Letter to the Editor

Response to "Assessment of Health Risk from Historical Use of Cosmetic Talcum Powder"

To the Editor:

Anderson et al. discounted the finding of four anthophyllite fibers in three of 18 talc samples:[1]

> No asbestos fibers were detected in any of the 18 samples analyzed. Of the 18 samples, two samples contained one fiber, and a third contained two fibers, which were initially reported as anthophyllite asbestos, noting that this classification was inconclusive due to the small number counted.

Documents released through deposition testimony have revealed that this explanation is misleading. Mark Floyd, the Analytical Microscopy Supervisor who was hired by Exponent to perform the analysis, classified the fibers as anthophyllite in his initial report. Author Patrick Sheehan directed Floyd to alter the report and add the qualification that "…this classification was inconclusive due to the small number counted."[1]

Floyd labelled two fibers from Sample S3-3-MR as "anthophyllite" in the initial report dated June 21, 2011. Figure 1 shows the initial report for the fiber identified in grid opening I9. [2] (Figure 1)

Following this first report, Patrick Sheehan, a toxicologist, emailed Floyd, "Please provide the lab report and micrographs and spectral composition for the 4 **anthophyllite** fiber identified. [sic] If you have any raw data sheets for these fibers, I would also like copies of these." [3] [Emphasis added]

Sheehan asked Floyd to, "Please resend with anthophyllite replaced with transition in the header."[2] Floyd complied. The same results for the two fibers in Sample S3-3-MR appeared in

the revised report dated October 28, 2011, but with the heading changed to "transition fiber." The altered report for the fiber in grid opening I9 is shown in Figure 2.[4] (Figure 2)

Footnote 3 of Exponent's report to Colgate-Palmolive reflects Patrick Sheehan's rationale for reclassifying these fibers. In a related email to Floyd, Sheehan wrote:[5]

> Below are two proposed alternatives for footnote 3. The current classification statement is not sufficiently clear to me and appears unnecessary. I believe that the final statement may also be misleading as written and may not be necessary. Are either of the two alternatives acceptable or could they be modified to be acceptable?
>
> Anthophyllite (AN) was the only amphibole or serpentine mineral type detected, and only **in some samples**. The classification of the anthophyllite fibers as asbestos **is inconclusive due to the small number of fibers** found at the specified analytical sensitivity which is approximately 5 fold below the applicable method detect limit for atmospheres free of interferences.
>
> Anthophyllite (AN) was the only amphibole or serpentine mineral type detected, and only **in some samples**. The classification of the anthophyllite fibers as asbestos **is inconclusive due to the small number of fibers found** based on the number of grid openings that were required for analysis to meet the specified analytical sensitivity of approximately 0.002 f/cm. [Emphasis added.]

After several email exchanges, Mr. Floyd issued a new report which incorporated not only the revised heading for Sample S3-3-MR (shown above) but also the bolded sections suggested by Mr. Sheehan. .[4, 6] Footnote 3 now read: "Anthophyllite (AN) was the only regulated asbestos type detected and only **in some sample**s. This classification of the AN fibers as asbestos **is inconclusive due to the small number counted**." [Emphasis added.][4]

Changing reports was not a standard practice for Floyd. At his deposition, he testified that his clients suggest language changes less than 1% of the time. Floyd admitted that, had Sheehan not requested modifications, he would have used the "boilerplate" language from his initial report. Despite the information in the revised report, Floyd testified that, by his method, asbestos was counted in the sample.[6]

Sheehan's requested revisions appear to have supported the intended use for Floyd's reports. In another email, Sheehan told Floyd:[7]

> Subject: SAED micrographs
>
> Thanks for the reply. Please remember that we need sufficient quality pictures to document the transitional nature of these three fibers as **this report will be used in future litigation cases**. Let me know if you are having trouble finding a scope and camera setup to use. [Emphasis added.]

As demonstrated here, Anderson et al.'s explanation for the reclassification of the anthophyllite fibers is misleading. Floyd, the microscopist who examined the samples, originally identified the fibers as anthophyllite. Sheehan, not Floyd, directed both the change in fiber classification and

the rationale for this revision. This was done in the explicit context of pending litigation against Colgate-Palmolive.

Anderson et al.'s risk assessment section begins with, "No asbestos fibers were conclusively identified resulting in no associated health risk, " contradicting long-standing admissions by the talc industry that, prior to 1976, talc used in cosmetics had "significant" asbestos content.[1, 8] The National Toxicology Program (NTP) considered adding "non-asbestiform" talc to the 10th and 12th Report on Carcinogens (RoC), based primarily on a series of epidemiologic studies that showed an elevated risk of ovarian cancer in talc users. Talc mining and product manufacturing companies and their trade organization argued that the epidemiological studies could not be used to evaluate "non-asbestiform" talc because talc manufactured prior to 1976 contained asbestos, a known ovarian carcinogen. Due to talc's extended shelf life and the lack of product recall, exposure to pre-1976 talc products extended though the 1980s and beyond.[8-13] Asbestos exposure from consumer talc powders is ongoing in part because the X-ray powder diffraction (XRD) screening step of the CTFA test method had a level of detection of 1-4% and was restricted to tremolite.[9, 13, 14]

For example, in response to the NTP's review of "non-asbestiform" talc for the 10th RoC, the Cosmetic, Toiletry, and Fragrance Association (the CTFA, now the Personal Care Products Council) wrote the following:[10]

> Second, contrary to the claim that the epidemiologic studies have evaluated exposure to talc that is "presumably cosmetic grade," *(i.e.,* non-asbestiform) there are at most only indirect and imprecise data on the risk associated with non-asbestiform talc. That claim is only inferred, based on exposure that took place after 1976. However, supplies of talc-

> containing powders may commonly have been stored before they were sold, after which they may then have been used for appreciable periods of time before fresh supplies were purchased. Thus the inference that after 1976, exposure was to non-asbestiform talc, may not be justified. **All that can be assumed is that at some unknown time after 1976, the ratio of the use of asbestiform to non-asbestiform talc presumably declined.** [Emphasis added]

The CTFA submitted the same argument in response to the NTP's review of talc for the 12th RoC.(11)

Luzenac America, a major talc supplier, wrote to the NTP with a similar admission during their review for the 10th RoC:(12)

> "Although talc's [sic] can be virtually free of fibrous materials, they also have been reported to contain asbestos fibers in quantities sometimes constituting almost half the total product weight (Dement and Zumwalde 1979). Surveys published in the late 1960s and 1970s reported that talcum powders contained measurable amounts of chrysotile,
>
> tremolite, and anthophyllite fibers that may be of asbestiform nature (Rohl et al. 1976). However, the purity of cosmetic talc appears to have improved as a result of voluntary guidelines proposed by the cosmetic industry in 1976 (see Section 2)." [Emphasis in original.]

The Center for Regulatory Effectiveness (CRE), an organization contracted by the CTFA and Luzenac, made the argument most forcefully:(8)

> **Prior to promulgation of a talc purity standard by the Cosmetic, Toiletry, and Fragrance Association in 1976, there was substantial evidence that some brands of cosmetic talc powder were contaminated with significant quantities of asbestos.** All of the epidemiologic studies of ovarian cancer considered during the 10th RoC reviews as possible support for listing involved pre-1976 exposures. Since there is no evidence that cosmetic talc currently used in the United States is contaminated with asbestos, and avoiding any such contamination is a commercial reality and is required by companies which use talc in their products, the studies involving such pre-1976 exposures cannot be used as a basis for listing in the RoC. [Emphasis added]

The many industry-based reports of talc powders containing asbestos prior to 1976 contradict Andersons et al.'s findings that Colgate-Palmolive products made in the 1960s and 1970s were essentially asbestos-free.

Finally, Anderson et al. claim that their paper is an "Assessment of Health Risk from Historical Use of Cosmetic Talcum Powder." However, they restrict their analysis to the issue of asbestos content, ignoring other well-defined and accepted risks of talc-related medical problems among users, like fatal aspiration and talcosis.[15-21] Anderson et al. also ignore a body of literature that indicates that "cosmetic talc" is a cause of ovarian cancer. As noted above, the talc mining and manufacturing companies argued that these studies were confounded by the fact that talc in cosmetics contained asbestos. Further, risks should not be isolated from benefits and reasonable alternatives. "Cosmetic talc" sold as dusting powders have no demonstrated health benefits. Moreover, there are safer substitutes that would eliminate both the asphyxiation and cancer risks. Roll-on talc powders are available for adult use and dustless baby powder is

available for infants.[22] Finally, corn starch has been used in cosmetic powders for decades. It is indisputable that corn starch does not contain asbestos and, if applied with an applicator, will not result in fatal aspiration.

Disclosure: The author has been retained in asbestos and talc toxic tort litigation at the request of injured consumers and workers and at the request of asbestos product manufacturing companies defending similar cases.

REFERENCES:

1. Anderson EL, Sheehan PJ, Kalmes RM, Griffin JR. Assessment of Health Risk from Historical Use of Cosmetic Talcum Powder. Risk Analysis. 2016:n/a-n/a. doi: 10.1111/risa.12664.

2. Deposition of Mark Floyd. Exhibit 42: Email from Patrick Sheehan to Mark Floyd dated May 1, 2012. In Re: New York City Asbestos Litigation. Dec. 4, 2012.

3. Deposition of Mark Floyd. Exhibit 35: Email from Patrick Sheehan to Mark Floyd dated August 11, 2011. In Re: New York City Asbestos Litigation. Dec. 4, 2012.

4. Deposition of Mark Floyd. Exhibit 2: Exposure Simulation for Historical Talcum Powder Report, May 2012. In Re: New York City Asbestos Litigation. Dec. 4, 2012.

5. Deposition of Mark Floyd. Exhibit 34: Email from Patrick Sheehan to Mark Floyd dated August 2, 2011. In Re: New York City Asbestos Litigation. Dec. 4, 2012.

6. Deposition of Testimony of Mark Floyd. Page 237-244. In Re: New York City Asbestos Litigation. Dec. 4, 2012.

7. Deposition of Mark Floyd. Exhibit 39: Email from Patrick Sheehan to Mark Floyd dated April 19, 2012. In Re: New York City Asbestos Litigation. Dec. 4, 2012.

8. Letter from William G Kelly of CRE, to Dr. CW Jameson of the NTP. Dated July 16, 2004.

9. Gordon R, Fitzgerald S, Millette J. Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women. International Journal of Occupational and Environmental Health. 2014;20(4):318-32.

10. Letter from Gerald McEwen, VP of Science for the CTFA, to Dr. Mary Wolfe, Executive Secretary of the NTP. Dated November 30, 2000.

11. Letter from Gerald McEwen, VP of Science for the CTFA, to Dr. CW Jameson of the NTP. Dated July 14, 2004.

12. Letter from Daniel D. Harris, President of Luzenac America, to Dr. CW Jameson of the NTP. Dated May 1, 2001.

13. Letter from Daniel D. Harris, President of Luzenac America, to Dr. CW Jameson of the NTP. Dated July 16, 2004.

14. Rohl A. Asbestos in Talc. Environmental Health Perspectives. 1974;9:129-32.

15. Nam K, Gracey D. Pulmonary Talcosis From Cosmetic Talcum Powder. JAMA. 1972;221(5):492-3.

16. Weiss B, Boettner E. Commercial Talc and Talcosis. Archives of Environmental Health. 1967;14:304-8.

17. Molnar JJ, Nathenson G, Edberg S. Fatal Aspiration of Talcum Powder by a Child. New England Journal of Medicine. 1962;266(1):36-7. doi: doi:10.1056/NEJM196201042660110. PubMed PMID: 14475255.

18. Brouillette F, Weber M. Massive Aspiration of talcum powder by an infant. CMA Journal. 1978;119:354-5.

19. Cotton W, Davidson P. Aspiration of Baby Powder. The New Englad Journal of Medicine. 1985:1662.

20. Hughes W, Kalmer T. Massive Talc Aspiration - Successful Treatment with Dexamethasone. The American Journal of Diseases of Children. 1966;111:65-6.

21. Mofenson H, Greensher J, DiTomasso A, Okun S. A Warning: An Epidemic of Baby Powder Aspiration. Pediatrics. 1981;67:A68.

22. Song J, Koch J, Squier M, inventors; Patty Cake, Inc., assignee. DUSTLESS BABY POWDER. United States patent US 5,747,007. 1998 May 5.