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TOPICS FOR MEETING WITH
DR. ALEXANDER M. SCHMIDT ON OCT. 18, 1973

1. The proposed regulations on talc published on August 12, 1972 and as republished on September 28, 1973 are ill-founded and not consistent with the facts.

2. The assumptions made and conclusions reached by FDA in August 1972 proposal were not valid and are wholly unsupportable; such as

   (a) Since asbestos is carcinogenic when inhaled, it may be injurious to health when ingested.

   (b) Talc can be processed to remove asbestos.

   (c) Asbestos contained in talc used in food packaging materials will migrate into food.

3. No evidence offered by FDA to support these assumptions and conclusions, except for reference to article by Dr. R. R. Merliss in Science (Sept. 17, 1971), in which Dr. Merliss attempts to show a causal relationship between the use of talc-polished rice and the high incidence of gastric cancer in Japan. The data used for this purpose is spurious, to say the least.

Wright

4. No other medical-scientific evidence offered by FDA in either proposals to prove that the ingestion of asbestos, and particularly tremolite, is injurious to health. As a matter of fact, the studies cited by FDA in the September 28 proposal indicate that ingestion is not injurious, based on the animal studies reported.

Wright

5. No one in the medical-scientific community has concluded that asbestos, when ingested is carcinogenic. Even in those studies where there is some suspicion that ingestion of asbestos may result in a higher incidence of gastrointestin cancer, this suspicion arises only in cases involving individuals most highly exposed to asbestos in occupational settings.

6. FDA has chosen to ignore all of the comments filed by J-M and others in response to FDA's August 1972 proposal. We are distressed with this fact. Why did FDA choose only to respond to the EDF-CSPI joint petition?

① Dan Shrake Schmidt

7. There are many valid points raised and studies cited by J-M in its comments, to which FDA has not responded:

   (a) All forms of asbestos do not react in the same biological way.

   (b) There is no health hazard resulting from ingestion of tremolite. Supporting evidence for this is in Dr. Morris Kleinfeld's on-going epidemiological study of New York State talc workers. There is an absence of evidence, even of a weaker association, in those persons exposed to anthophyllite mining and milling or to tremolite in the occupation of mining and milling commercial talc. There is further supporting evidence in the animal experiments of Dr. William Smith.

   (c) The more strongly cancer-associated forms of asbestos, namely crocidolite and amosite, do not exist in commercial talc. Both tremolite and anthophyllite have been shown to be free of association with an excess of either mesothelioma or gastrointestinal cancer.

   (d) Tremolite contained in talc used in food packaging material does not migrate into food.

   (e) There is a dose-risk relationship between exposure to asbestos and the possibility of a carcinogenic effect, and this risk is also related to the type of fiber exposure.

   (f) Talc cannot be processed to remove asbestos.

8. The test method proposed by FDA for identifying the presence of asbestos in talc is not a scientifically valid test method and the limits established by this method assure a degree of purity far greater than 99.9% for amphiboles and 99.99% for chrysotile.

9. What is the medical-scientific foundation for the limits on the number of asbestos fibers permissible in talc under FDA's proposed test method? No such evidence has been offered by FDA.

10. No medical-scientific evidence, i.e., medical studies, offered by FDA in its September 28, 1973 Notice in support of its talc proposal. All of the studies cited relate to the asbestos filter issue. Why was no reference made to studies on talc, i.e., Dr. Morris Kleinfeld and Dr. William Smith.

11. No evidence offered by FDA to even attempt to prove that asbestos contained in talc used in food packaging material will migrate to food.

12. Based on FDA's actions thus far, we have no choice but to conclude that the FDA's actions are not well founded in fact, but may solely be a reaction to pressure from EDF and CSPI, whose petition is ill-founded, to say the least.

    (a) Studies cited in petition relate to insulation workers most heavily exposed to asbestos, in occupational settings, for prolonged periods of time.

    (b) No studies cited in petition relating to effect of ingestion of tremolite. These studies conspicuously missing.

    (c) Critique of EDF-CSPI petition by Dr. Wright.

13. The portion of FDA's September 28th proposal which presents the Commissioner's conclusions is quite disorganized and conspicuously omits reference to many relevant studies

    (a) Critique by Dr. Wright on FDA proposal.

14. If FDA intent on promulgating this proposal as a permanent regulation as soon as a test method is validated, it may well destroy the U.S. talc industry. J-M's talc does not pass the FDA proposed test method and the talc of other talc producers does not pass. Without a food packaging material market, there is no way J-M can economically remain in the talc business.