proposed Regulations	FDA Proposed Regulations
1. Prohibit the use of asbestos filters in processing food and beverages.	1. No action proposed.
2. Prohibit the use of asbestos filters in preparing parenteral drugs.	2. Same as EDF/CSPI, with some minor exceptions.
3. Establish a zero tolerance for asbestos fibers in talc used as a food additive.*	3. Same, except under FDA's testing procedures, some (most?) fibers would escape detection.

EDF & CSPI Proposed Regulations	FDA Proposed Regulations
4. Establish zero tolerance for asbestos fibers in talc used as a component of drugs.	4. Same, except under FDA's testing procedures, some (most?) fibers would escape detection.

*The FDA had proposed such a zero tolerance regulation in the Federal Register on August 12, 1972, more than 14 months ago. In our petition we asked the agency to promulgate a final version of that regulation immediately. Instead, the FDA has re-proposed it but in a slightly weakened version.

In addition, we had argued in our petition that since asbestos is carcinogenic when inhaled, when injected, and probably when ingested, it should be prohibited from food and beverages by the Delaney Caluse. The FDA responded in its introductory statement by minimizing the potential carcinogenicity of asbestos fibers in food and drugs, without taking any position on the health effects of ingesting asbestos, and without mentioning the Delaney Clause. It decided to regulate asbestos in food and drugs "as part of good manufacturing practices," rather than because of a risk to health. This is disappointing, because we had hoped to have the FDA on record that asbestos may be carcinogenic when ingested to help us in the Reserve Mining case in which the ingestion of asbestos is a central issue. The FDA's proposed regulations will not be much assistance to either side, however, since the agency conspicuously avoided taking a position on this issue.

The FDA's caution was probably dictated not only by the impact its decision might have on the Reserve trial, but also by the burden this might put on its own regulatory program. If asbestos in food is considered carcinogenic, then water used in food processing that contains asbestos fibers, such as Duluth water, would also be a carcinogenic food additive in violation of the Delaney Clause. Duluth is not the only major metropolitan area where millions of asbestos fibers per liter have been detected in the water supply. All food processed in these areas using public water could be contaminated. Thus, both FDA and EPA would face severe regulatory crunches if either were to publicly acknowledge that asbestos is just as lethal when ingested as when inhaled or injected. This factor has not been overlooked by top officials of either agency, I can assure you.

B. EDF and CSPI Response

EDF and CSPI must now decide what responses, if any, to make to the FDA's counterproposals. Comments are due by December 27. The Center has asked EM-Ventions, a private laboratory specializing in electron microscope research, to assist us in our comments. Jim Turner, a lawyer specializing in FDA matters, has offered to consult with us on legal strategy. (Turner is a member of EDF's Environmental Health Program Advisory Committee.) There are several significant deficiencies in the FDA's counterproposals which, in my opinion, deserve a strong response:

1. Asbestos Filters. The FDA has not proposed any regulations to prohibit the use of asbestos filters in processing foods and beverages. This is arguably a violation of the Delaney Clause. However, that issue need not necessarily be reached. The regulation of filters used in processing foods and beverages is also arguably compelled by the FDA's own policy statement on good manufacturing practices contained in the preamble to the FDA's proposed regulations on talc and parenteral drugs:

> It is therefore reasonable to require precautions to be taken in the manufacture of food and drugs, as part of good manufacturing practices, to assure that the amount of asbestos fibers in any food or drug is reduced to the minimum feasible level. 38 Fed. Reg. 27079 (emphasis added).

The failure to apply this policy to the use of filters for food and beverages is, to say the least, arbitrary and capricious.

2. Talc. More than 14 months have elapsed since the FDA initially proposed to take talc contaminated with asbestos off the GRAS list and to eliminate its prior sanction. 37 Fed. Reg. 16407 (August 12, 1972). This new proposal does nothing to advance the ball. Although the carcinogenicity of asbestos when ingested has not been positively established, there is certainly enough evidence to show that it does not meet the GRAS list criteria, i.e., "it is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures. . . to be safe under the conditions of its intended use." 21 U.S.C. 321(s). FDA regulations further specify that when the safety of a substance previously listed as GRAS is under investigation, "[t]he initial results of a new investigation, even if not convincing with respect to the potential harm, may establish that the substance in question can no longer be considered as GRAS." 21 C.F.R. 121.3(f). This would appear to apply to our case. Although there is considerable room for the exercise of administrative discretion in applying the above criteria, discretion must

be based on reason, and we can make a very strong showing that there is no sound reason for permitting talc containing asbestos to remain on the GRAS list or to retain its prior sanction any longer. The FDA's claim that it is conducting a study to determine an appropriate testing procedure is not a valid reason for delay, since the FDA has claimed to be conducting such an investigation for more than 14 months already. At some point the administrative process must arrive at a conclusion.

3. Test Procedures for Talc. The test procedures for detecting asbestos fibers in talc proposed in §121.2006(c) are deficient in several respects. Counting fibers more than 5 microns in length under a light microscope is hopelessly inadequate. In the Reserve Mining case, for example, EPA studies indicate that virtually all of the asbestos fibers involved were less than 5 microns long and require sophisticated electron microscopes for detection. The FDA's proposal is based on an AOAC (Association of Official Analytical Chemists) method that certainly has not kept pace with the recent rapid developments in asbestos detection techniques.*

Lucile Adamson and I believe there is a sound alternative to the approach taken by FDA. Not all talc deposits are contaminated with asbestos. Some are relatively pure deposits. Therefore, it might make more sense to require certification of deposits of talc which can be used for food and drug processing rather than require inadequate and expensive monitoring of each product or component. This does not conflict with our original proposal, since we did not address the question of the appropriate test methodology in our petition.

During the next few weeks, we will be exploring the issues discussed above and the possible alternative courses of action. Your individual or collective comments are most welcome. I will try to complete any comments we submit to the FDA prior to leaving the Washington office, at the latest by December 1st. Whether we take this further and go into court will depend at least to some extent on whether we can interest other staff attorneys or perhaps pro bono attorneys in the suit.

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*Jim Turner thinks this may be a suitable case to launch an attack against the AOAC, which Turner says is controlled by FDA (e.g., the AOAC office is at FDA's headquarters) and frequently used by FDA to justify the adoption of antiquated testing procedures such as the one proposed here. This is an issue Lucile and I would have missed, which demonstrates the importance of having the right people on EDF's program advisory committees.