Supplement

A Review of the Talc Industry's Influence on Federal Regulation and Scientific Standards for Asbestos in Talc

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Note: Wherever page numbers are found in parentheses, this indicates the pages in the source material where the cited data can be found.

Section 1: Further information on conversations with the press and Environmental Defense Fund.

In January of 1973, Dr. Seymour Lewin, a Professor of Chemistry at New York University (NYU), told a journalist at the *Wall Street Journal* that his tests on talc revealed that "10% of [cosmetic] talc products he examined contained 2 to 3% asbestos", information which the journalist then discussed with Dr. Wilson Nashed, Johnson & Johnson's (J&J) Associate Director of Research.[1, 2] Nashed responded that "although we had not talked to Dr. Lewin the FDA was very clear in stating that Lewin had found our products to be free of asbestos" (p. 2).[2] Nashed assured the journalist that J&J "not only ha[s] a good source of talc, but we subject it to refining with multiple washing before we obtain the baby powder grade; this together with extensive studies by world experts assures its freedom from asbestos" (p. 3).[2] This contradicted what J&J knew about the inadequacies of the "clean-mine" approach by 1973.[3-5]

After the publication of the *Wall Street Journal* article, the U.S. Food and Drug Administration (FDA) received a letter from the Environmental Defense Fund concerning the

health hazards of asbestos in talc.[6] In his response in March of 1973, Dr. Alfred Weissler, the Acting Director of Cosmetics at the FDA, characterized Lewin's previously positive test results as over-zealous:[6]

> *In his eagerness to protect the public interest to the fullest extent, Dr. Lewin in certain cases interpreted borderline results as showing the presence of asbestos, in his earlier reports, but he later used a more conservative interpretation. He has spent a lot of time- and energy in creative scientific work aimed at resolving the ambiguities (for which the public and FDA owe him a debt of gratitude) and he has succeeded for the most part. (p. 2)*

The FDA also assured the Environmental Defense fund that Lewin's results were based on "creative scientific work aimed at resolving the ambiguities (for which the public and FDA owe him a debt of gratitude)" (p. 2).[6]

Section 2: McCrone Labs Report.

J&J hired Walter C. McCrone Associates, Inc. to test their products. On October 27, 1972, McCrone provided a report to J&J finding asbestiform tremolite at varying percentages in two bottles of J&J Baby Powder.[7] The results of the first test, and original report were marked DO NOT USE THIS REPORT. REPLACED BY ANOTHER VERSION (Figure 1 in article).[8] Another copy of the report shows handwritten edits (Figure 2 in article).[7] On November 15, 1972, after retesting the same two samples, McCrone told J&J that "After looking at several fresh samples on the light microscope, we have not been able to substantiate the tremolite levels we originally reported" (p. 1-5)[7] Rather than issue a second report, disclosing the results of both tests, McCrone edited the original report, reflecting their "modified thinking," and changed the

results to conform to the results of the second test.[7] They dated it to October 27, 1972, the date of the original test results. The new report deleted the percentage details of what was found (as noted in **Error! Reference source not found.**), reporting only "a few isolated crystals" of tremolite rather than 0.2-0.5% tremolite, as noted in the original report.[7] J&J gave the modified report to the FDA.[9]

Section 3: Further details on the Concentration Method.

a. By 1973, Dr. Fred D. Pooley of University College, in Cardiff, Wales, developed a method for preconcentration to better detect amphibole asbestos nicknamed the "Pooley method".[10] J&J noted that the "Pooley method" "has not been written up yet, but evidently when applied to Vermont talc, 0.05% of tremolite-type [asbestos] is found. The limitation of the method is that it may be too sensitive" (p. 6).[10] The Colorado School of Mines Research Institute (CSMRI) also recommended a pre-concentration method to J&J in 1973: "As a result of the requirement to detect the proverbial 'needle in a haystack,' we have evolved a procedure which preconcentrates the impurities prior to examination" (p. 3).[11] CSMRI concluded, "Based on past experience with detecting and identifying minerals when present at low levels, a concentration of the phases to be detected was considered essential to the success of any suggested procedure" (p. 4).[11] Robert C. Reynolds at Dartmouth College also shared a concentration method with J&J's talc mining subsidiary, Windsor Minerals, in March of 1974.[12] Reynolds found asbestos in J&J's Vermont talc with his method and J&J later replicated this positive result using the same method.[13] In 1991, another J&J consultant, Alice Blount, developed a similar method using centrifugation to concentrate asbestos and found asbestos in J&J talc ores used in J&J cosmetic powders and in off-the-shelf J&J Baby Powder.[14-17] By 1993, J&J

consultants R.J. Lee had also adopted the Blount concentration method.[18] In 2014, the International Organization for Standardization (ISO) published a concentration method for asbestos in bulk materials.[19]

b. In 1976, J&J's William Ashton, who was responsible for evaluating potential talc mines, expressed concerns about an FDA proposal that was "more disturbing" than others because of its relationship to "concentration proceedures":[20]

> *I find this proposal more disturbing than other proposals up to now because it aims at separation and isolation of asbestos from a wide scope of products and animal tissues. Up to now, our main problems have had to do with identification, whereas, now it looks like the FDA is getting into separation and isolation methodology which will mean concentration procedures. As I have pointed out many times, there are many talcs on all markets which will be hard pressed in supporting purity claims, when ultra sophisticated assay separation and isolation techniques are applied. Chances are that this FDA proposal will open up new problem areas with asbestos and talc minerals. (p. 2)*

Section 4: Further details on XRD and TEM.

Minutes from a December 4, 1974 meeting of the Cosmetic, Toiletry and Fragrance Association (CTFA) talc subcommittee state: "It was concluded that we can recommend [to the FDA] x-ray diffraction with the optical microscope as back-up for the detection of amphibole at a 1% level" (p. 3).[21] This level of detection was ten times less sensitive than the proposed FDA limit for amphiboles in talc and 100 times greater than the FDA-proposed limit for chrysotile.[22] Per the CTFA, it was also ten times less sensitive than TEM analysis.[23] The CTFA continued to pursue optical microscopy methods despite finding that "false negatives are possible" (p. 3).[24]

Section 5: Convincing the FDA that testing for chrysotile was not needed despite finding chrysotile in undisclosed tests.

By 1975, before a scheduled meeting with the FDA, the CTFA "planned to propose the 0.5 to 1.0% limit for each fibrous tremolite and chrysotile in cosmetic talc" (p. 4).[25] However, when they met with the FDA, the CTFA questioned the need to test for chrysotile in talc at all on the basis that "no [talc] sample has yet to be confirmed as containing this material" (p. 3).[26] This was not true. The discussion went as follows:

> *Dr. Berdick questioned the need for a regulation on chrysotile since no sample has yet to be confirmed as containing this material.*
>
> *Mr. Eiremann responded that he sees no problem with a regulation covering both amphiboles and chrysotile, since "if chrysotile is not there, you should have no problems."*
>
> *Dr. Estrin and Dr. Berdick objected, stating that Mr. Eiremann was proposing regulations for the sake of regulation, and has not considered the wasteful tax on resources that would arise from inclusion of a standard for chrysotile. Dr. Berdick and Dr. Estrin concluded that if a regulation is not necessary, it should not be proposed.*
>
> *Dr. Schaffner responded with a suggestion that CTFA send in a letter with documentation, showing the extent of tests and results which would support a recommendation about the inappropriateness of a regulation for chrysotile.*
>
> *It was noted that Professor Lewin was the only scientist to ever have mentioned chrysotile in his report and the lack of confirmation of his results by other scientists*. (p. 3)

Two other testing facilities found chrysotile in Whittaker, Clark, & Daniels talc ore;[27, 28] Johns-Manville found chrysotile in Val Chisone talc ore, which was used in Avon, Colgate-

Palmolive, and J&J cosmetic talc products;[29] and McCrone found chrysotile in Cashmere Bouquet.[30] The CTFA justified its failure to test for chrysotile in a January/February 1976 issue of the CTFA journal.[31] Sandland of Bristol-Myers, the author of the article and chairman of the CTFA talc subcommittee, wrote that the equipment for detecting chrysotile was expensive and "not readily available" (p. 6).[31] He explained that because "the committee had been unable to find a sample of cosmetic talc containing naturally occurring chrysotile […] therefore, a backup method would not be necessary anyway" (p. 6).[31]

Section 6: CTFA submissions to FDA.

a. On September 23, 1975, the CTFA sent the FDA "the latest approved CTFA Cosmetic Talc Standard" and a "summary of 3,397 analyses of talcs from the United States and other parts of the world, along with documenting correspondence from five companies" (p. 1).[32] They told the FDA that:[32]

> *The statistically significant limit of detection for amphibole is about 0.5%. While this number is greater than the level originally recommended in the September 28, 1973 Proposed Regulations, it represents the realistic limitation of the average instrumentation and technology available in the industry today. (p. 4)*

The following table illustrates talc mining and manufacturing companies' (TM&MCs) misrepresentations to the FDA in a March 15, 1976 submission.[33]

Company	1976 misrepresentation to the FDA	One contradictory finding to TM&MCs' claim*
Avon	"A total of 170 samples of talcs used in our products were examined [for chrysotile] by McCrone […] and can be reviewed by authorized people. The results were negative. Since February, 1974, we have analyzed about 250 samples of talc receipts in-house by DTA for chrysotile and IR for tremolite […] The results were negative." [33] (p.2)	3/14/1972: 3-10% tremolite in three samples of talc[34]
Colgate-Palmolive	"The results of these analyses indicate to us that talc products produced by the Colgate-Palmolive Company since 1972 are free of asbestos minerals when subjected to the most sophisticated methodology available." [33] (p. 3)	2/5/1974: chrysotile fibers in Cashmere Bouquet, N.C. Regal, and Sample 516 (using transition electron microscopy and electron diffraction)[30]
J&J	"During the period December 1972 to October 1973, 93 lots were individually sampled and examined by X-ray diffractometry for the presence of asbestos minerals. No amphiboles or serpentine minerals were detected in any sample. Beginning in October 1973 […] differential thermal analysis and X-ray diffractometry were instituted for the routine examination of sequential lots. A further 100 lots have since been examined […] Again, no amphibole or serpentine minerals have been detected." [33] (p. 6, emphasis in original)	J&J's had numerous positive tests before the time period described to the FDA (see Table 1 in article); e.g. tremolite needles in baby powder;[35] chrysotile in Val Chisone talc, 2-3% Chrysotile in J&J Baby Powder and Shower to Shower;[36] chrysotile fibers in J&J medicated powder and Shower to Shower.[37]
McCrone Associates	"No chrysotile asbestos was found in these talcs [examined before 1973]. [33] (p. 8)	10/27/1972: McCrone removed percentages of tremolite findings, noting "a few individual

		crystals" (see Section 2).[8]
	"Since 1973 none of the talcs which we have examined and which have been identified to us as production materials have shown any detectable levels of either chrysotile or asbestiform amphibole."[33] (p. 8)	5/14/1974: Chrysotile fibers in Windsor Minerals talc, 66 used in J&J Baby Powder[38]
Whittaker, Clark & Daniels (WCD)	"In August 1971 a test program was instituted by our company to ensure customers using our cosmetic grade talcs that they are free of fibrous asbestos […] Our file contains reports on various grades of cosmetic talc […] based on approximately 74 ground ore samples analyzed over a period of four years all of which show non-detectable amounts of fibrous asbestos form minerals. [33] (p.9)	10/16/1973: Chrysotile found in WCD talc[28]

**There are more positive test results for asbestos in cosmetic talcum products that are too voluminous to include here.*[39]*

b. **Company resistance to providing further updates:** After the FDA requested that the companies periodically report results of their own analyses of talc, the companies resisted. According to the minutes of a March 15, 1976 meeting of the CTFA talc subcommittee, Dr. Murray Berdick of Chesebrough-Ponds "stated categorically it was not feasible to develop a statistically valid sampling plan for talc" (p. 3) while Dr. Norman Estrin, the Senior Vice President of Science for the CTFA, "expressed bewilderment that after reviewing the nearly 4,000 analyses provided at this meeting, FDA would need anything further" (p. 3).[40] While Estrin promised to give serious consideration to the FDA request, in a March 31, 1976 meeting of the CTFA subcommittee, he "suggested the subcommittee should not obligate itself to give periodic reports to FDA but urged members to build their database so that at some time in the

future the subcommittee can decide whether the time is right to present FDA with an update on industry analysis" (p. 2).[41]

Section 7: Eiermann's Mixed Messaging.

Dr. Heinz Eiermann was the FDA commissioner in charge of cosmetics from 1973 to 1991. As we note in the article, he privately criticized industry testing. In response to the CTFA test results submitted in March 1976, Eiermann concluded:[42]

> *In summary, though the submission by the CTFA Talc Subcommittee looks impressive at first hand, it* ***does not offer much assurance that cosmetic talcs are adequately tested for asbestos.*** *If this is all that can be expected from the cosmetic industry in the form of analytical effort in the light of the asbestos in talc publicity since 1971,* ***we have not much choice but to move ahead as speedily as possible with a proposal of a regulation on asbestos in talc*** *using X-RD and DTA procedures and basing the levels of adulteration of talc with asbestos fibers on the levels of sensitivity provided by these methods. (p. 3 emphasis added)*

However, Eiermann had publicly defended J&J talc just one week earlier, stating that their talc "has been found to be virtually free of asbestos" (p. 4) and that there is "no evidence" baby powder is hazardous (p. 3), citing J&J's own testing of talc.[43] Eiermann conceded that, "because talc and asbestos often are mixed together in infinitely variable concentrations, tests on such small samples do not accurately reflect asbestos levels in larger samples of talc" (p. 3).[43] He further stated that the FDA supports a bill "which would require cosmetic manufacturers to safely test their products and to submit the test results to the FDA for approval before the products could be sold" (p. 3).[43] Despite the fact the FDA's own tests had found asbestos in commercial talc products in 1974, in October 1976, Eiermann told the *Washington Post* that,

"Once the methodology has been worked out to our satisfaction we may propose regulations on asbestos. Our investigations of talc products demonstrated that none of the talcs used in these products contained asbestos as a contaminant."[44] However, *The New York Times* also reported in 1976 that:[45]

> *The tests at Mt. Sinai, which Federal health officials described as the country's leading research facility looking into the possible dangers of asbestos, used an electron microscope, which Heinz J. Eirmann [sic], director of cosmetics technology in the Food and Drug Administration, said was too expensive and time-consuming for his agency to use.*

In a 1978 article, Eiermann wrote that FDA efforts to improve the levels of detection for asbestos was "met with little success" and that "disappointments in analytical research have been somewhat offset by the virtual disappearance of asbestos-contaminated talc from cosmetic raw material inventories" (p.159).[46] Eiermann also complained about the FDA cosmetics division's limited resources and lack of industry cooperation.[43, 46] In 1976, he stated that his division only had eight chemists to monitor 250,000 cosmetic products and 4,000-5,000 manufactures.[43] Two years later he complained his department suffered an increase in research duties with no increase in staff, and that the department suffered "major disappointments."[46] In 1978, his division had a 28-person staff, a budget of $2.85 million to monitor over 25,000 different products and 2,500 manufacturing facilities.

Section 8: Final CTFA Specification.

The CTFA Method J4-1 stated that XRD results should be reported as either "Non Detected" or "Detected at approximately X% level" and Optical Microscopy and Dispersion-Staining Method results should be reported as "Asbestiform Amphibole Present" or

"Asbestiform Amphibole Absent."[47] If XRD was negative optical microscopy was not to be performed. Thus, if asbestos was not detected at the XRD LOD of 0.5%, the product was passed and sold. XRD cannot distinguish fibers from non-fibrous amphiboles and thus some form of microscopy (light or electron) is needed to determine if fibers are present (chrysotile only forms as fibers).[47] However, fibers that are thin or in low concentrations may be missed using microscopy.[3] For this reason, the British cosmetic industry organization, in which J&J was a member, had a standard that called for the rejection of any talc with a positive XRD result for any mineral with asbestos chemistry and did not require microscopy.[48]

The 90% definition for purity was suggested to differentiate cosmetic talc from industrial talc "on the basis of composition, especially talc purity."[49] During the deliberating meetings, J&J "pleaded for (1) adoption of the 90% talc limit in the general definition for the CTFA cosmetic talc, and (2) setting a quantitative limit of 0.5% for fibrous tremolite (matching the limit of reliability of the method)" (p. 2).[49] Both proposals were "met with general opposition from other CTFA committee representatives" (p. 2).[49] Estrin suggested that the "'non detectable fibrous amphibole' phraseology" was "more palatable to reviewing bodies" (p. 3).[49] J&J continued to stress "the danger of being tied to more sensitive methodology which may evolve in the future" (p. 3).[49] Harold Stanley, a research chemist from Pfizer, who was not in attendance at the meeting noted that "had I been there I would have objected to their definition." (p. 1)[50] He particularly objected to the requirement that talc contain "no detectable asbestos," writing that the omission of a specific detection level "can lead to some very serious breaks in communication between the buyer and the seller" (p. 1).[50]

Section 9: Round robin test of CTFA J4-1 method.

As noted in the article, in 1977, the CTFA coordinated a round robin to test the J4-1 method. J&J sent talc spiked with 0.5% tremolite and 3.5% anthophyllite as well as seven cosmetic talcs purchased on the open market, to seven laboratories, including the FDA, for analysis.[51] Three of the open market products tested positive for more than 0.5% asbestos in two to three labs.[52] All seven of the spiked talc detected anthophyllite, but only one lab (the FDA's) was able to detect 0.5% tremolite; thus, the round robin results demonstrate a false negative rate of 86%.[52] The meeting minutes from May 1977 reported that the objective of an "accurate, reliable, and practical" method had not been achieved and that those products with "inconsistent results" would be retested (p. 1).[52] We could not locate the results of the second round robin. However, in October 1977, the CTFA received a report from Dr. Rohl, a researcher at Mt. Sinai, who found 0.9 to 1.8 % tremolite and 2.0 to 3.2 % anthophyllite in four of the original seven round robin samples using his own method.[53] Then, in March of 1978, the CTFA disclosed the round robin results to the manufacturers of the products tested, after which the CTFA said they would destroy the only copy of the table of codes that identified the individual product results.[54] The CTFA also told the companies that "no talcum product failed CTFA Method J4-1, Parts I and II; i.e., no product was found to contain asbestiform amphibole at a level equal to or greater than 0.5% by weight" (p. 1, emphasis in original).[54] We have not been able to locate an explanation for the different findings in the first and second round robins and the Mount Sinai tests.

Section 10: FDA Petitions & FOIA Requests.

a. **1977:** The FDA received a FOIA request for safety data on J&J baby powder.[55] Dr. Robert Schaffner, the Associate Director of Technology for the FDA, told W.C.

Waggoner at J&J that the FDA "had no data." Waggoner suggested that J&J "prepare a summary package of published information on J&J's baby powder and send it to the FDA. This package could then be used for FOI requests on the product" and "Dr. Schaffner agreed that it would be an appropriate step" (p. 2).[55]

b. **1978:** Public Citizen cited two letters to the *New England Journal of Medicine* suggesting that asbestos in talc was a potential carcinogen and requested that the FDA ban its use in drugs and cosmetics.[56] The FDA denied the petition, claiming that "there is to date no conclusive evidence that talc is carcinogenic in man or animals" (p. 2).[56] They instead blamed asbestos contamination of talc as the "offending exposure" and that the industry had improved the "mining and processing of talc to minimize asbestos contamination" (p. 2).[56] The letter further summarized a 1977 investigation of forty-six talc samples, and noted that J&J had done extensive testing and that "all results to date have been negative" (p.3). The response attached a package of information that likely had been supplied to the FDA by J&J in response to the 1977 FOI request.

c. **1983:** In November of 1983, Phillipe Douillet, a graduate student in marine biology, petitioned the FDA to require a "warning on the hazardous effects produced by asbestos in cosmetic talc" (p. 1) due to concern about talc causing mesothelioma.[57] In early 1984, John Wenninger of the FDA cosmetics division informed J&J of the citizen's petition, thanked them for the information they had already provided, and stated that they did not have any data on currently marketed talc products.[58] On March 5, 1984, J&J hired Wayne Pines, a former FDA employee and then crisis manager for Burson-Marsteller, a public relations firm, to contact the FDA about the

petition.[59] Pines wrote: "At the present time it appears likely the agency will reject the petition. There appears to be no new data in the petition and the agency feels comfortable that there is no asbestos in talc" (p. 2).[59] On July 11, 1984 Wenninger wrote an "FDA memo" denying the petition (this memo is cited in another document and it is unclear who it was to).[60] Five months later, in November 1984, an FDA analyst, Linda Taylor, Ph.D., completed a *Quantitative analysis of Risk from Potential Exposure to Asbestos from Cosmetic Talc Use* and concluded: "The exposure of a baby from baby powder could be 6.6×10^6 f/year […] If a more realistic value of 1% asbestos is used, the number of fibers is calculated to be 6.6×10^4 f/year" (p. 25)[61] She later stated: "Infants exposed to asbestos from talc could be exposed to an additional amount above the background [exposure to asbestos] of the order of 0.04 to 0.08 f/cc for 2 years. This would result in an increase of 0.05% in the cumulative lifetime exposures […] with a similar increase in the lifetime risk. [...] the estimated exposure level is 100 to 200 times greater than background" (p. 26). On June 6, 1985, her supervisor, Robert Brown, revised Taylor's risk estimate to: "less than 10^{-8} added lifetime [cancer] risk" including mesothelioma and lung cancer (p. 9).[60] He noted it could be "possibly several orders of magnitude lower risk still, depending on assumptions and uncertainties alluded to above, especially those regarding geometrical shape of any possible asbestos fibers in talc, and limits of detection for asbestos in talc" (p. 9). On July 11, 1986, the FDA Acting Associate Commissioner for Regulatory Affairs, H.J.W. Swanson, wrote to Douillet denying the petition. The letter explained the FDA's position:[62]

> *Because of the questionable nature of analytic results, the agency was not able to assess reliability of the levels of asbestiform minerals in cosmetic talc then in the*

marketplace. Under these circumstances, FDA decided that the most appropriate actions that it could take to protect the public health would be to make the reports public and to request assistances from the affected industry in developing acceptable analytical procedures. This approach apparently has led to considerable improvement in the quality of this talc. (p. 1-2)

The letter then informed Douillet of the CTFA's specification and concluded:[62]

Consequently, we find that there is no basis at this time for the agency to conclude that there is a health hazard attributable to asbestos in cosmetic talc. Without evidence of such a hazard, the agency concludes that there is no need to require a warning label on cosmetic talc. (p. 2)

d. **1994:** On November 17, 1994, the Cancer Prevention Coalition petitioned the FDA to place carcinogenic labeling on all cosmetic talc products.[63] This petition, citing Cramer et al. (1982) and Harlow et al. (1992), asserted that "talc is a carcinogen with or without the presence of asbestos-like fibers" (p. 3).[63-65] On June 16, 1995, the CTFA submitted a comment to the FDA claiming that, "the Petitioner's arguments are without scientific merit" (p. 1) and that "there is no evidence to suggest that cosmetic-grade talc is a human carcinogen" (p. 5).[66] Contrary to their internal analyses in 1973, the CTFA told the FDA that cosmetic talc was mined from asbestos-free ore and that asbestos could be avoided by selective mining.[66] The CTFA also cited a 1994 workshop where "a panel of experts" reviewed "the latest toxicological and epidemiological studies on talc," and concluded that there is "not sufficient warning for concern" (p. 5).[66] After the workshop, in July 1995, Bailey

responded to the 1994 petition (from the Cancer Prevention Coalition), stating that "we have not been able to reach a decision on your petition […] because of the limited availability of resources and other agency priorities" (p. 1).[67]

e. **2008:** the Cancer Prevention Coalition submitted another petition to the FDA calling for ovarian cancer warnings to be placed on baby powder products.[63] In July, Dr. Kathleen Wille, the Senior Director of Scientific and External Regulatory Policy, judged that the petition "singled out" (p. 2) J&J and determined that the next steps were to "secure funding and engage experts" and "determine level of external support" from their supplier (Luzenac) and the CTFA (p. 3).[68] J&J and Luzenac agreed to pay Drs. Huncharek and Muscat of the Meta-Analysis Research Group to conduct a narrative review and meta-analysis of talc and ovarian cancer via a law firm, Crowell & Moring, "so as to preserve the benefit of the attorney work product privilege, which is helpful in protecting confidentiality" (p. 2).[69] Huncharek and Muscat agreed that the funders could review the report and suggest changes before submission to the National Toicology Program (NTP) and publication.[70] By November 2008, Craig Bernard of Rio Tinto Minerals noted that "a key figure" at the FDA planned to rule against the petition, but that they needed "scientific support from industry that will help justify their position" from the TM&MCs:[71]

> *Kathy Wille at J&J informed me that at a recent science meeting in Washington DC she had a side conversation with a key figure from the FDA cosmetic group that is responsible for responding to the Citizen's Petition. He indicated that the FDA would rule against the petition and would not require warning labels on cosmetic products. But the FDA is looking for scientific support from industry that will help justify their position. She suggested that there is a collective group*

working to have comments submitted to the FDA. Principal among this effort will be comments that Professors Muscat and Huncharek are co-developing. (p .1)

The CTFA presented the Huncharek and Muscat report to the FDA in May 2009.[72] After the presentation, the FDA indicated "that the Citizens Petition is not on their priority list, and they will likely not respond" (p. 2).[73]

Section 11: CTFA influence on 1994 workshop to counter NTP animal and epidemiology studies

a. As we note in the article, the FDA and industry co-funded a workshop, *Talc: Consumer Uses and Health Perspectives,* with the International Society of Regulatory Toxicology & Pharmacology (ISRTP), an industry-funded organization which had a direct influence on those in attendance at the workshop. The CTFA sent the ISRTP names and addresses of participants they wanted to attend the workshop.[74] Several speakers did not disclose their affiliations with industry.[75] Dr. John Bailey and Dr. Gio Gori co-chaired the symposium. Dr. Gori had previously consulted for tobacco industry lawyers and served as Vice President of a consulting firm that received large sums of money from the tobacco industry.[76, 77] At least one participant noted the meeting's slant: Bev Zacharias, of the Woman's Cancer Advocacy Group, expressed that the panel had "strong bias against the consumer and patient" (p. 14).[78] Indeed, "only two consumer representatives attended" (p. 2).[78]

b. The TM&MCs used the workshop as a platform to attempt to discredit a recently-completed NTP animal study demonstrating talc lung carcinogenicity. The NTP animal study was a 1993 technical report that found a statistically significant increase

of alveolar/bronchiolar adenoma, carcinoma, and adenoma or carcinoma (combined) in female rats and concluded that there was "clear evidence of carcinogenic activity of talc" in rats (p. 7).[79] The CTFA funded Drs. Gori and Carr, secretary of ISRTP, to prepare a set of papers from the 1994 conference for publication in the April 1995 issue of the ISTRP's journal that undermined the cancer findings of the NTP study.[80, 81] The CTFA made suggestions on a draft of least one of these papers, entitled, *The lack of an ovarian effect of lifetime talc exposure in F344/N rats and B6C3F1 mice*.[82, 83] Dr. Gettings of the CTFA advised the author of this paper, Dr. Boorman, against using the term "talc fiber," which the industry was concerned about perpetuating, and use "talc particle" instead.[84, 85] However, following this advice, Boorman still used "fibers" in the minutes of a National Institute of Environmental Health Sciences (NIEHS) meeting. Ashton of J&J encouraged the CTFA to make another effort to have Boorman change his paper.[86] Dr. Boorman changed "fibers" to particles throughout the published version of his paper.[82]

Section 12: Influence on the NTP

a. **Center for Regulatory Effectiveness (CRE):** In 1996, Jim Tozzi, who had been director of the Office of Management and Budget's (OMB) Office of Regulatory Affairs under President Reagan,[87] founded the Center for Regulatory Effectiveness. CRE is a consulting firm and lobbying group that represents itself to the public as an agency that provides Congress "independent analyses of agency regulations."[87, 88] CRE also does business as the Multinational Business Services, Inc. (MBS).[89] In its mission statement, CRE claims it is a "regulatory watchdog" that "ensures regulators

comply with the 'good government' laws that 'regulate the regulators.'"[88] Under "CRE Accomplishments," CRE claims credit for the establishment of the Office of Information and Regulatory Affairs within the OMB, the passage of the Data Quality Act of 2002 (also known as the Information Quality Act), and the introduction of benefit-cost analysis into federal rulemaking.[88] CRE used the Data Quality Act of 2002 to facilitate challenges to regulations, including challenging the listing of talc on the NTP's 12th *Report on Carcinogens* (see 12b below).[90]

As we note in the article text, Luzenac retained CRE in November 2000 at a "retainer rate of $12,000 per month to work on the NTP talc listing" (p. 2).[89] The CRE/MBS sent itemized invoices to Luzenac (and later Imerys, which acquired Luzenac in 2011) for $6,000-$24,000 a month from 2001 to 2015 for "services rendered."[91] One Imerys document describes CRE's role as follows:[92]

> *CRE is not a traditional "contractor" or "consultant." It is a federal regulatory "watchdog" organization that assists mainly corporations with advice and intervention in federal regulatory issues that threaten their business. Its staff is comprised mainly of former federal government officials and lawyers who understand and intervene in the regulatory system.* ***Companies who enlist the assistance of CRE are considered "sponsors" who make "donations" to CRE and request its help on specific issues that have wide significance.*** *In doing its work for such sponsors, CRE retains a high degree of independent judgment and decision-making, and does not "represent" companies in the traditional legal sense. However, CRE is part of a consortium of companies that work on regulatory/informational issues, and that consortium includes Multinational Legal Services (MLS), PLLC, a law firm, and Multinational Business Services, Inc, a*

traditional consulting firm. ***At times, Luzenac has dealt with MLS in order to have the benefit of attorney/client relationship.*** *(p. 1) [Emphasis added]*

Luzenac used their attorney-client relationship with the CRE to cloak certain activities in secrecy: they withheld over 8,000 documents as privileged under their attorney-client relationship with Luzenac. [93] The CRE told the NTP, IARC, and the Cosmetic Ingredient Review (CIR) it was independent of industry ties and never disclosed the dual nature of its relationship with Luzenac.[94]

CRE's Political Clout: In his 2020 book*, The Triumph of Doubt,* David Michaels described how "over the next few years, Tozzi and CRE kept up the pressure on the NTP, regularly conveying a message that they could inflict pain, and that the pain would disappear if the NTP dropped talc from consideration." (p. 154).[95] In 2004, for instance, the CRE wrote to the Department of Health and Human Services, asking them to review the budget for the *Report on Carcinogens.*[90] According to CRE, as a "highly influential scientific assessment," the Report was subject to the new information quality peer review requirement (the Data Quality Act of 2002), which barred government employees from participating in the listing process.[96] In response to CRE complaints, the head of the White House Office of Information and Regulatory Affairs wrote to the Director of the National Institutes of Health (NIH) and required several changes to the NTP process for the *Report on Carcinogens*.[97] Please see David Michael's book for a more complete review of this period.

Section 13: Influencing Other Regulatory Bodies.

a. In 2005, IARC announced that it would evaluate non-asbestiform talc for its forthcoming monograph 93.[98] IARC ultimately concluded that there was inadequate evidence that inhaled talc not containing asbestos or asbestiform fibers caused cancer in humans, but that there was limited evidence of the carcinogenicity of perineal talc use.[99] The IARC monograph 93 noted the 1976 voluntary CTFA guidelines for asbestos in talc and specified that, although studies suggested the presence of anthophyllite, chrysotile, and tremolite in consumer talc products in the past, "after 1976, these powders probably did not contain anthophyllite, chrysotile or tremolite …." (p. 309).[99] They reiterated that the agency considers talc containing asbestos or other asbestiform fibers a Group-1 carcinogen in humans.

b. In 2012, CIR, an "independent" review body supported by the FDA, the Consumer Federal of America, and the Personal Care Products Council (PCPC), began a safety assessment of talc as used in cosmetics.[100] Luzenac again retained the CRE's services to respond.[91] The CRE again used the "fatal flaw" argument in comments to the CIR to argue against talc carcinogenicity.[101] The CIR concluded in its final Safety Assessment that "talc is safe in the present practices of use and concentration described in this safety assessment" and cited the CRE's comments (submitted by Kelly) as evidence against the possibility of transvaginal talc migration.[100] Kelly expressed shock that the CIR relied on his comments for medical questions, commenting that "it's very unusual. Perhaps they think I am a Ph.D. gynecologist!" (p. 2). [102] The CIR claims it provides independent safety reviews.[103] However, Kelly noted that "we [the CRE] engineered the CIR report from the outset …." (p. 2-3).[104] As part of its effort to "market the [CIR] report" (p. 2) at Luzenac's request, Tozzi

and Kelly of the CRE discussed using the FedFocus.org to post information "showing that the CIR is unbiased" (p. 1) because the CRE website "is a .com and has acquired an industry reputation)."[104] According to its website, Federal Focus is a "non-profit research and educational foundation," funded by "grants, contributions, or cooperative arrangements."[105] They provide a list of entities that have given such contributions, which primarily includes businesses and industry groups. Federal Focus is recognized as an industry front group chaired by Jim Tozzi.[106]

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