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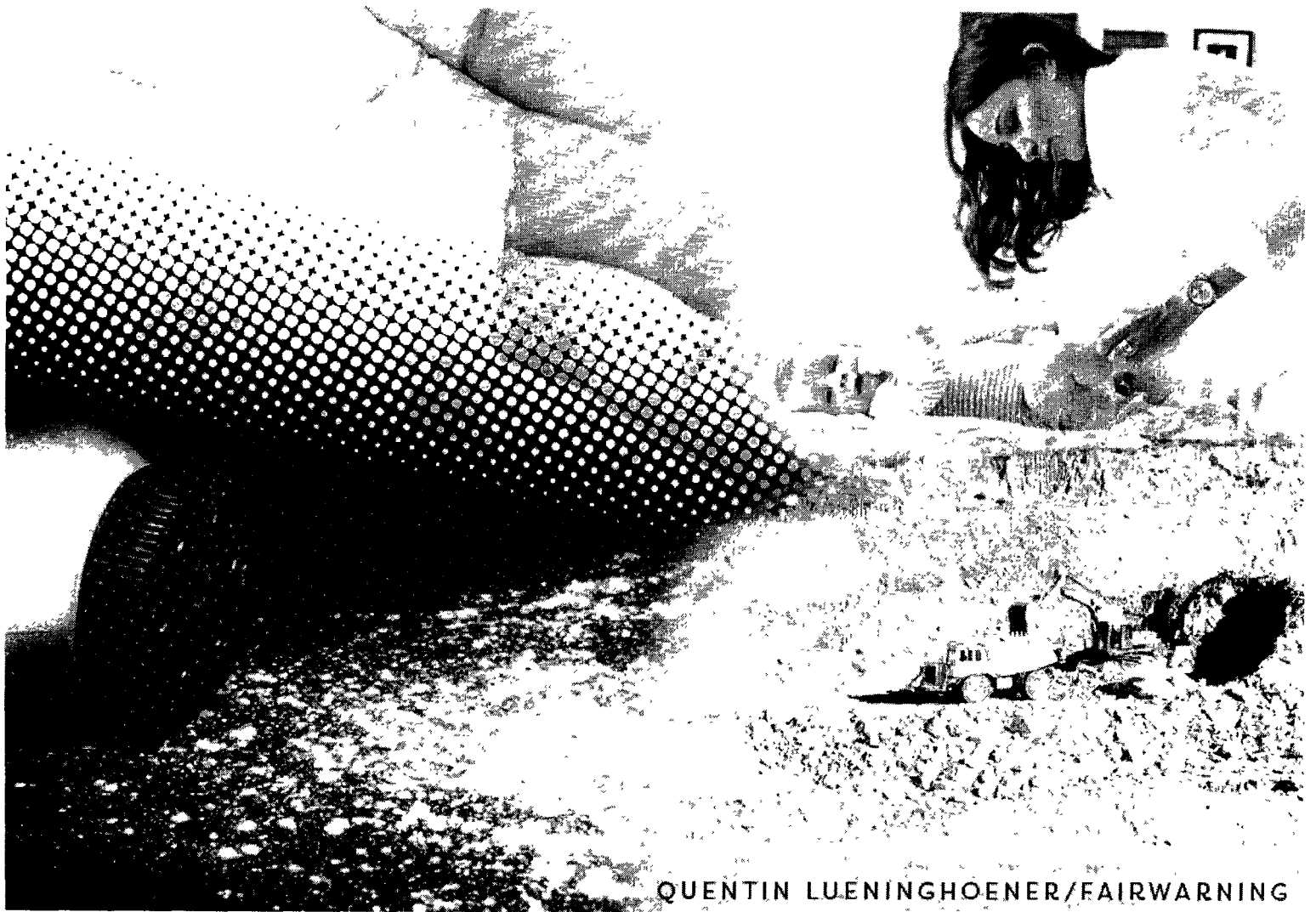
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Baby Powder Battles: Johnson & Johnson Internal Documents Reveal Asbestos Worries

By [Myron Levin](#) on January 16, 2018

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In the early 1970s, a Johnson & Johnson official posed a question that haunts the company today. If Johnson's Baby Powder contained asbestos at a level of, say, 1 percent, how much of the cancer-causing substance would a baby inhale when dusted with the powder?

The executive's handwritten memo reached what, at the time, may have seemed a comforting conclusion: The baby's exposure would be far less than the legal limit for an asbestos miner, the main standard then in place.

But the memo and other internal company records cast doubt on J&J's assertions that its powders have always been asbestos-free. If they never contained the carcinogen, why then did officials bother to estimate the potential exposure for a baby?

Drawn from a trove of about 175,000 pages of J&J documents, the revealing memos have helped to ignite a burst of litigation against the pharmaceutical and consumer products giant. The lawsuits are by victims of mesothelioma, a rare and lethal form of asbestos-related cancer that typically strikes decades after initial exposure. At issue is whether talc powders were contaminated by traces of asbestos, and whether, after years of routinely sprinkling on the powders, plaintiffs unwittingly inhaled enough of the microscopic fibers to contract the deadly illness

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FairWarning reviewed thousands of pages of documents in preparing this story, including internal company memos and transcripts of legal proceedings as well as material obtained under the Freedom of Information Act; most of this material has not been previously reported.

The intriguing documents don't settle the safety issue. But they raise questions about J&J's candor on the incendiary topic of asbestos and talc

J&J, which declined interview requests, has said its powders are perfectly safe, and could not have caused mesothelioma.

In November, the company won a big victory in its first mesothelioma trial, when a Los Angeles Superior Court jury found J&J and co-defendant Imerys Talc America were not responsible for the mesothelioma of Tina Herford, 61. Herford, of Camarillo, Calif., said she had used the company's talc powders for about 35 years. J&J settled a second case, and faces at least several dozen more lawsuits. Similar lawsuits are targeting other companies, including Colgate-Palmolive, which used to produce Cashmere Bouquet powder.

Opening arguments are set for Jan. 22 in the next trial against J&J and a group of talc suppliers, this one in Middlesex County Superior Court in New Brunswick, N.J. The suit contends that Stephen Lanzo III, from the time of his birth in 1972, frequently used asbestos-contaminated powder, causing him to contract mesothelioma.

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The documents show that in contrast to their public assurances, J&J officials privately acknowledged decades ago that they had an asbestos problem. They tried to persuade federal regulators that no one would be harmed if talc powder had up to 1 percent asbestos. Moreover, J&J and its industry allies successfully lobbied for a test protocol — still on the books today — that is too crude to detect trace amounts of the carcinogen in talc powders and cosmetics.

Talc, the softest known mineral, has a wide range of uses in cosmetic, pharmaceutical and food products, but talc deposits are sometimes contaminated by naturally-occurring asbestos.

Damage control

The documents echo an asbestos scare that rocked the cosmetics industry in the 1970s. The uproar began when researchers at New York University and Mount Sinai Hospital separately reported finding asbestos in a number of popular talc-based powders and cosmetics. For makers of such up close and personal products, no stigma could be worse, and the industry scurried to contain the damage. For J&J, the bombshell findings were a threat to its wholesome image and to an iconic product that a company memo called "the cornerstone of our baby products franchise."

It turned out that the reports of contamination were somewhat exaggerated. At the time, analytical methods for detecting low levels of asbestos in talc were evolving — sometimes yielding false negatives or false positives. Other labs could not confirm certain of the results, and the NYU and Mount Sinai researchers wound up retracting some of their positive findings.



Celeste Monforton, a former U.S. Department of Labor official and an adjunct professor of occupational and environmental health, at left speaking with a labor activist last year in Morganton, N.C. (Photo courtesy of Oxfam America).

For its part, J&J sought to reassure consumers in a June 29, 1971 [press release](#). "Johnson & Johnson takes great care to assure the purity of its products. ... Over fifty years of research and knowledge in this area indicates that there is no asbestos contained in the powder manufactured by Johnson & Johnson."

But inside the company, a different conversation was taking place. Soon after the press release, a company official declared in a [memo](#): "It would seem more than appropriate that we upgrade the quality control on our talc and baby powder, particularly as to the potential asbestos content."

[Another company memo](#) in April, 1973, noted that "occasionally, sub-trace quantities" of minerals were found in Johnson's Baby Powder that "might be classified as asbestos fiber."

Records show that J&J ran experiments aimed at finding ways to destroy or remove asbestos from talc ores. In a [May, 1974, memo](#), Vernon Zeitz, head of research and development for Windsor Minerals, J&J's talc mining operation, said that pursuing such methods "is strongly urged by this writer to provide the protection against what are currently considered to be materials presenting a severe health hazard and are potentially present in all talc ores in use at this time."

The asbestos scare revealed a general lack of rigor in screening cosmetic talc for low levels of asbestos. Talc suppliers and manufacturers weren't doing much and the U.S. Food and Drug Administration, which has limited authority over cosmetic safety, was doing even less. To assuage public concern, they had to come up with a test procedure that would allow them to confirm their talc was asbestos-free.

But when no asbestos is found in screening tests, it can mean one of two things: Either there is no asbestos, or the test method is not sensitive enough to find it.

Records show that J&J and its allies successfully pushed for a relatively permissive test protocol, fearing that more sensitive procedures would result in high analytical costs and discovery of trace asbestos that could require them to discard talc supplies. They also fended off calls for FDA regulation, successfully lobbying for an industry-administered test developed by their trade group—the Cosmetics, Toiletries and Fragrance Association (since renamed the Personal Care Products Council).

Deploying a small army

J&J rallied a small army to press these objectives. In a December, 1973 [FDA memo](#) that FairWarning obtained under the Freedom of Information Act, an agency official marveled that "in one meeting that we had with them [Johnson & Johnson], 16 technical people from United States and Europe presented a seminar covering analytical methods, toxicology and mining technology."

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This is where the babies-to-miners comparisons came in. J&J sought to convince the FDA that even if small amounts of asbestos slipped, undetected, into cosmetics and powders, no one would be harmed, because the exposures would be a tiny fraction of occupational standards in place at that time.

“Our very preliminary calculation indicates that substantial asbestos can be allowed safely in a baby powder,” a J&J executive wrote after a meeting with the FDA in January, 1974. The memo noted that an FDA official “appeared skeptical” and “implied that what is safe for a miner may not be safe for a baby.”

The company then pressed the argument in a letter to Dr. Robert Schaffner, a senior FDA official. “The calculation shows that a substantial safety factor can be expected with talc containing 1% ... asbestos fibers. Therefore, methods capable of determining less than 1 % asbestos in talc are not necessary to assure the safety of cosmetic talc.”

At a meeting in February, 1975, however, Schaffner dismissed the argument as “foolish since no mother was going to powder her baby with 1% of a known carcinogen regardless of the large safety factor,” a memo said.

“It seems ludicrous to me that you would even be making that calculation,” said Celeste Monforton, a former U.S. Labor Department official who teaches occupational and environmental health at Texas State University. According to Monforton, who reviewed some of the documents at the request of FairWarning, “In this time period of the 1970s it was well established that asbestos was a carcinogen, and the notion that some amount is OK as long as it’s just a little ... is unconscionable.”

There is consensus among experts that a safe level of asbestos exposure has not been determined. In an article published in 2014, an expert panel of USP, a nonprofit scientific standards group, noted that asbestos concentrations “well below 1 percent by weight ... can generate potentially hazardous exposures.” This issue “may be particularly relevant for talc used in powders and cosmetics,” the article said.

For a while it appeared that the FDA might impose test standards by federal regulation, rather than let the industry police itself. An FDA official complained in a memo that the companies weren’t moving quickly enough to address the problem. “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 in 1971,” he wrote, “we have not much choice but to move as speedily as possible with a proposal of a regulation on asbestos.”

Critical timing

For their part, the companies pressed for agency buy-in on their proposed test protocol. “We believe it is critical ... to now recommend these methods to the FDA before the art advances to more sophisticated techniques with higher levels of sensitization,” according to a memo by a J&J executive.

Ultimately, the FDA backed off and accepted the industry test method, which was adopted in 1976.

Although a detection limit of 1 percent asbestos was scrapped—it was set at 0.5% instead—many experts say the test does not assure that potentially hazardous levels of asbestos will be detected.

J&J and at least some other companies supplement the method with additional tests, but those aren’t required—a fact that even some in the industry have criticized. As an executive of the talc mining firm Luzenac (now called Imerys) said in an email to the FDA in 2001: “I think we all recognize” that standard test methods “are simply not sensitive enough to provide complete assurance that the talc is free of detectable asbestos.”

SHOWER
SHOWER

Johnson's
baby
powder

Johnson & Johnson is battling litigation asserting that people contracted mesothelioma, an asbestos-related cancer, from years of using the company's talc powders—Johnson's Baby Powder and Shower to Shower, a product J&J sold to another company in 2012. J&J says the powders are perfectly safe and do not contain asbestos.

FDA officials concluded that the industry test had a positive impact. In 1986, they rejected a citizen's petition to require an asbestos warning on talc products, stating in [a letter](#) that the quality of cosmetic talc had "significantly improved. ... Your petition has not persuaded us that the cosmetic talc that is presently being produced contains significant amounts of asbestiform minerals."

Concern has flickered over the years, however. In [a paper published in 1991](#), Alice M. Blount, a Rutgers University researcher, said she had found asbestos fibers in some talc samples, including in a sample of Johnson's Baby Powder.

Following reports of asbestos contamination in some consumer products, the FDA in 2009-2010 conducted [a survey](#), purchasing 34 talc-based cosmetics and powders, including Johnson's Baby Powder, from retailers in the Washington, D.C. area. The agency also asked nine suppliers to provide samples of raw talc, though only four complied. The samples were analyzed by a sophisticated method called transmission electron microscopy, which uses electron beams to achieve a high level of magnification. No asbestos was detected in any of the products or samples.

"The results were limited, however, by the fact that only four talc suppliers submitted samples and by the number of products tested," the FDA cautioned in its report. Accordingly, the results "do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United State are likely to be free of asbestos contamination."

Targeting the deep pockets

Mesothelioma strikes an average of [about 3,200 U.S. residents per year](#), most dying within a couple of years of diagnosis. Most victims have had identifiable workplace exposures, but others appear to have had little or no contact with asbestos—apart from alleged exposure through years of using talc-based powders and cosmetics. As a result, asbestos lawyers are now targeting deep-pocketed makers of these products.

Separately, J&J faces thousands of lawsuits contending that use of its talc powders for feminine hygiene caused ovarian cancer.

In the mesothelioma case won by J&J last year, Herford's lawyers showed jurors test reports, mostly from the 1970s, appearing to show contamination of talc ore and even finished powders. William Longo, a materials scientist and plaintiff expert, testified that he had analyzed talc containers purchased from collectors on eBay, and found trace levels of asbestos in 17 of 30 containers—including in a container sold as recently as 2016.

"They knew it had asbestos in it ... They were reckless with peoples' lives," Chris Panatier, a lawyer for Herford, told the jury.

J&J lawyers and witnesses disputed all findings of asbestos contamination. They presented documents that they said showed that positive tests were later debunked in follow-up analyses—a result, they said, of such things as lab contamination or analysts mistaking non-asbestos particles for asbestos.

Reports of asbestos contamination have "never been proven to be correct," declared John Hopkins, a toxicologist and former J&J executive.

Defense lawyers made a plausible case for a different cause of Herford's mesothelioma: the aggressive radiation treatments she received for breast cancer in 1998. Therapeutic radiation is one of the only suspected causes of mesothelioma other than asbestos.

Following its victory, J&J blasted the "baseless theory" that its powders could be harmful. "Johnson's Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma," according to the company's statement.

But in December, as a second trial in Los Angeles was about to start, J&J agreed to a settlement with mesothelioma victim Barbara Wittman, and her husband John. In that case, too, a plaintiff's expert had reported finding traces of asbestos in a container of Shower to Shower, another J&J powder.

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Myron Levin is editor of FairWarning.

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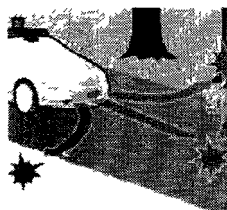
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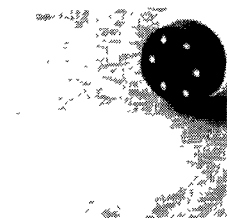


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