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“Nondetected”: The Politics of Measurement of Asbestos in Talc, 1971–1976

David Rosner, PhD, MPH, Gerald Markowitz, PhD, and Merlin Chowkwanyun, PhD, MPH

The recent lawsuits against Johnson & Johnson have raised the issue of what and when talcum powder manufacturers knew about the presence of asbestos in their products and what they did or did not do to protect the public. Low-level exposure to asbestos in talc is said to result in either mesothelioma or ovarian cancer. Johnson & Johnson has claimed that there was “no detectable asbestos” in their products and that any possible incidental presence was too small to act as a carcinogen. But what exactly does “nondetected” mean? Here, we examine the historical development of the argument that asbestos in talcum powder was “nondetected.” We use a unique set of historical documents from the early 1970s, when low-level pollution of talc with asbestos consumed the cosmetics industry. We trace the debate over the Food and Drug Administration’s efforts to guarantee that talc was up to 99.99% free of chrysotile and 99.9% free of amphibole asbestos. Cosmetic talc powder manufacturers, through their trade association, pressed for a less stringent methodology and adopted the term “nondetected” rather than “asbestos-free” as a term of art. *Am J Public Health*. Published online ahead of print May 16, 2019; e1–e6. doi: 10.2105/AJPH.2019.305085)

The recent lawsuits against Johnson & Johnson, and particularly the \$4.8 billion verdict against the company, have raised the issue of what and when talcum powder manufacturers knew about the presence of asbestos in their products and what they did or did not do to protect the public.¹

Since the mid-1960s, asbestos, even at low levels, has been recognized as a cause of lung cancer and mesothelioma. Since the early 1970s, the cosmetics industry, as represented by the Cosmetic, Toiletry, and Fragrance Association (CTFA), has claimed that there was either no asbestos or that any residual asbestos in their products was “nondetected.” But what exactly does “nondetected” mean? Here, we examine the historical development of the argument that asbestos in talcum powder was nondetectable.

We use a unique set of historical documents from the early 1970s,² when the Food and Drug Administration (FDA)

raised concerns over findings of low level pollution of talc with asbestos. We trace the debate over the FDA’s efforts to guarantee that talc was up to 99.99% free of chrysotile and 99.9% free of amphibole asbestos. Talc powder companies’ counterproposals were less stringent; they proposed methodologies that were capable of detecting asbestos up to 99.5%. The difference in these methodologies meant that potentially billions of asbestos fibers could be released into the air when babies were powdered or adults powdered themselves.

Cosmetic talc powder manufacturers pressed for the less stringent methodology and adopted the term “nondetected” asbestos, rather than “asbestos-free” as a term of art. The CTFA, the industry trade association, which represented companies such as Johnson & Johnson, Colgate, Pfizer, Mennen, Avon, and other manufacturers of cosmetic talc products, spearheaded the efforts to define how to measure asbestos in talc.

These contests over methodology were enormously important. They should be seen as part of parallel battles over operationalization of regulatory terms. Since 1958, the FDA had been embroiled in controversy over proper interpretation of the so-called “Delaney clause,” which banned approval of food additives that were carcinogenic. But how exactly to “define zero,” as historian Sarah Vogel puts it, was far from self-evident and resulted in decades of debates over the clause’s interpretation.³ When the controversy over talc began, the National Institute for Occupational Safety and Health (NIOSH) was arguing that only an asbestos exposure approaching zero could ensure workers’ protection against cancers.⁴ If asbestos could cause cancer among workers even at minimal levels of exposure, then consumer advocates and federal officials worried that everyday users of products with asbestos were at risk, too. In earlier articles, we have traced how two other trade associations representing manufacturers of asbestos products reacted to the changing political, scientific, and regulatory efforts to control asbestos exposure.⁵ Here, we look at a third, the CTFA, representing an industry whose market was the broad public: men and women, mothers and fathers, and even babies.

ORIGINS OF THE CONCERN OVER TALC

The suspicion that asbestos was a dangerous pollutant in

talc can be traced back to the 1930s, when a number of clinical reports appeared indicating that talc workers were suffering from a pneumoconiosis whose symptoms resembled asbestosis, the insidious lung disease that was of major concern at the time. For example, Waldemar Dreessen published a study of workers in two mills in 1933 and concluded that “[t]he silicate dusts of tremolite talc [i.e., talc mixed with tremolite, one of the six major forms of asbestos] and slate induce a fine, diffuse bilateral fibrosis of the lungs which is definitely demonstrable in the X-ray.”⁶ In 1942, FW. Porro and his associates presented 15 cases of talc miners and millers with pneumoconiosis. They wrote: “It would appear from a consideration of Dreessen’s analysis that the dust responsible for the disabling pneumoconiosis must be the talc itself in the form of tremolite or soapstone or both.” They also commented that “common to all cases is moderately frequent presence of asbestos bodies in the lesions. . . . The presence of asbestos bodies in fibrotic areas implies a degree of similarity between asbestosis and pneumoconiosis due to talc.”⁷

In 1956, A.C. Hunt, publishing in *Thorax*, wrote that “commercial talc is a mixture of the pure mineral talc (hydrated magnesium silicate) with related minerals such as dolomite, serpentine, anthophyllite and tremolite. The amount of pure talc in commercial specimens is very variable.”⁸ In 1963, the National Safety Council, an historically management-friendly group, founded in 1912 by industry to inform companies about—and help them address—ongoing health and safety problems in their plants, issued a pamphlet that stated: “Talcosis is usually associated with tremolite talc.” The council noted that the

diseases “[produce] changes in the lungs and symptoms similar to those of asbestosis.”⁹

By the mid-1960s, miners of talc had been identified by occupational health researchers as at increased risk for lung cancer. Morris Kleinfeld and his colleagues conducted a study “to ascertain the health hazards associated with exposure to dust in talc mining and milling.” They concluded that “the data on carcinoma of the lung and pleura shows an overall mortality from carcinoma of the lung and pleura to be approximately four times that expected.”¹⁰ The asbestos manufacturers identified tremolite in some “body talcum powders.”¹¹ In addition, researchers identified tremolite in samples of cosmetic talc products. Louis Cralley and his colleagues analyzed 22 talcum products and found that all of them had “an appreciable fiber content, ranging from 8 to 30%. . . . The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite and chrysotile as these are often present in fibrous talc mineral deposits.”¹² Some went even farther, arguing that cosmetic products were a threat to consumers: “It is difficult to conceive of a better way of having fibers inhaled than the use of cosmetic talcum powders.”¹³

In light of growing suspicion that asbestos, even at minimal levels, was carcinogenic, the FDA called representatives of a wide range of cosmetics manufacturers and scientists to Washington in August 1971 to “discuss in detail analytical methods for the determination of minor amounts of ‘asbestos like’ materials in talc with particular reference to cosmetic grade talcs,” or, as one member of the CTFA called it, “the asbestos in talc

problem.” The meeting brought together a number of parties: talc manufacturers, including Johnson & Johnson and Pfizer; government officials from the FDA, the Bureau of Mines, NIOSH, and the US Geological Survey; physicians and scientists such as Irving Selikoff, William Nicholson, and Arthur Langer of Mt. Sinai School of Medicine and Seymour Lewin of New York University; and representatives of Johns Manville and the Consumers Union.¹⁴ At the meeting, as reported by Pfizer researchers, attendees discussed a number of different methods for identifying asbestos in talc, including light microscopy, x-ray diffraction, electron microscopy, and electron diffraction.¹⁵ The meeting laid out the evolving concerns of industry, consumers, researchers, and the FDA regarding how to evaluate the dangers from asbestos contamination in their products in light of the growing evidence that even the smallest exposures to asbestos could prove carcinogenic.

By August 1972, some results had begun to come in from both inside and outside NIOSH indicating that there was a problem. NIOSH had independently been testing “nine commercially available baby powders” by using electron microscopy. Its study indicated “possible asbestos fiber contamination of commercial baby powders.”¹⁶ A month later, Seymour Lewin, under contract with the FDA, began reporting his findings of the contamination of talcum powders. Of the 102 samples “of standard, commercial products containing talc” that he tested, x-ray diffraction showed “that 59 of the products [had] no detectable amounts of any asbestiform minerals. . . .”¹⁷; “20 had small but definite percentages of both tremolite and chrysotile,” and “7 had substantial percentages

of one or both of these asbestiform minerals.”¹⁸ In a memo, CTFA representatives noted Lewin’s conclusion that “over 40 percent of the samples may contain asbestiform minerals such as chrysotile or tremolite.”¹⁹

There was a lot at stake for both the industry and consumers. The *Wall Street Journal*, in February 1973, gave a detailed summary of Lewin’s findings, telling its readers that “10% [of the 200 talcum powders tested] contain 2% to 4% asbestos impurities, with a handful running as high as 10% to 20%.” The impact was expected to fall primarily on “manufacturers of dusting powders, baby powders, after shave products and the talc-containing cosmetics.” The *Journal* reported that the FDA would “impose stringent limits” on these products but optimistically predicted that manufacturers would likely support these changes. “Most cosmetic concerns agree that asbestos must be eliminated from their products and some have already moved to do so, partly under FDA pressure.”²⁰

Apart from economic considerations, the political milieu of the time also gave both the manufacturers and the FDA reason to worry. Skepticism of large institutions was burgeoning, with activist ire aimed at everything from major research universities to the military to large corporations. Advocacy for the interests of the everyday consumer, particularly around health and safety concerns, was exemplified by the attorney Ralph Nader, who became the public face of a revived consumer movement that thrived from the early 1960s into the 1980s. Nader had made his mark with a scorching investigation of automobiles, entitled *Unsafe at Any Speed*, which had shaken the entire industry and led to sweep-

ing legislative reforms.²¹ He subsequently led young investigative teams—dubbed “Nader’s Raiders”—that wrote critical and detailed reports on other targets, including government agencies like the Federal Trade Commission and Department of Veterans Affairs.²²

The FDA was no exception to this muckraking. One Nader-spawned entity, Public Citizen, created a Health Research Group, headed by the physician Sidney Wolfe. It focused on pharmaceutical safety and transparency in the approval process, taking advantage of new laws like the Freedom of Information Act to request previously classified material.²³ Other groups, most notably activists in the women’s health movement, set their sights on the safety of synthetic hormones and contraceptives.²⁴ Corporations and the FDA both faced a new culture of accountability: for corporations, over the safety of their products; for the FDA, over the ability to ensure that safety if corporations themselves could not provide it. It is in this context that the exchanges on methodology between the CTFA and the FDA occurred.

THE INDUSTRY GOES ON THE OFFENSIVE

In the fall of 1973, the FDA announced its proposed rule in the *Federal Register*: “Any drug, drug ingredient, or drug packaging material containing talc that fails to meet the specifications . . . as determined by the method set out . . . shall be deemed to be adulterated in violation of . . . the Act” and thus not a substance “generally recognized as safe.” The standard was exacting: The FDA proposed using a polarizing microscope that they believed could accurately ensure “a purity

of talc at least 99.9 percent free of amphibole types of asbestos fibers and at least 99.99 percent free of chrysotile asbestos fibers.”²⁵

The industry reacted immediately and negatively to the proposed rule. Two weeks after the announcement in the *Federal Register*, the CTFA Subcommittee of Scientific Advisory Committee on Asbestos in Talc met and attacked the FDA’s methodology as “not completely reliable and discriminatory,” arguing it was not clear that the methods used really measured true asbestos fibers. The CTFA suggested that the methods could actually be finding nonfibrous or nontoxic materials. “[C]hrysotile might fall within the critical range of refractive indices used,” the CTFA contended. Further, committee members claimed that the counting, even if accurate, would take an inordinate amount of time—perhaps six hours—for a technician to reach a “tentative identification” of the asbestos content. “The tedium effect on the person counting is obvious,” the committee maintained.²⁶

The CTFA organized a “round robin” test to determine the reliability of the methodologies proposed by the FDA. After distributing samples of talc from a variety of mines from a number of states, it asked various companies to have their experts determine whether the samples contained chrysotile or amphibole asbestos. The CTFA had provided samples that they had “spiked” with known amounts of different asbestos fibers to see how accurately or inaccurately the methodologies performed. The round robin test revealed “strong inconsistency” among “the different scientists applying the method to the same group of coded talc samples.” The CTFA

“concluded that the method published in the *Federal Register* does not provide a truly reliable means for the detection of asbestos in talc.” Given that the methodology was “tedious and may consume as much as one half day per sample,” the “subcommittee urge[d] that the Food and Drug Administration defer finalizing the proposed optical microscopic method and proceed [to a] program which would combine FDA and Industry in a strong effort to develop a truly reliable method.” The CTFA subcommittee estimated “that a satisfactory method will take at least six months to a year to develop” if industry and the FDA worked together.²⁷ The industry was willing to challenge the FDA since some privately believed that the “FDA is reluctant to take any legal action in any problems with industry.” The CTFA had been told that the FDA had “neither the money nor the manpower to pursue matters so that they will have airtight cases in scientific matters.”²⁸

The CTFA also challenged the government even though one representative of Johns Manville reported that some talc suppliers were distributing products with high amounts of three of the major forms of asbestos—chrysotile, tremolite, and anthophyllite—and might be lying to the government about it. R.S. Lamar of Johns Manville was specifically referring to “R.T. Vanderbilt Company talc products,” which “always have and continue to contain chrysotile as a significant mineral component (in addition to tremolite and anthophyllite).” He concluded his private correspondence with another Manville executive: “It is apparent that the R.T. Vanderbilt presentation to OSHA [Occupational Safety and Health Administration], NIOSH,

FDA, MESA [Mine Enforcement Safety Administration], etc. are based on something less than the truth.”²⁹

This struggle between the government and industry over the FDA recommendation was highly consequential. In March 1975, the objections of industry to the earlier FDA notice of rule-making in the *Federal Register* had undermined the FDA’s efforts to adopt stricter standards. “The Food and Drug Administration has . . . examined numerous talc samples of undefined grade in the past two years, using the proposed methodology,” the *Federal Register* had announced, “and finds that approximately two-thirds of such samples are within these limitations” of 99.9% amphibole free and 99.99% chrysotile free. The implication of this was that possibly one third were not free of asbestos. “The Commissioner therefore concludes that the proposed limitations would not impose an unreasonable burden on manufacturers of talc if these limitations were adopted.” But industry was objecting and, hence, “The Commissioner . . . decided to delay any final regulation for talc until an acceptable method for determining the presence of asbestos particles can be developed for this substance.”³⁰

The industry had won a major battle, and it proceeded to promulgate its own methodology, referred to as J4-1, and its own definition of talc: “Cosmetic talc is a white, essentially odorless, fine powder, ground from naturally occurring rock ore, consisting mainly of magnesium silicate . . . with lesser amounts of naturally associated minerals . . . and containing *no detectable* fibrous asbestos minerals [emphasis added].” J4-1 was less stringent than the FDA standard; it was only reliable to 0.5%

as compared with the FDA’s methodology, which claimed accuracy to 0.01%. This meant that future cosmetic talc products might, in fact, contain asbestos below the 0.5% detectable limit. Furthermore, the CFTA promulgated its own definition of talc’s purity by avoiding precise statements in favor of vaguer language in its description of the asbestos content of the manufacturers’ products. “After extensive discussions of advantages and disadvantages of listing a 0.5% maximum limit as opposed to ‘nondetected’ terminology, the Standards Committee voted for the use of . . . ‘nondetected.’”³¹ One industry representative, however, acknowledged the dishonesty in using “nondetected” as the definition for safety of cosmetic talc products: “You will notice that a talc standard definition for cosmetic talc was adopted unanimously,” H.D. Stanley of Pfizer wrote to R.E. Norwood following a July 8, 1976 meeting of the CTFA. “Had I been there I would have objected to their definition. I particularly object to the section . . . that reads – containing no detectable asbestos minerals.” Stanley pointed out the irony that a “nondetected” level depended on the adequacy—or inadequacy—of the methods used to detect it. Using an insensitive method would allow manufacturers to claim that asbestos had not been detected but would simultaneously lead to “serious breaks in communication between the buyer and the seller,” who would believe that the product was truly asbestos-free.³² This observation was not trivial and got to the heart of the problem the cosmetics industry faced. As Arthur Rohl, a researcher in Irving Selikoff’s department at Mt. Sinai School of Medicine, pointed out, if the wrong

methodology was used, billions of particles of asbestos could escape detection. He wrote that “Even at the lowest level of detection by x-ray diffraction, i.e., 0.25%, there would be about 10^9 fibers/mg. Cosmetic talcum powder, for example, which had been step-scanned and chrysotile not found might contain billions of fibers released during dusting with a half-gram dose.”³³ How dangerous talc products were, then, depended on what one used to measure risk.

Industry objections to research that found asbestos in talc was noted by researchers themselves. In 1976, following publications by Mt. Sinai researchers of the presence of asbestos in commercial talcum powders bought off the shelf in local stores, representatives of the CTFA visited Mt. Sinai in an apparent effort to get the institution and the researchers to qualify, if not retract, their findings. In one such meeting, the primary authors of the Mt. Sinai studies informed the industry group that they had found asbestos in 10 samples by using x-ray diffraction and transmission electron microscopy. In a memo, the Mt. Sinai authors wrote: “Dr. Langer was somewhat disgusted by the talc industry’s attitude. He said the results of his work ha[d] been known to the industry for several years but nothing was done until the . . . results became public.”³⁴ A few days after that meeting, the industry was partially mollified when the dean of Mt. Sinai, Thomas Chalmers, was quoted in the media as qualifying news reports claiming that “most of the talcum powder currently on the market contain[ed] asbestos.”³⁵ “It is the opinion of Mount Sinai’s Department of Pediatrics that baby talc is a useful and safe product,” he stated to WCBS.³⁵

CONCLUSION: LEGACY OF THE CTFA CAMPAIGN

By 1977, the FDA essentially gave up its efforts to regulate asbestos in talc, as the J4-1 method created by the CTFA had been adopted by the industry despite the CTFA’s own acknowledgment that its methodology was inadequate to the task. John Schelz of Johnson & Johnson, who was chair of the CTFA Taskforce on Round Robin Testing of Consumer Talcum Products, reported on a round robin test of samples of talc and found that J4-1 had failed its test for identifying “asbestiform amphibole contaminants” with accuracy, reliability, and practicality. “These objectives have *not yet* been achieved [emphasis in original],” he wrote, and suggested a partial retest.³⁶ Despite this, the J4-1 method, one that the industry itself acknowledged is incapable of determining low-level pollution, is still the standard within industry.

The industry methodology was no more capable of determining low-level exposures than was the methodology the FDA first proposed, and may have been less accurate than were the time-consuming methods they critiqued. For the following half century, the debate over the presence or absence of asbestos in talc has continued. The implications of this for science, regulation, and consumer safety have resulted in conferences, symposia, and many scientific papers ever since. But it is no mere scholastic issue. In 1995, for example, Edward Kavanaugh, president of the CTFA, responded to a petition by a citizen advocacy group, the Cancer Prevention Coalition, that asked the FDA to label cosmetic talc products as potential carcinogens. He reiterated the industry’s long-standing position

that such warnings were “not necessary to protect the health of consumers and would unnecessarily alarm consumers regarding the use of safe cosmetic products.”³⁷ The FDA did not act on the petitioners’ appeal.

The recent lawsuits against various talc manufacturers have once again brought the issue of asbestos in talc to public attention. The consequences of industry’s actions and inactions—and of its knowledge or lack thereof—that were identified a half century ago are still with us. *AJPH*

ABOUT THE AUTHORS

David Rosner, Gerald Markowitz, and Merlin Chowkwanyun are with the Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, New York, NY. Gerald Markowitz is also with the John Jay College and Graduate Center, City University of New York, New York, NY.

Correspondence should be sent to David Rosner, PhD, Mailman School of Public Health, Columbia University, 722 West 168th St, Room 935, New York, NY 10032. Reprints can be ordered at <http://www.ajph.org> by clicking the “Reprints” link.

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CONTRIBUTORS

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CONFLICTS OF INTEREST

David Rosner and Gerald Markowitz wrote a 2017 Report to the Court in a legal case that formed the original basis of this article. They received funding from plaintiffs’ law firms for research and writing. Merlin Chowkwanyun has no potential conflict of interest.

ENDNOTES

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