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COMMENTS OF ENVIRONMENTAL DEFENSE FUND AND CENTER FOR SCIENCE IN THE PUBLIC INTEREST ON THE FDA'S PROPOSED REGULATIONS ON ASBESTOS FILTERS AND TALC

1. Introduction

The Environmental Defense Fund (EDF) and the Center for Science in the Public Interest (CSPI) welcome the opportunity to comment on the FDA's proposed regulations restricting the use of asbestos filters and asbestos-contaminated talc in the manufacture of food and drugs, 38 Fed. Reg. 27076 et seq. (Sept. 28, 1973). The FDA's proposed regulations were published in response to the petition submitted by EDF and CSPI on June 27, 1973, calling for an immediate end to the use of asbestos filters and asbestos-contaminated talc in food and drug manufacturing.

For all the reasons stated in their original petition and the reasons stated below, Petitioners again request the Commissioner of Food and Drugs to promulgate the proposed regulations submitted in their June 27th petition and published in the Federal Register, 38 Fed. Reg. 27076 (Sept. 28, 1973). 1/

1/ The FDA published in the Federal Register the proposed regulations submitted by EDF and CSPI in their petition, but did not publish Petitioners' statement in support of their proposals.

Although the Commissioner's own proposed regulations represent an important step in the right direction, in Petitioners' opinion they fall far short of what is required of him by law to protect the public health and safety.

2. The Commissioner's Response to the EDF/CSPI Petition

In their original petition, EDF and CSPI requested the Commissioner to publish and promulgate four regulations. These would, respectively, require the FDA to:

1. Prohibit the use of asbestos filters in all food and beverage manufacturing;

2. Prohibit the use of asbestos filters in all drug manufacturing;

3. Prohibit the use of talc as a direct or indirect additive in food and food packaging materials, unless the manufacturer first demonstrates by appropriate tests that the talc is free of asbestos particles; 2/ and

4. Prohibit the use of talc as a component of any drug or drug packaging material, unless the manufacturer first demonstrates by appropriate tests that the talc is free of asbestos particles. 3/

In response to the EDF/CSPI petition, and after a lengthy review of the scientific literature on the health hazards of asbestos exposure, the Commissioner has concluded that:

2/ EDF and CSPI did not recommend "appropriate tests" for detecting the presence of fibers in talc in their original petition. Petitioners discuss this problem, however, in these "Comments," infra, pp. 15 to 16.

> 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.

In accordance with this declaration of FDA policy, and as part of "good manufacturing practices," the Commissioner has proposed a more limited version of three of the four regulations requested by Petitioner. [3/] These would:

1. Prohibit the use of asbestos filters, or require membrane filtration following asbestos filtration, in the manufacture of parenteral drugs and parenteral drug ingredients;

2. Prohibit the use of talc as an additive to food or food packaging material, unless the manufacturer determined, after viewing under the light microscope at 400X, that a milligram of such talc contained less than 1000 amphibole asbestos fibers or 100 chrysotile asbestos fibers greater than 5 microns in length; and

3. Prohibit the use in drugs of talc containing asbestos, as determined by the same test procedure proposed for detecting asbestos fibers in talc used in food.

The differences between Petitioners' proposed regulations and those proposed by the Commissioner can be briefly summarized as follows:

1. Asbestos filters

   -- EDF and CSPI would prohibit all use of asbestos filters in food and drug manufacturing.

3/ The Commissioner has proposed no regulations governing the use of asbestos filters in food and beverage manufacturing or in the manufacture of non-parenteral drugs.

-- FDA would prohibit and/or substantially reduce their use only in the manufacture of parenteral drugs and parenteral drug ingredients, but continue to permit their use in the filtration of all foods, beverages, and non-parenteral drugs.

2. Talc

-- EDF and CSPI would prohibit the use of talc

-- FDA would permit the use of talcs containing small amounts of asbestos fibers as determined by optical microscopy. FDA, in effect, has proposed a "tolerance" for asbestos fibers in foods and drugs.

These differences are obviously significant and are discussed in more detail below.

3. The Commissioner's Proposed Regulations on Asbestos Filters are Internally Inconsistent

The Commissioner's unexplained decision to impose restrictions on some but not all uses of asbestos filters in food and drug manufacturing is perplexing and apparently quite arbitrary. The Commissioner has failed to explain why, in his judgment, there is sufficient medical evidence to prohibit the addition of asbestos-contaminated talc to any food or drug and to prohibit the use of asbestos filters in the manufacture of parenteral drugs, but not to prohibit the use of asbestos filters in the manufacture of foods, beverages and non-parenteral drugs.

This is an inconsistency which obviously requires explanation if the Commissioner's proposed regulations are to withstand judicial scrutiny. It seems axiomatic that all avenues by which asbestos may enter the body through foods or drugs should be subject to the same or equal restrictions by the FDA, unless there is a clear scientific basis for treating them differently. If the Commissioner has deemed parenteral drugs to be "adulterated" from asbestos filters within the meaning of section 501(a) of the Act, 21 U.S.C. 10.1, and foods to be "adulterated" from asbestos in talc within the meaning of section 402(a) of the Act, then what are his grounds for maintaining that foods and non-parenteral drugs that are equally contaminated when they are filtered through asbestos filters are safe under those same statutory provisions? At the very least the Commissioner is required to explain these apparent inconsistencies. In our opinion, however, they cannot be rationally explained.

Petitioners have urged and the Commissioner has agreed at least in principle, that "the amount of asbestos fibers in any food or drug [should be] reduced to the minimum feasible level." 38 Fed. Reg. at 27079 (emphasis added). The Commissioner, however, points out in a lengthy review of the evidence

concerning the possible hazard from inhalation, injection or ingestion of asbestos fibers, 38 Fed. Reg. at 27076-27079, that:

> Asbestos fibers thus are ubiquitous in air, water and a large percentage of the earth's crust. The amount of this material which additionally is added to the environment and to food and drugs by the use of asbestos filters is not known. Therefore it is obvious that the presence of asbestos in these products is only one small source of exposure. Id., at 27077.

This non sequitur seems to be the rationale for his decision not to prohibit the use of asbestos filters in the manufactured foods, beverages and non-parenteral drugs. But this rationale is deficient for at least three reasons. First, he has not presented data to show that the amounts contributed by filters are in fact "small." Second, the Commissioner lacks data to show that even small amounts of asbestos are harmless to health. And third, even assuming, arguendo, that asbestos filters are "only one small source of exposure," and that such a small amount may not be harmful in itself, it does not follow logically that the responsibility of the Food and Drug Administration is somehow lessened. If anything, the fact that there are so many other sources of asbestos to which modern man can be exposed argues strongly

in favor of prohibiting those few non-essential uses that can easily be dispensed with such as the use of asbestos filters in food and drug manufacturing. Other federal agencies are required to do their part in controlling many of the other uses of asbestos. See Petition, pp. 12-13. If every federal agency shrugged off its responsibility with the nonchalant attitude of the FDA, this ubiquitous hazard would never be controlled.

Petitioners recognize that the Commissioner lacks authority to control many sources of asbestos, such as air and water pollution, which may accidentally contribute asbestos fibers to food and drug products. Petitioners seek only to have the Commissioner exercise that authority which he undeniably does have, i.e. to keep potentially hazardous agents such as asbestos from being intentionally added to food and drugs by food and drug manufacturers. This is strictly in accordance with the Commissioner's non-delegable, non-discretionary duty to prohibit the adulteration of foods and drugs moving in interstate commerce. It is also in accord with the policy that he himself announced in the Federal Register Notice: that it is "reasonable" to require that "the amount of asbestos fibers in any food or drug [be] reduced to the minimum feasible level." Supra, p. 3 . We can see no rational basis for not applying this policy with an even hand to all uses of asbestos filters for foods and drugs.

4. The Weight of the Available Evidence Favors the Conclusion that Ingestion of Asbestos Fibers Leads to an Increase in Gastrointestinal Cancers.

In response to the EDF/CSPI petition, the Commissioner prepared an extensive review of the scientific literature concerning the hazards of inhaling, injecting and ingesting asbestos fibers. 38 Fed. Reg. at pp. 27076-27081. From this review, the Commissioner concluded that "the evidence concerning the possible hazard from ingestion of asbestos particles is contradictory and inconclusive." Id., at 27077.

Petitioners disagree with this characterization of the available evidence. Contrary to the Commissioner's conclusion, the available evidence certainly establishes at least a strong presumption that asbestos is carcinogenic when ingested. For example, long-term epidemiological studies of asbestos workers have consistently shown an increased incidence of gastrointestinal tract cancers over that of the general population. See, e.g., the studies by Selikoff et al., and by Elms and Simpson cited in our June 27th petition, p. 10. See also P. Enterline, P. DeCoufle, and V. Henderson, "Mortality in Relation to Occupational Exposure in the Asbestos Industry," J. of Occup. Med., Vol. 14, Dec. 1972, pp. 897-903. And see other articles cited on p. 9 , infra. This evidence is sufficient for a regulatory agency to conclude that ingestion of asbestos fibers may contribute to the incidence of gastrointestinal tract cancers.

Dr. Selikoff has testified that this is his firm belief. Most recently, Dr. Joseph Wagoner, Director of the Division of Field Studies and Clinical Investigation, the National Institute for Occupational Safety and Health, Department of Health, Education and Welfare, has testified that he is also of the considered opinion that ingestion of asbestos fibers is a carcinogenic hazard. Transcript of Proceedings, United States, et al. v. Reserve Mining Company, et al., No. 5-72 Civil 19, U.S. District Court, District of Minnesota, Fifth Division, Vol. 31, pp. 4371-4537. Dr. Wagoner cited six studies which he believes support his opinion. 4/ These studies all indicate that the incidence of G.I. cancer among asbestos workers is significantly higher than that for the population as a whole.

4/ These studies include:

1. P.C. Elms and M.J.C. Simpson, "Insulation Workers in Belfast, III, 1940-1966", Brit. J. of Indust. Med., Vol. 28, pp. 226-236 (1971);
2. E.E. Keal, "Asbestosis and Abdominal Neoplasms," Lancet, Vol. 2, (1960), p. 1210;
3. P.E. Enterline and M.A. Kendrick, "Asbestos-Dust Exposures at Various Levels and Mortality," Arch. Envir. Health, Vol. 15, pp. 181-186 (1967);
4. M.L. Newhouse, "Cancer Among Workers in the Asbestos Textile Industry," presented at the Lyons Conference, Oct. 2-5, (1972);
5. I.J. Selikoff, E.C. Hammond, and J. Churg, "Carcinogenicity of Amosite Asbestos," Arch. Envir. Health, Vol. 25, Sept. 1972, pp. 183-186; and
6. J. Wagoner, "A Report of the U.S. Public Health Service on the Incidence of Site Specific Cancer Among Asbestos Textile Workers Based on Observations Over the Period from 1940 to 1967".

It is quite striking that none of these references appeared among the 52 references listed by the Commissioner in his review of the medical evidence published in the Federal Register. At least two of these papers were referred to by Petitioners in their June 27th Petition. See Petition, p. 10. It is indeed puzzling that the Commissioner should cite earlier reports by some of these same authors as well as several "unpublished" animal feeding studies that were negative, while disregarding the more recent published evidence of cancer of the G-I tract among humans exposed to asbestos. The Commissioner, therefore, appears to have based his assessment of the evidence on an incomplete and distorted record of the medical evidence. Perhaps had he consulted these other studies he might have come to a different conclusion concerning the potential harm from ingestion of asbestos. We strongly urge him to consider them now.

Some researchers may speculate that the excess of G-I cancers among workers is not from ingestion but rather from the migration of fibers inhaled into the lungs, where they pass into the bloodstream and into the G-I tract. Dr. Selikoff, Dr. Wagoner and others, however, maintain that workers who are exposed to dust in the atmosphere also ingest many fibers which are removed from the lungs by mucociliary clearance and swallowed. The latter position is supported by several animal

studies cited by FDA. See, in particular, References 42 and 44, 38 Fed. Reg. at pp. 27078-27079. There are no comparable studies cited by FDA which would support the contrary theory that workers do not ingest significant numbers of fibers or that gastrointestinal cancers are caused by fibers which migrate directly from the lung through the tissues to the gastro-intestinal tract.

The position of Selikoff, Wagoner and others, that ingested asbestos is harmful received even further support at a recent conference on "Biological Effects of Ingested Asbestos" sponsored by the National Institute for Environmental Health Sciences, November 18-20, 1973. Dr. Volkeimer and Dr. Zaidi pointed out at that conference that submicroscopic particles are able to rapidly penetrate the lining of the gastrointestinal tract and are "persorbed" into the blood and lymph systems. Co-factors such as nicotine and caffeine apparently facilitate "persorbtion," presumably by attacking the mucous barrier. These multiple-factor conditions, which more nearly reflect human experience, were contrasted with Swinburn's unpublished rat feeding experiments using asbestos in butter, cited by the FDA, Ref. 40. Butter, it was believed, helps to naturally coat the intestinal walls and hinder persorbtion of micro-particles. Pontefract also reported at the conference the preliminary results of his unpublished study in which rats were fed 1% asbestos in their diet in

corn oil. Three of the 9 rats developed tumors, which is the first experimental evidence that ingested asbestos is harmful. See J.E. Brody, "Conferees Study Asbestos Hazard," New York Times, Nov. 11, 1973, p. 32 (Attachment "A").

Therefore, while the evidence now available may not be sufficient to establish unequivocally which is the valid explanation for the increase of gastrointestinal cancers among asbestos workers, the weight of the evidence certainly favors the conclusion that this increase may well be due to ingestion. At the very least, there is enough evidence to establish a presumption that ingestion of asbestos fibers represents a potentially grave health hazard. The Commissioner apparently agrees with this conclusion, or he would not have proposed restrictions on the use of asbestos-contamined talc as a food additive. And he would not have declared an FDA policy of reducing exposure to asbestos to the "minimum feasible level." See page 3, supra. It is almost impossible, therefore, to explain his failure to apply his conclusions to the filtration of foods, beverages, and non-parenteral drugs through asbestos filters.

5. The FDA's Proposed Test for Detecting Fibers in Talc is Illegal and Inaccurate

a. Illegality

The FDA has recommended the use of polarized optical microscopy as the method for detecting the presence of asbestos

fibers in talc. Under this test procedure, only fibers greater than 5 microns in length and less than 5 microns in width will be counted. A talc sample that contains not more than 1000 such amphibole fibers and/or not more than 100 such chrysotile fibers per milligram will pass the FDA's test and be permitted for use in food and drugs. According to the FDA, this test procedure will "assure a purity of talc at least 99.9 percent free of amphibole types of asbestos and at least 99.99 percent free of chrysotile asbestos fibers." 38 Fed. Reg. at 27080.

Not only will this test not assure the degree of purity claimed by the FDA, but even assuming that it did, it would probably still permit the addition of perhaps millions of asbestos fibers less than 5 microns in length per milligram of talc to enter the body through the diet or through drugs. 5/

The net effect of this test procedure is to set a permissible level or "tolerance" for asbestos fibers in food. Asbestos, however, is a carcinogen, and one for which there is still no known safe exposure level. The FDA's proposed

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5/ See I.J. Selikoff, W.J. Nicholson, and A.M. Langer, "Asbestos Air Pollution", Arch. Envir. Health, Vol. 25, 1972, p. 10, for a rule of thumb that one nanogram of chrysotile may contain about 1,000,000 tiny fibrils 300-400 Å in diameter and 2,000 Å in length.

tolerance, therefore, would not be legally permissible under Section 409(c)(3)(A) of the Food, Drug and Cosmetic Act, 21 U.S.C. 348(c)(3)(A), which prohibits the promulgation of a regulation establishing such a tolerance --

> (c)(3) . . . if a fair evaluation of the data before the Secretary --
>
> > (A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or it is found, after tests which are appropriate for the evaulation of the safety of food additives, to induce cancer in man or animal.

Petitioners submit that there has been no evidence presented to or by the Commissioner that establishes that even a fraction of a milligram of asbestos can be safely ingested. To the contrary, "a fair evaluation of the data" appears to establish at least a strong presumption that asbestos fibers are carcinogenic when ingested, as they are when inhaled. Therefore, until such time as "tests which are appropriate for the evaluation of the safety of food additives" are conducted and show that asbestos is not carcinogenic, it seems quite clear that the law does not permit the Commissioner to set the kind of tolerance for asbestos fibers in food-grade talc which he has in fact proposed.

b. Inaccuracy

Even assuming, arguendo, that the FDA's tolerance for asbestos fibers in talc were legally permissible, it would still be insufficient because the recommended test procedure is incapable of accurately measuring the number of asbestos fibers present in talc. The recommended procedure utilizes only an optical microscope and is designed to count only fibers greater than 5 microns in length. This is about the limit of fiber size that can be detected with an optical microscope at 400X. This would be acceptable if one of two conditions prevailed: either (1) the vast majority of fibers in talc were greater than 5 microns; or (2) the fiber size distribution were uniform enough to predict with reasonable accuracy the total number of fibers given only the number greater than 5 microns in length. Unfortunately, neither condition prevails. The likelihood is that the vast majority of fibers in talc, particularly talc that is crushed prior to commercial sale, are less than 5 microns in length and will go unnoticed under the FDA's recommended procedure. There is also no way to predict the total number of fibers present with any degree of certainty, if only the number greater than 5 microns is known, since both fiber content and fiber size distribution are subject to substantial variations in given talc deposits. These conclusions were confirmed at the recent

conference on "Biological Effects of Ingested Asbestos". Dr. Rohl, of Mount Sinai School of Medicine in New York, stated that optical microscopy is incapable of quantifying the amount of asbestos in talc because the majority of fibers present are less than 5 microns in length. The optical microscope, therefore, should not be used as a tool for quantifying asbestos in talc. 6/

Thus, the FDA's test procedure is not capable of achieving the degree of accuracy required to meet the agency's proclaimed goals of talc purity -- 99.9% free of amphibole asbestos fibers and 99.99% free of chrysotile asbestos fibers. Just as there is no data supplied by the Commissioner to substantiate the safety of these goals (or tolerances), there is also no data presented to substantiate the degree of accuracy proclaimed for the test procedure. Thus, the entire talc standard, including the monitoring requirements, seems to be based on no more than guesswork, which runs counter to the rapidly accumulating knowledge we now have about the effects of asbestos on health and the great difficulty of quantifying the number and size distribution of fibers present in talc.

6/ See "Comments Pertaining to the FDA Publication in the Federal Register Vol. 33, #188, September 28, 1973, section 121.2006, Paragraph C," prepared by EMventions, office of the hearing clerk, November, 1973.

CONFEREES STUDY ASBESTOS HAZARD

125 From 13 Countries Find That Lethal Mineral Is Present Everywhere

By JANE E. BRODY

DURHAM, N.C.—More than 125 scientists from 13 countries gathered here in the midst of the tobacco country last week to grapple with an urgent public health question: What risk does the general public face from the ingestion of asbestos, a mineral of a thousand uses whose potentially lethal fibers pervade the human environment?

In three days of intense discussion and debate, no final conclusions were reached, a few worrisome preliminary findings were presented and hundreds of as-yet unanswered questions were raised.

Only two facts went unchallenged: that abestos is everywhere—in the air, in waterways, in drinking water, in foods and beverages, drugs and talcum powder; and that when inhaled in large quantities, asbestos is dangerous, causing incapacitating lung disease and highly lethal cancers.

The conference, called by the National Institute of Environmental Health Sciences, was prompted largely by the discovery earlier this year that the drinking water of Duluth, Minn., and other cities on Lake Superior was heavily contaminated with asbestos, the presumed result of pollution by a mining company that has been dumping 67,000 tons of rocky waste into the lake each day for 17 years.

The Government is seeking to end the dumping of these asbestos containing wastes into Lake Superior in an action currently being heard in United States District Court in Minneapolis. But what can and what should it do about the countless other sources of asbestos contamination?

"Asbestos represents a classic problem that our modern industrial society will face over and over again," remarked Dr. David R.F., director of the National Institute. "It's a vital substance, so we can't ban it, but there's a growing concern about its possible health effects."

And since the health effects of asbestos often do not show up until 20 to 30 years after initial exposure, "even if we stop all asbestos exposure today, we will continue to see evidence of disease well into the next century," said Dr. Robert Burrell, a microbiologist at West Virginia University.

Virtually all the reliable information about the harm asbestos can wreak on the human body is derived from the experience of asbestos workers who have inhaled large quantities of the fibers.

In addition to succumbing to the chronic lung disease asbestosis, these workers are far more likely than the general population to die from lung cancer and mesothelioma, an incurable cancer that affects the lining of the chest or abdomen.

Recently Dr. Irving J. Selikoff, who directs a Federally sponsored asbgestos research center at Mount Sinai Medical Center, reported that asbestos workers also had an increased risk of developing cancer of the gastrointestinal tract.

An estimated 100,000 new cases of gastrointestinal cancer will be diagnosed in the United States next year, and although it is the nation's most common type of internal cancer, its cause remains unknown.

A big question explored at last week's meeting was how inhaled asbestos might damage the digestive tract. Dr. Sidney Laskin of New York University noted that 25 to 50 per cent of inhaled particles were likely to be coughed up and then swallowed.

Intensive studies of the effects of asbestos consumption on a variety of experimental animals are just getting under way. But preliminary findings presented to the meeting indicate that the fibrous mineral can pass through the wall of the small intestine, get into the bloodstream and lymph system and become widely distributed throughout the body organs, including the brain.

Dr. Selikoff said that an unexpectedly large number of asbestos workers he has been studying had died of brain tumors, although the significance of this observation was not yet clear.

A pilot study conducted in Canada resulted in kidney and chest-wall tumors in three of nine rats fed asbestos mixed with corn oil, although none of the animals given corn oil alone developed cancer.

Dr. Gerhard Volkheimer of Berlin reported that particles similar to asbestos fibers were "resobed" between cells of the gastrointestinal tract much more rapidly after the consumption of caffeine or nicotine. He said that resorbed particles could be found in breast milk and could cross the placenta to the fetus.

Dr. John Goldsmith of the National Cancer Institute urged that "all unnecessary sources of asbestos be eliminated." Toward this end, the Center for Science in the Public Interest and the Environmental Defense Fund have requested a ban on asbestos filters, used to process many beverages and drugs, and elimination of asbestos from talc, used in foods as well as in cosmetic powder.

N. Y. Times
Nov. 25, 1973