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Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder

A REUTERS INVESTIGATION

REUTERS/Mike Wood

Facing thousands of lawsuits alleging that its talc caused cancer, J&J insists on the safety and purity of its iconic product. But internal documents examined by Reuters show that the company's powder was sometimes tainted with carcinogenic asbestos and that J&J kept that information from regulators and the public.

By [LISA GIRION](#) in Los Angeles Filed Dec. 14, 2018, 2 p.m. GMT

Darlene Coker knew she was dying. She just wanted to know why.

She knew that her cancer, mesothelioma, arose in the delicate membrane surrounding her lungs and other organs. She knew it was as rare as it was deadly, a signature of exposure to asbestos. And she knew it afflicted mostly men who inhaled asbestos dust in mines and industries such as shipbuilding that used the carcinogen before its risks were understood.

Coker, 52 years old, had raised two daughters and was running a massage school in Lumberton, a small town in eastern Texas. How had she been exposed to asbestos? “She wanted answers,” her daughter Cady Evans said.

Fighting for every breath and in crippling pain, Coker hired Herschel Hobson, a personal-injury lawyer. He homed in on a suspect: the Johnson’s Baby Powder that Coker had used on her infant children and sprinkled on herself all her life. Hobson knew that talc and asbestos often occurred together in the earth, and that mined talc could be contaminated with the carcinogen. Coker sued Johnson & Johnson, alleging that “poisonous talc” in the company’s beloved product was her killer.



EARLY INDICATION: Cady Evans (left) and her sister, Crystal Deckard, surrounded by pictures of their mother, Darlene Coker, whose lawsuit against Johnson & Johnson 20 years ago was one of the first to allege that the company's Baby Powder caused cancer. REUTERS/Mike Blake

J&J didn't tell the FDA that at least three tests by three different labs from 1972 to 1975 had found asbestos in its talc – in one case at levels reported as “rather high.”

J&J denied the claim. Baby Powder was asbestos-free, it said. As the case proceeded, J&J was able to avoid handing over talc test results and other internal company records Hobson had requested to make the case against Baby Powder.

Coker had no choice but to drop her lawsuit, Hobson said. “When you are the plaintiff, you have the burden of proof,” he said. “We didn't have it.”

That was in 1999. Two decades later, the material Coker and her lawyer sought is emerging as J&J has been compelled to share thousands of pages of company memos, internal reports and other confidential documents with lawyers for some of the 11,700 plaintiffs now claiming that the company's talc caused their cancers — including thousands of women with ovarian cancer.

A Reuters examination of many of those documents, as well as deposition and trial testimony, shows that from at least 1971 to the early 2000s, the company's raw talc and finished powders sometimes tested positive for small amounts of asbestos, and that company executives, mine managers, scientists, doctors and lawyers fretted over the problem and how to address it while failing to disclose it to regulators or the public.

The documents also depict successful efforts to influence U.S. regulators' plans to limit asbestos in cosmetic talc products and scientific research on the health effects of talc.

A small portion of the documents have been produced at trial and cited in media reports. Many were shielded from public view by court orders that allowed J&J to turn over thousands of documents it designated as confidential. Much of their contents is reported here for the first time.

The earliest mentions of tainted J&J talc that Reuters found come from 1957 and 1958 reports by a consulting lab. They describe contaminants in talc from J&J's Italian supplier as

RELATED CONTENT

fibrous and “acicular,” or needle-like, tremolite. That’s one of the six minerals that in their naturally occurring fibrous form are classified as asbestos.

At various times from then into the early 2000s, reports by scientists at J&J, outside labs and J&J’s supplier yielded similar findings. The [reports](#) identify contaminants in talc and finished powder products as asbestos or describe them in terms typically applied to asbestos, such as “fiberform” and “rods.”

In 1976, as the U.S. Food and Drug Administration (FDA) was weighing limits on asbestos in cosmetic talc products, J&J [assured the regulator](#) that no asbestos was “detected in any sample” of talc produced between December 1972 and October 1973. It didn’t tell the agency that at least three [tests](#) by three different labs from 1972 to 1975 had found asbestos in its talc – in one case at levels reported as “[rather high](#).”

Most internal J&J asbestos test reports Reuters reviewed do not find asbestos. However, while J&J’s testing methods improved over time, they have always had limitations that allow trace contaminants to go undetected – and only a [tiny fraction](#) of the company’s talc is tested.

The World Health Organization and other authorities recognize no safe level of exposure to asbestos. While most people exposed never develop cancer, for some, even small amounts of asbestos are enough to trigger the disease years later. Just how small hasn’t been established. Many plaintiffs allege that the amounts they inhaled when they dusted themselves with tainted talcum powder were enough.

The evidence of what J&J knew has surfaced after people who suspected that talc caused their cancers hired lawyers experienced in the decades-long deluge of litigation involving workers exposed to asbestos. Some of the lawyers knew from those earlier cases that talc producers tested for asbestos, and they began demanding J&J’s testing documentation.



A guiding hand on talc safety research



Read the documents cited in this article



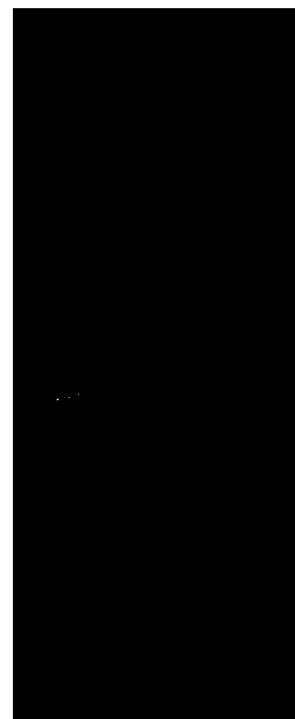
After damaging Reuters report, J&J doubles down on talc safety message

■ A big verdict fuels a reporter's curiosity. REUTERS/Mike Wood

What J&J produced in response to those demands has allowed plaintiffs’ lawyers to refine their argument: The culprit wasn’t necessarily talc itself, but also asbestos in the talc. That assertion, backed by decades of solid science showing that asbestos causes mesothelioma and is associated with ovarian and other cancers, has had mixed success in court.

In two cases earlier this year – in New Jersey and California – juries awarded big sums to plaintiffs who, like Coker, blamed asbestos-tainted J&J talc products for their mesothelioma.

A third verdict, in St. Louis, was a watershed, broadening J&J’s potential liability: The 22 plaintiffs were the first to succeed with a claim that asbestos-tainted Baby Powder and Shower to Shower talc, a longtime brand the company sold in 2012, caused ovarian cancer, which is much more common than mesothelioma. The jury awarded them \$4.69 billion in damages. Most of the talc cases



have been brought by women with ovarian cancer who say they regularly used J&J talc products as a perineal antiperspirant and deodorant.

At the same time, at least three juries have rejected claims that Baby Powder was tainted with asbestos or caused plaintiffs' mesothelioma. Others have failed to reach verdicts, resulting in mistrials.

J&J has said it will appeal the recent verdicts against it. It has maintained in public statements that its talc is safe, as shown for years by the best tests available, and that the information it has been required to divulge in recent litigation shows the care the company takes to ensure its products are asbestos-free. It has blamed its losses on juror confusion, "junk" science, unfair court rules and overzealous lawyers looking for a fresh pool of asbestos plaintiffs.

"Plaintiffs' attorneys out for personal financial gain are distorting historical documents and intentionally creating confusion in the courtroom and in the media," Ernie Knewitz, J&J's vice president of global media relations, wrote in an emailed response to Reuters' findings. "This is all a calculated attempt to distract from the fact that thousands of independent tests prove our talc does not contain asbestos or cause cancer. Any suggestion that Johnson & Johnson knew or hid information about the safety of talc is false."

J&J declined to comment further for this article. For more than two months, it turned down repeated requests for an interview with J&J executives. On Dec. 8, the company offered to make an expert available. It had not done so as of Thursday evening.

The company referred all inquiries to its outside litigation counsel, Peter Bicks. In emailed responses, Bicks rejected Reuters' findings as "false and misleading." "The scientific consensus is that the talc used in talc-based body powders does not cause cancer, regardless of what is in that talc," Bicks wrote. "This is true even if - and it does not - Johnson & Johnson's cosmetic talc had ever contained minute, undetectable amounts of asbestos." He dismissed tests cited in this article as "outlier" results.

In court, J&J lawyers have told jurors that company records showing that asbestos was detected in its talc referred to talc intended for industrial use. Other records, they have argued, referred to non-asbestos forms of the same minerals that their experts say are harmless. J&J has also argued that some tests picked up "background" asbestos - stray fibers that could have contaminated samples after floating into a mill or lab from a vehicle clutch or fraying insulation.

The company has made some of the same arguments about lab tests conducted by experts hired by plaintiffs. One of those labs found asbestos in Shower to Shower talc from the 1990s, according to an Aug. 11, 2017, court report. Another lab found asbestos in more than half of multiple samples of Baby Powder from past decades - in bottles from plaintiffs' cupboards and acquired from eBay, and even a [1978 bottle](#) held in J&J's corporate museum. The concentrations were great enough that users "would have, more likely than not, been exposed," the plaintiffs' lab report presented in several cases this year concluded.

Matthew Sanchez, a geologist with consultants RJ Lee Group Inc and a frequent expert witness for J&J, dismissed those findings in testimony in the St. Louis trial: "I have not found asbestos in any of the current or modern, what I consider modern, Johnson & Johnson talc products," Sanchez told the jury.

Sanchez did not return calls seeking comment. RJ Lee said it does not comment on the work it does for clients.

Since 2003, talc in Baby Powder sold in the United States has come from China through supplier Imerys Talc America, a unit of Paris-based Imerys SA and a co-defendant in most of the talc litigation. Imerys and J&J said the Chinese talc is safe. An Imerys spokesman said the company's tests "consistently show no asbestos. Talc's safe use has been confirmed by multiple regulatory and scientific bodies."

J&J, based in New Brunswick, New Jersey, has dominated the talc powder market for more than 100 years, its sales outpacing those of all competitors combined, according to Euromonitor International data. And while talc products contributed just \$420 million to J&J's \$76.5 billion in revenue last year, Baby Powder is considered an essential facet of the healthcare-products maker's carefully tended image as a caring company - a "sacred cow," as one 2003 internal email put it.

"When people really understand what's going on, I think it increases J&J's exposure a thousand-fold," said Mark Lanier, one of the lawyers for the women in the St. Louis case.

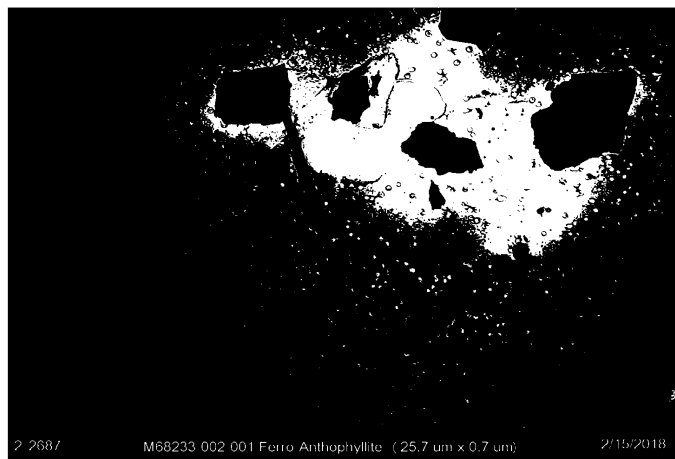
The mounting controversy surrounding J&J talc hasn't shaken investors. The share price is up about 6 percent so far this year. Talc cases make up fewer than 10 percent of all personal injury lawsuits pending against J&J, based on the company's Aug. 2 quarterly report, in which the company said it believed it had "strong grounds on appeal."

J&J Chairman and Chief Executive Officer Alex Gorsky has pledged to fight on, telling analysts in July: "We remain confident that our products do not contain asbestos."

Gorsky's comment, echoed in countless J&J statements, misses a crucial point. Asbestos, like many environmental carcinogens, has a long latency period. Diagnosis usually comes years after initial exposure - 20 years or longer for mesothelioma. J&J talc products today may be safe, but the talc at issue in thousands of lawsuits was sold and used over the past 60 years.

That point is recognized in a 2013 markup of a statement for the “Safety & Care Commitment” page of J&J’s website. The original version conveyed a blanket assurance of safety. The edited version was less definitive: “Our talc-based consumer products are have always been (we cannot say “always”) asbestos free, as confirmed by regular testing since the 1970s.”

2013



NEEDLES IN A HAYSTACK: Bundles (top, center) and a single fiber (bottom) that a plaintiffs’ lab found in a 1978 bottle of Baby Powder from J&J’s corporate museum show the telltale needle-like shape of asbestos. Photo courtesy of Mark Lanier.

JOHNSON’S® talc products are made using U.S. Pharmacopeial (USP) grade talc to ensure it meets the highest-quality, purity and compliance standards. Our talc-based consumer products are have always been (we cannot say “always”) asbestos free, as confirmed by regular testing conducted since the 1970s. We also make JOHNSON’S® Baby Powder that contains cornstarch.

THEN AND NOW: A 2013 markup of a statement for J&J’s website implicitly recognizes the possibility that the company’s talc could have been tainted in earlier times.

“Safety first”

In 1886, Robert Wood Johnson enlisted his younger brothers in an eponymous startup built around the “Safety First” motto. Johnson’s Baby Powder grew out of a line of medicated plasters, sticky rubber strips loaded with mustard and other home remedies. When customers complained of skin irritation, the brothers sent packets of talc.

Soon, mothers began applying the talc to infants’ diaper-chafed skin. The Johnsons took note. They added a fragrance that would become one of the most recognizable in the world, sifted the talc into tin boxes and, in 1893, began selling it as Johnson’s Baby Powder.

In the late 1950s, J&J discovered that talc from its chief source mine for the U.S. market in the Italian Alps contained tremolite. That’s one of six minerals – along with chrysotile, actinolite, amosite, anthophyllite and crocidolite – that occur in nature as crystalline fibers known as asbestos, a recognized carcinogen. Some of them, including tremolite, also occur as unremarkable “non-asbestiform” rocks. Both forms often occur together and in talc deposits.

J&J’s worry at the time was that contaminants made the company’s powder abrasive. It sent tons of its Italian talc to a private lab in Columbus, Ohio, to find ways to improve the appearance, feel and purity of the powder by removing as much “grit” as possible. In a pair of reports from 1957 and 1958, the lab said the talc contained “from less than 1 percent to about 3 percent of contaminants,” described as mostly fibrous and “acicular” tremolite.

Most of the authors of these and other J&J records cited in this article are dead. Sanchez, the RJ Lee geologist whose firm has agreed to provide him as a witness in up to 100 J&J talc trials, has testified that tremolite found decades ago in the company’s talc, from Italy and later Vermont, was not tremolite asbestos at all. Rather, he has said, it was “cleavage fragments” from non-asbestiform tremolite.

J&J’s original records don’t always make that distinction. In terms of health risk, regulators since the early 1970s have treated small fiber-shaped particles of both forms the same.

The U.S. Environmental Protection Agency, for example, “makes no distinction between fibers and (comparable) cleavage fragments,” agency officials wrote in a response to an RJ Lee report on an unrelated matter in 2006, the year before the firm hired Sanchez. The Occupational Safety and Health Administration (OSHA), though it dropped the non-fibrous forms of the minerals from its definition of asbestos in 1992, nonetheless recommends that fiber-shaped fragments indistinguishable from asbestos be counted in its exposure tests.

And as the product safety director for J&J’s talc supplier acknowledged in a 2008 email to colleagues: “(I)f a deposit contains ‘non-asbestiform’ tremolite, there is also asbestiform tremolite naturally present as well.”



“SACRED COW”: Today, Baby Powder accounts for only a small portion of J&J’s annual revenue, but is considered essential to the company’s caring image. REUTERS/Mike Segar

“The lungs of babies”

In 1964, J&J's Windsor Minerals Inc subsidiary bought a cluster of talc mines in Vermont, with names like Argonaut, Rainbow, Frostbite and Black Bear. By 1966, it was blasting and bulldozing white rock out of the Green Mountain state. J&J used the milled powder in its cosmetic powders and sold a less-refined grade to roofing, flooring and tire companies for use in manufacturing.

Ten years after tremolite turned up in the Italian talc, it showed up in Vermont talc, too. In 1967, J&J found traces of tremolite and another mineral that can occur as asbestos, according to a table attached to a Nov. 1, 1967, memo by William Ashton, the executive in charge of J&J's talc supply for decades.

J&J continued to search for sources of clean talc. But in an April 9, 1969, memo to a company doctor, Ashton said it was "normal" to find tremolite in many U.S. talc deposits. He suggested J&J rethink its approach. "Historically, in our Company, Tremolite has been bad," Ashton wrote. "How bad is Tremolite medically, and how much of it can safely be in a talc base we might develop?"

Since pulmonary disease, including cancer, appeared to be on the rise, "it would seem to be prudent to limit any possible content of Tremolite ... to an absolute minimum," came the reply from another physician executive days later.

The doctor told Ashton that J&J was receiving safety questions from pediatricians. Even Robert Wood Johnson II, the founder's son and then-retired CEO, had expressed "concern over the possibility of the adverse effects on the lungs of babies or mothers," he wrote.

"We have replied," the doctor wrote, that "we would not regard the usage of our powders as presenting any hazard." Such assurances would be impossible, he added, "if we do include Tremolite in more than unavoidable trace amounts."

The memo is the earliest J&J document reviewed by Reuters that discusses tremolite as more than a scratchy nuisance. The doctor urged Ashton to consult with company lawyers because "it is not inconceivable that we could become involved in litigation."

Never "100% clean"

By the early 1970s, asbestos was widely recognized as the primary cause of mesothelioma among workers involved in producing it and in industries that used it in their products.

Regulation was in the air. In 1972, President Richard Nixon's newly created OSHA issued its first rule, setting limits on workplace exposure to asbestos dust.

By then, a team at Mount Sinai Medical Center led by pre-eminent asbestos researcher Irving Selikoff had started looking at talcum powders as a possible solution to a puzzle: Why were tests of lung tissue taken post mortem from New Yorkers who never worked with asbestos finding signs of the mineral? Since talc deposits are often laced with asbestos, the scientists reasoned, perhaps talcum powders played a role.

They shared their preliminary findings with New York City's environmental protection chief, Jerome Kretchmer. On June 29, 1971, Kretchmer informed the Nixon administration and called a press conference to announce that two unidentified brands of cosmetic talc appeared to contain asbestos.

The FDA opened an inquiry. J&J issued a statement: "Our fifty years of research knowledge in this area indicates that there is no asbestos contained in the powder manufactured by Johnson & Johnson."

Later that year, another Mount Sinai researcher, mineralogist Arthur Langer, told J&J in a letter that the team had found a "relatively small" amount of chrysotile asbestos in Baby Powder.



ROCK STEADY: Dr Arthur Langer, who was part of a Mount Sinai team researching asbestos in talc in the 1970s, says he stands by his finding of small amounts of asbestos in Baby Powder. REUTERS/Julia Rendleman



SPREADING THE WORD: Jerome Kretchmer was New York City's environmental protection chief when he announced that the Mount Sinai research team had found what appeared to be asbestos in two unidentified brands of cosmetic talc. REUTERS/Jeenah Moon

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W. NASHED
JOHNSON & JOHNSON

Johnson & Johnson

New Brunswick, N.J.
November 29, 1972

**Subject: Antagonistic Personalities
In The Talc Story In The U.S.A.**

NOTORIETY: Langer and Kretchmer ended up on an internal J&J list of "antagonistic personalities."

Langer, Selikoff and Kretchmer ended up on a J&J list of "antagonistic personalities" in a Nov. 29, 1972, memo, which described Selikoff as the leader of an "attack on talc."

"I suppose I was antagonistic," Langer told Reuters. Even so, in a subsequent test of J&J powders in 1976, he didn't find asbestos – a result that Mount Sinai announced.

Langer said he told J&J lawyers who visited him last year that he stood by all of his findings. J&J has not called him as a witness.

Selikoff died in 1992. Kretchmer said he recently read that a jury had concluded that Baby Powder was contaminated with asbestos. "I said to myself, 'How come it took so long?'" he said.

In July 1971, meanwhile, J&J sent a delegation of scientists to Washington to talk to the FDA officials looking into asbestos in talcum powders. According to an FDA account of the meeting, J&J shared "evidence that their talc contains less than 1%, if any, asbestos."

Later that month, Wilson Nashed, one of the J&J scientists who visited the FDA, said in a memo to the company's public relations department that J&J's talc contained trace amounts of "fibrous minerals (tremolite/actinolite)."

As the FDA continued to investigate asbestos in talc, J&J sent powder samples to be tested at private and university labs. Though a private lab in Chicago found trace amounts of tremolite, it declared the amount "insignificant" and the samples "substantially free of asbestiform material." J&J reported that finding to the FDA under a cover letter that said the "results clearly show" the samples tested "contain no chrysotile asbestos." J&J's lawyer told Reuters the tremolite found in the samples was not asbestos.

But J&J's FDA submission left out University of Minnesota professor Thomas E. Hutchinson's finding of chrysotile in a Shower to Shower sample – "incontrovertible asbestos," as he described it in a lab note.



TOP TESTER: Irving Selikoff, who led the Mount Sinai team that investigated asbestos and talc, was also listed among J&J's "antagonistic personalities." Photo courtesy of Arthur Langer

1972

to estimate the relative ~~an~~ area of asbestos
and ~~the~~ talc ~~area~~. One fifth of one square
contained incontrovertible asbestos. while
approximately 1550 squares were covered
with talc. This yield an area percentage

NO DOUBT: In a lab note, a University of Minnesota professor recorded finding "incontrovertible asbestos" in a sample of J&J's Shower to Shower talc.

The FDA's own examinations found no asbestos in J&J powder samples in the 1970s. Those tests, however, did not use the most sensitive detection methods. An early test, for example, was incapable of detecting chrysotile fibers, as an FDA official recognized in a J&J account of an Aug. 11, 1972, meeting with the agency: "I understand that some samples will be passed even though they contain such fibers, but we are willing to live with it."

By 1973, Tom Shelley, director of J&J's Central Research Laboratories in New Jersey, was looking into acquiring patents on a process that a British mineralogist and J&J consultant was developing to separate talc from tremolite.

"It is quite possible that eventually tremolite will be prohibited in all talc," Shelley wrote on Feb. 20, 1973, to a British colleague. Therefore, he added, the "process may well be valuable property to us."

At the end of March, Shelley recognized the sensitivity of the plan in a memo sent to a J&J lawyer in New Jersey: "We will want to carefully consider the ... patents re asbestos in talc. It's quite possible that we may wish to keep the whole thing confidential rather than allow it to be published in patent form and thus let the whole world know."

J&J did not obtain the patents.

While Shelley was looking into the patents, J&J research director DeWitt Petterson visited the company's Vermont mining operation. "Occasionally, sub-trace quantities of tremolite or actinolite are identifiable," he wrote in an April 1973 report on the visit. "And these might be classified as asbestos fiber."

J&J should "protect our powder franchise" by eliminating as many tiny fibers that can be inhaled in airborne talc dust as possible, Petterson wrote. He warned, however, that "no final product will ever be made which will be totally free from respirable particles." Introducing a cornstarch version of Baby Powder, he noted, "is obviously another answer."

1973

undertaken with a good chance of success in this area. It should be cautioned, however, that no final product will ever be made which will be totally free from respirable particles. We are talking about a significant reduction in fine particle count but not 100% clean-up.

UNACHIEVABLE: J&J research director DeWitt Petterson warned the company that producing pure talc was impossible.

Bicks told Reuters that J&J believes that the tremolite and actinolite Petterson cited were not asbestos.

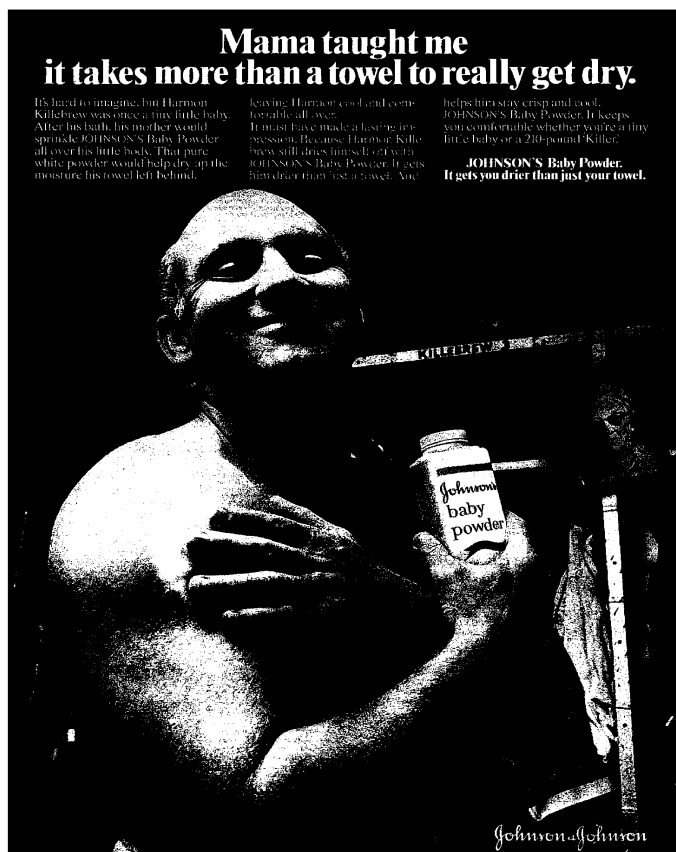
Cornstarch came up again in a March 5, 1974, report in which Ashton, the J&J talc supply chief, recommended that the company research that alternative "for defensive reasons" because "the thrust against talc has centered primarily on biological problems alleged to result from the inhalation of talc and related mineral particles."

"We may have problems"

A few months after Petterson's recognition that talc purity was a pipe dream, the FDA proposed a rule that talc used in drugs contain no more than 0.1 percent asbestos. While the agency's cosmetics division was considering similar action on talcum powders, it asked companies to suggest testing methods.

At the time, J&J's Baby Powder franchise was consuming 20,000 tons of Vermont talc a year. J&J pressed the FDA to approve an X-ray scanning technique that a company scientist said in an April 1973 memo allowed for "an automatic 1% tolerance for asbestos." That would mean talc with up to 10 times the FDA's proposed limit for asbestos in drugs could pass muster.

The same scientist confided in an Oct. 23, 1973, note to a colleague that, depending on what test the FDA adopted for detecting asbestos in cosmetic talc, "we may have problems."



1972: Baseball Hall of Fame slugger Harmon Killebrew plugs Baby Powder.

The best way to detect asbestos in talc was to concentrate the sample and then examine it through microscopes, the Colorado School of Mines Research Institute told J&J in a Dec. 27, 1973, [report](#). In a [memo](#), a J&J lab supervisor said the concentration technique, which the company's own researchers had earlier used to identify a "tremolite-type" asbestos in Vermont talc, had one limitation: "It may be too sensitive."

"No mother was going to powder her baby with 1% of a known carcinogen regardless of the large safety factor."

An FDA official commenting in 1975 on the talc testing method J&J backed

In his email to Reuters, J&J's lawyer said the lab supervisor's concern was that the test would result in "false positives," showing asbestos where there was none.

J&J also launched [research](#) to find out how much powder a baby was exposed to during a diapering and how much asbestos could be in that powder and remain within OSHA's new workplace exposure [limits](#). Its researchers had strapped an air sampling device to a doll to take measurements while it was powdered, according to J&J memos and the minutes of a Feb. 19, 1974, meeting of the Cosmetic Toiletry and Fragrance Association (CTFA), an industry group.

"It was calculated that even if talc were pure asbestos the levels of exposure of a baby during a normal powdering are far below the accepted tolerance limits," the minutes state.

In a Sept. 6, 1974, [letter](#), J&J told the FDA that since "a substantial safety factor can be expected" with talc that contains 1 percent asbestos, "methods capable of determining less than 1% asbestos in talc are not necessary to assure the safety of cosmetic talc."

Not everyone at the FDA thought that basing a detection method on such a calculation was a good idea. One official called it "foolish," adding, according to a J&J [account](#) of a February 1975 meeting: "No mother was going to powder her baby with 1% of a known carcinogen regardless of the large safety factor."

"Misrepresentation by omission"

Having failed to persuade the FDA that up to 1 percent asbestos contamination was tolerable, J&J began promoting self-policing as an alternative to regulation. The centerpiece of this approach was a March 15, 1976, package of letters from J&J and other manufacturers that the CTFA gave to the agency to show that they had succeeded at eliminating asbestos from cosmetic talc.

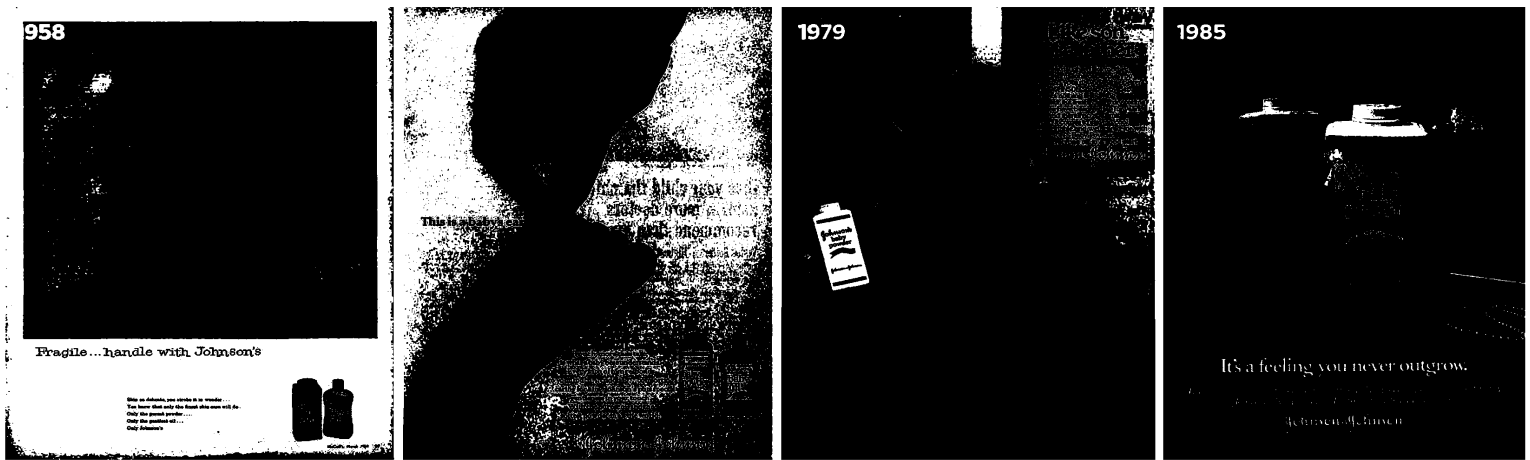
"The attached letters demonstrate responsibility of industry in monitoring its talcs," the [cover letter](#) said. "We are certain that the summary will give you assurance as to the freedom from contamination by asbestos for materials of cosmetic talc products."

In its [letter](#), J&J said samples of talc produced between December 1972 and October 1973 were tested for asbestos, and none was detected "in any sample."

J&J didn't tell the FDA about a 1974 [test](#) by a professor at Dartmouth College in New Hampshire that turned up asbestos in talc from J&J – "fiberform" actinolite, as he put it. Nor did the company tell the FDA about a 1975 report from its longtime lab that found particles identified as "asbestos fibers" in five of 17 samples of talc from the chief source mine for Baby Powder. "Some of them seem rather high," the private lab wrote in its [cover letter](#).

Bicks, the J&J lawyer, said the contract lab's results were irrelevant because the talc was intended for industrial use. He said the company now believes that the actinolite the Dartmouth professor found "was not asbestiform," based on its interpretation of a [photo](#) in the original lab report.

Just two months after the Dartmouth professor reported his findings, Windsor Minerals Research and Development Manager Vernon Zeitz wrote that chrysotile, "fibrous anthophyllite" and other types of asbestos had been "found in association with the Hammondsville ore body" – the Vermont deposit that supplied Baby Powder talc for more than two decades.



FOR EVERYONE: For decades, J&J has promoted its iconic Baby Powder as a safe, gentle product for babies and adults alike.

Zeitz's May 1974 report on efforts to minimize asbestos in Vermont talc "strongly urged" the adoption of ways to protect "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."

Bicks said that Zeitz was not reporting on actual test results.

The following year, Zeitz reported that based on weekly tests of talc samples over six months, "it can be stated with a greater than 99.9% certainty that the ores and materials produced from the ores at all Windsor Mineral locations are free from asbestos or asbestiform minerals."

J&J's selective use of test results figured in a New Jersey judge's decision this year to affirm the first verdict against the company in a case claiming asbestos in J&J products caused cancer. "Providing the FDA favorable results showing no asbestos and withholding or failing to provide unfavorable results, which show asbestos, is a form of a misrepresentation by omission," Middlesex County Superior Court Judge Ana Viscomi said in her June ruling.

"J&J respectfully disagrees with the Judge's comments," Bicks said. "J&J did not withhold any relevant testing from FDA."

The FDA declined to comment on the ruling.

Lacking consensus on testing methods, the FDA postponed action to limit asbestos in talc. Years later, it did set limits on asbestos in talc used in drugs. It has never limited asbestos in cosmetic talc or established a preferred method for detecting it.

Instead, in 1976, a CTFA committee chaired by a J&J executive drafted voluntary guidelines, establishing a form of X-ray scanning with a 0.5 percent detection limit as the primary test, the method J&J preferred. The method is not designed to detect the most commonly used type of asbestos, chrysotile, at all. The group said the more sensitive electron microscopy was impractical.

The CTFA, which now does business as the Personal Care Products Council, declined to comment.

X-ray scanning is the primary method J&J has used for decades. The company also periodically requires the more sensitive checks with electron microscopes. J&J's lawyer said the company's tests exceed the trade association standard, and they do. He also said that today, J&J's X-ray scans can detect suspect minerals at levels as low as 0.1 percent of a sample.

But the company never adopted the Colorado lab's 1973 recommendation that samples be concentrated before examination under a microscope. And the talc samples that were subjected to the most sensitive electron microscopy test were a tiny fraction of what was sold. For those and other reasons, J&J couldn't guarantee its Baby Powder was asbestos-free when plaintiffs used it, according to experts, including some who testified for plaintiffs.

As early as 1976, Ashton, J&J's longtime talc overseer, recognized as much in a memo to colleagues. He wrote that talc in general, if subjected to the most sensitive testing method, using concentrated samples, "will be hard pressed in supporting purity claims." He described this sort of testing as both "sophisticated" and "disturbing."

By 1977, J&J appeared to have tamped down concerns about the safety of talc. An internal August report on J&J's "Defense of Talc Safety" campaign noted that independent authorities had deemed cosmetic talc products to be "free of hazard." It attributed "this growing opinion" to the dissemination to scientific and medical communities in the United States and Britain of "favorable data from the various J&J sponsored studies."

In 1984, FDA cosmetics chief and former J&J employee Heinz Eiermann reiterated that view. He told the New York Times that the agency's investigation a decade earlier had prompted the industry to ensure that talc was asbestos-free. "So in subsequent analyses," he told the paper, "we really could not identify asbestos or only on very rare occasions."

Two years later, the FDA rejected a citizen request that cosmetic talc carry an asbestos warning label, saying that even if there were trace contamination, the use of talc powder during two years of normal diapering would not increase the risk of cancer.

In 1980, J&J began offering a cornstarch version of Baby Powder – to expand its customer base to people who prefer cornstarch, the company says.

The persistence of the industry's view that cosmetic talc is asbestos-free is why no studies have been conducted on the incidence of mesothelioma among users of the products. It's also partly why regulations that protect people in mines, mills, factories and schools from asbestos-laden talc don't apply to babies and others exposed to cosmetic talc – even though Baby Powder talc has at times come from the same mines as talc sold for industrial use. J&J says cosmetic talc is more thoroughly processed and thus purer than industrial talc.

Until recently, the American Cancer Society (ACS) accepted the industry's position, saying on its website: "All talcum products used in homes have been asbestos-free since the 1970s."

After receiving inquiries from Reuters, the ACS in early December revised its website to remove the assurance that cosmetic talcs are free of asbestos. Now, it says, quoting the industry's standards, that all cosmetic talc products in the United States "should be free from detectable amounts of asbestos."

The revised ACS web page also notes that the World Health Organization's International Agency for Research on Cancer classifies talc that contains asbestos as "carcinogenic to humans."

Despite the success of J&J's efforts to promote the safety of its talc, the company's test lab found asbestos fibers in samples taken from the Vermont operation in 1984, 1985 and 1986. Bicks said: "The samples that we know of during this time period that contained a fiber or two of asbestos were not cosmetic talc samples."

Then, in 1992, three years after J&J sold its Vermont mines, the new owner, Cyprus Minerals, said in an internal report on "important environmental issues" in its talc reserves that there was "past tremolite" in the Hammondsville deposit. Hammondsville was the primary source of Baby Powder talc from 1966 until its shutdown in 1990.

Bicks rejected the Cyprus report as hearsay, saying there is no original documentation to confirm it. Hammondsville mine records, according to a 1993 J&J memo, "were destroyed by the mine management staff just prior to the J&J divestiture."

Bicks said the destroyed documents did not include talc testing records.

1993

****(Note: The specifics of the mining operation at Hammondsville are uncertain, as most of the pre-Luzenac records were destroyed by the mine management staff just prior to the J&J divestiture and the Cyprus purchase. However, several former Hammondsville miners are still employed at the Ham mine, and they provided us with useful information as to the nature of the underground works.)***

MISSING: A J&J memo reveals that records of the Hammondsville mine, the main source of Baby Powder talc from 1966 until 1990, were destroyed by mine managers while J&J still owned the business.

In 2002 and 2003, Vermont mine operators found chrysotile asbestos fibers on several occasions in talc produced for Baby Powder sold in Canada. In each case, a single fiber was recorded – a finding deemed "BDL" – below detection limit. Bicks described the finding as "background asbestos" that did not come from any talc source.

In 2009, the FDA, responding to growing public concern about talc, commissioned tests on 34 samples, including a bottle of J&J Baby Powder and samples of Imerys talc from China. No asbestos was detected.

FDA Commissioner Scott Gottlieb said the agency continues to receive a lot of questions about talc cosmetics. "I recognize the concern," he told Reuters. He said the agency's policing of cosmetics in general – fewer than 30 people regulating a "vast" industry – was "a place where we think we can be doing more."

Blair Brown for Johnson's Baby ...



Actress Blair Brown touts Baby Powder in this 1970s-era TV commercial

Gottlieb said the FDA planned to host a public forum in early 2019 to “look at how we would develop standards for evaluating any potential risk.” An agency spokeswoman said that would include examining “scientific test methods for assessment of asbestos.”

“Fishing expedition”

Before law school, Herschel Hobson worked at a rubber plant. There, his job included ensuring that asbestos in talc the workers were exposed to didn’t exceed OSHA limits.

That’s why he zeroed in on Johnson’s Baby Powder after he took on Darlene Coker as a client in 1997. The lawsuit Coker and her husband, Roy, filed that year against J&J in Jefferson County District Court in Beaumont, Texas, is the earliest Reuters found alleging Baby Powder caused cancer.

Hobson asked J&J for any research it had into the health of its mine workers; talc production records from the mid-1940s through the 1980s; depositions from managers of three labs that tested talc for J&J; and any documents related to testing for fibrous or asbestiform materials.

J&J objected. Hobson’s “fishing expedition” would not turn up any relevant evidence, it asserted in a May 6, 1998, motion. In fact, among the thousands of documents Hobson’s request could have turned up was a letter J&J lawyers had received only weeks earlier from a Rutgers University geologist confirming that she had found asbestos in the company’s Baby Powder, identified in her 1991 published study as tremolite “asbestos” needles.

Hobson agreed to postpone his discovery demands until he got the pathology report on Coker’s lung tissue. Before it came in, J&J asked the judge to dismiss the case, arguing that Coker had “no evidence” Baby Powder caused mesothelioma.

Ten days later, the pathology report landed: Coker’s lung tissue contained tens of thousands of “long fibers” of four different types of asbestos. The findings were “consistent with exposure to talc containing chrysotile and tremolite contamination,” the report concluded.

“The asbestos fibers found raise a new issue of fact,” Hobson told the judge in a request for more time to file an opposition to J&J’s dismissal motion. The judge gave him more time but turned down his request to resume discovery.

Without evidence from J&J and no hope of ever getting any, Hobson advised Coker to drop the suit.

Hobson is still practicing law in Nederland, Texas. When Reuters told him about the evidence that had emerged in recent litigation, he said: “They knew what the problems were, and they hid it.” J&J’s records would have made a “100% difference” in Coker’s case.

Had the information about asbestos in J&J’s talc come out earlier, he said, “maybe there would have been 20 years less exposure” for other people.

Bicks, the J&J lawyer, said Coker dropped her case because “the discovery established that J&J talc had nothing to do with Plaintiff’s disease, and that asbestos exposure from a commercial or occupational setting was the likely cause.”

Coker never learned why she had mesothelioma. She did beat the odds, though. Most patients die within a year of diagnosis. Coker held on long enough to see her two grandchildren. She died in 2009, 12 years after her diagnosis, at age 63.

Coker’s daughter Crystal Deckard was 5 when her sister, Cady, was born in 1971. Deckard remembers seeing the white bottle of Johnson’s Baby Powder on the changing table where her mother diapered her new sister.

“When Mom was given this death sentence, she was the same age as I am right now,” Deckard said. “I have it in the back of my mind all the time. Could it happen to us? Me? My sister?”



NO SATISFACTION: Lacking the evidence she needed, Darlene Coker, here with one of her doctors, died without ever finding out what caused her mesothelioma. Cady Evans/Handout via REUTERS

A guiding hand on talc safety research

By [LISA GIRION](#)

Johnson & Johnson developed a strategy in the 1970s to deal with a growing volume of research showing that talc miners had elevated rates of lung disease and cancer: Promote the positive, challenge the negative.

That approach was summed up by a J&J applied research director in a “strictly confidential” March 3, 1975, memo to managers of the baby products division, which used the talc in J&J’s signature Baby Powder.

“Our current posture with respect to the sponsorship of talc safety studies has been to initiate studies only as dictated by confrontation,” the [memo](#) said. “This philosophy, so far, has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc.”

1973

Our current posture with respect to sponsorship of talc safety studies has been to initiate studies only as dictated by confrontation. This philosophy, so far, has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc. The principal advantage for this operating philosophy lies in the fact that we minimize the risk of possible self-generation of scientific data which may be politically or scientifically embarrassing.

A J&J executive laid out the company’s policy of countering negative research about the health effects of talc in a memo to managers.

Also, the memo said, “we minimize the risk of possible self-generation of scientific data which may be politically or scientifically embarrassing.”

J&J’s effort to protect its iconic Baby Powder franchise by shaping research was led by physician and scientist executives. An early 1970s study of 1,992 Italian talc miners shows how it worked: J&J commissioned and paid for the study, told the researchers the results it wanted, and hired a ghostwriter to redraft the article that presented the findings in a journal.

The effort entailed other attempts to influence research, including a U.S. government study of the health of talc workers in Vermont. J&J’s Windsor Minerals Inc subsidiary, one of several mine operators involved in the study, developed a relationship with the U.S. National Institute of Occupational Safety and Health researchers to “even influence the conclusions” through suggestions of “subjective interpretations,” according to a 1973 Windsor Minerals [memo](#).

Peter Bicks, outside counsel for J&J, told Reuters in an email that for the Vermont study, company “representatives acted in an ‘educational and advisory capacity’ to provide the researchers with a realistic study plan.”

A 1979 article in the Journal of Environmental Pathology and Toxicology detailing the findings of the study was not good news for talc. It reported a “significant increase” in “respiratory cancer mortality” among miners. A subsequent analysis of the underlying data published in 1988 determined that at least one of the workers died of mesothelioma, the cancer most closely associated with asbestos.

The proposal to study the health of miners of the Italian talc used in Baby Powder for decades came from William Ashton, J&J’s longtime talc supply chief. Ashton had obtained a summary of miners’ medical records compiled by an Italian physician, who also happened to control the country’s talc exports.

J&J should use those records “for maximum benefit,” Ashton said in a May 8, 1973, [letter](#) to Dr Gavin Hildick-Smith, J&J’s director of medical affairs. “It seems to me that the Italian records give us the opportunity to fortify a position on talc safety.”

At the time, the U.S. Food and Drug Administration was considering a limit on asbestos in talcs. In an Oct. 18, 1973, [memo](#), Hildick-Smith advised J&J: “The risk/benefit ratio of conducting an epidemiological study in these mines must be considered.”

By early 1974, the study was a go. Hildick-Smith sent money to the Italian talc exporter-physician to hire a team of researchers. Hildick-Smith told the lead researcher in a June 26, 1974, [letter](#) exactly what J&J wanted: data that “would show that the incidence of cancer in these subjects is no different from that of the Italian population or the rural control group.”

That is exactly what J&J got, Hildick-Smith told colleagues a few months later. At a meeting on Sept. 27, 1974, for a “Talc/powder Safety Studies Review,” he [reported](#) the Italian study would dispel the “cancer concern associated with exposure to talc.”

The following spring, Hildick-Smith got a draft of the Italian study from the lead researcher. It needed work to meet the “form and style” requirements of the target journal, he told colleagues in a March 31, 1975, memo. He added that he would send it to a scientific ghostwriter “who will hold it in confidence and rewrite it.”

The article that appeared in 1976 in the Journal of Occupational and Environmental Medicine reported results even better than J&J had bargained for. The study found fewer lung cancer deaths than expected, a result that the authors said supported “the thesis of no cancerogenic effect attributable to pure talc.”

It also found no mesothelioma, the signature cancer of asbestos exposure. There is no evidence J&J manipulated or misused the data. Experts for plaintiffs have testified that the Italian study was too small to draw any conclusions about the incidence of such a rare cancer. J&J’s expert witnesses have concluded the opposite.

Bicks noted that the Italian study has been updated three times – in 1979, 2003 and 2017 – “confirming the lack of association between exposure to asbestos-free talc, lung cancer and mesothelioma.”

J&J got a lot of mileage out of the study. It was cited in a review article titled “The Biology of Talc,” published Nov. 1, 1976, in the British Journal of Industrial Medicine. In addition to dozens of published studies, the review cited unpublished research, including one experiment that used a doll as a proxy for infants and that supported the company’s position on the safety of talc. It didn’t disclose that J&J had commissioned the unpublished research.

The author of the review article concluded that the “concern that has been expressed about the possible health hazard from consumer exposure to cosmetic talc is unwarranted ... There is no evidence that its normal use poses a hazard to health.”

The author was Hildick-Smith, the J&J physician executive who had overseen the Italian study and played a key role in the company’s talc safety research. The article did not disclose his J&J connection, identifying him only as a Rutgers University clinical assistant professor. Hildick-Smith died in 2006.

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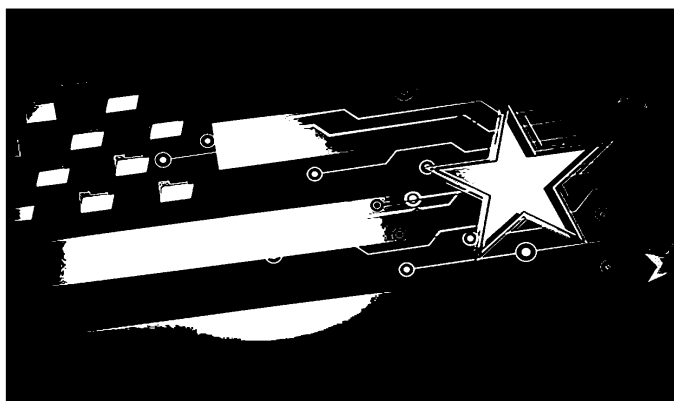


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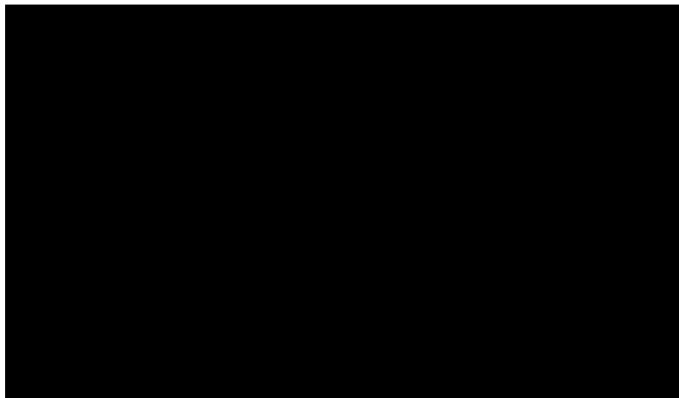


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