

Talc-Ovarian Cancer Link Sparks Growing Legal Battle

By [Myron Levin](#) on April 29, 2015



Deane Berg, who filed a first-of-its kind lawsuit blaming her ovarian cancer on Johnson & Johnson talc powders

Deane Berg's doctor called her in the day after Christmas, 2006, to give her the crushing news. She'd had her ovaries removed, the pathology results were back, and they could not have been much worse. Berg had [stage III](#) ovarian cancer, and her prognosis was poor.

Despite her 25 years as a physician's assistant, Berg, then 49, knew next to nothing about ovarian cancer. Grappling with the "why me?" question, she studied the [risk factors](#), finding just one that could apply: regular use of talcum powder for feminine hygiene.

Talc powder might be a cause ovarian cancer—who knew? It turned out that some people did. Berg was stunned to learn that since the early 1980s, a slew of studies had found that women who regularly used talc powder for feminine hygiene had higher than average rates of ovarian cancer. Yet the evidence—which fell short of proving causation—was mostly confined to medical journals and had barely made a blip on the public radar.

For millions of women, Berg included, dusting the genitals or underwear with powder was a daily ritual, like brushing teeth. Since her teens, Berg had used Johnson's Baby Powder and Shower to Shower, another Johnson & Johnson powder marketed to women. "A sprinkle a day keeps odor away," the ads said. "Your body perspires in more places than just under your arms."

How could a product meant for babies be dangerous? "This is crazy," Berg recalled thinking. "Why aren't they warning women about it?"

So after painful rounds of chemotherapy, Berg filed a first-of-its-kind lawsuit against J&J in federal court in her home town of Sioux Falls, S.D. A mystifying verdict in October, 2013, enabled both sides to declare victory. The jury found Johnson & Johnson Consumer Cos., guilty of negligence for failing to warn of the risk of ovarian cancer, but awarded zero damages to Berg. More on this later.

Yet the case brought a slow-building controversy to a head. Plaintiff lawyers, heartened by a liability finding in arch-conservative South Dakota, have since brought claims for about 700 ovarian cancer victims or their survivors, blaming the disease on exposure to talc powder. More cases are in the pipeline. Along with J&J, the suits name Imerys Talc America, Inc., part of the global mining concern that supplies talc to J&J. Other marketers of talc powder and the Personal Care Products Council, a Washington, D.C. trade group for cosmetics makers, are named in some of the cases.

"We use this on children ... and it had to be a good thing, right?" said plaintiff Deborah Gianneccchini, 62, a Modesto, Calif., hospital secretary diagnosed with metastatic ovarian cancer in November 2012.

"This is an ugly disease," she told FairWarning. "I sure would have appreciated being given the chance to say this is worth the risk or it isn't."

In J&J, "we're dealing with a company that has done nothing to inform customers of the risk and, in fact, I believe has taken steps to hide the risk from the public," said Ted Meadows, a lawyer with the Montgomery, Ala., firm of Beasley, Allen, which is involved in many of the cases.





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- Deborah Giannecchini, ovarian cancer victim and plaintiff in a lawsuit against Johnson & Johnson

Imerys and the Personal Care Products Council wouldn’t comment, and J&J refused interview requests, but released a statement: “We have no higher responsibility than the health and safety of consumers who rely on our products. It is important for consumers to know that the safety of cosmetic talc is supported by decades of scientific evidence and independent peer-reviewed studies.”

The companies contend that statistical associations between talc use and ovarian cancer are weak, and may result from bias in the study methods. A causal link is not biologically plausible, they say, since there is no proof that talc particles can pass through the genital tract to the ovaries or that, once there, they could cause malignant growths. There is no causal link, they argue, so warnings were unnecessary.

Most of the lawsuits have been filed in New Jersey, where J&J is headquartered, or in state court in St. Louis, Mo., considered a favorable venue for plaintiffs. The first trials are scheduled for early 2016.

About 20,000 U.S. women annually are diagnosed with ovarian cancer, and more than 14,000 die. Ovarian cancer strikes about one woman in 70. Studies showing a higher rate of the disease with talc use have typically

found an increased risk of about 35 percent—which would put the odds at about one in 50.

Talc, the softest of minerals, has a multitude of industrial and consumer product uses, including in the manufacture of paints, paper, rubber, roofing and ceramic materials, and even as a food additive, a filler in capsules and pills and in cosmetics.

Complicating the health question is that talc deposits are often interlaced with other minerals, including asbestos. That means the danger, if any, may be due to impurities, rather than talc itself. Over the years, some groups of talc miners have been stricken with asbestos diseases. Talc suppliers have also paid settlements or judgments to factory workers, such as tire makers, who contracted asbestos-related illnesses following exposure to industrial grade talc.

In 1976, researchers at Mount Sinai Hospital in New York published test results on 20 talc-based consumer products, including baby and facial powders. They found two types of asbestos, tremolite and anthophyllite, in 10 of the 20 products. That same year, the Personal Care Products Council (then called the Cosmetic, Toiletry and Fragrance Association) issued a standard requiring “a complete absence of detectable asbestos in cosmetic talc.”

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- Statement by Johnson & Johnson

[J&J vows](#) that its talc is “asbestos free, as confirmed by regular testing conducted since the 1970s.” The ovarian cancer suits take the claim at face value, asserting that talc itself, not impurities, caused the disease. The suits charge J&J with failing to take the precaution of replacing talc with cornstarch, which has similar skin-soothing properties but has not been linked to health risks. While defending the safety of talc, J&J has offered powders with cornstarch or cornstarch-talc blends.



“This is crazy. Why aren’t they warning women about it?”

- Deane Berg

In October 2012, for reasons neither company would discuss, J&J sold North American [marketing rights](#) to Shower to Shower to Valeant Pharmaceuticals.

“Inaccurate, to phrase it euphemistically”

Suspicious about talc and ovarian cancer go back decades. In 1971, [British researchers](#) analyzed 13 ovarian tumors under a microscope and found talc particles “deeply embedded” in 10.

In 1982, the journal Cancer [published the first](#) study showing a statistical link between genital talc use and ovarian cancer. Soon after, lead author Dr. Daniel Cramer, a gynecologist and Harvard Medical School professor, was visited by a senior scientist from J&J. He “spent his time trying to convince me that talc use was a harmless habit,” Cramer recalled in

[a document filed in court](#), “while I spent my time trying to persuade him ... that women should be advised of this potential risk.”

Altogether, [about 20 epidemiological studies have found increased rates](#) of ovarian cancer risk for women using talc for hygiene purposes. [One of these reports](#), published by Cramer and several co-authors in 1999, said talc use could be the cause of about 10 percent of ovarian cancers in the U.S.—or some 2,000 cases per year. “Balanced against what are primarily aesthetic reasons for using talc in genital hygiene, the risk benefit decision is not complex,” the study said. “Appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area.”

In response to such findings, the Cancer Prevention Coalition, an advocacy group, asked the Food and Drug Administration in 1994 to require warnings against talc use for genital hygiene. The agency said it lacked evidence to require warnings, and J&J refused to issue them voluntarily.

Instead, the company and its allies circled the wagons. In 1992, the cosmetic and fragrance association [launched a Talc Interested Party Task Force](#) to develop talking points and find experts to rebut studies linking talc to ovarian cancer.

But some statements by the trade group were “inaccurate, to phrase it euphemistically,” a consultant for J&J warned. In two 1997 letters to company officials ([here](#) and [here](#)), toxicologist Alfred P. Wehner attacked statements that “the scientific evidence did not demonstrate any real association between talc use in consumer products and ovarian tumors.”

“There are at least 9 epidemiological studies published in the professional literature describing a statistically significant (albeit weak) association between hygienic talc use and ovarian cancer,” Wehner wrote.

“Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.”

“Arrogance and insolence”

As debate continued in scientific circles, the National Toxicology Program, part of the U.S. Department of Health and Human Services, ruled in 2005 that existing data were insufficient to list talc as a cancer-causing agent.

The following year, however, the International Agency for Research on Cancer, part of the World Health Organization, classified talc as a 2B agent—“possibly carcinogenic to human beings,”—based on the “remarkably consistent” results of epidemiological studies. “A positive association was observed,” IARC said, “but chance, bias or confounding factors cannot be ruled out with reasonable confidence.”

Industry officials have downplayed the significance of the IARC action, noting that coffee drinking is also listed 2B for possible links to bladder cancer. But emails produced in the Berg case show industry officials were deeply upset by the IARC ruling.

A senior executive with J&J talc supplier Luzenac America (now known as Imerys), condemned the decision as “a travesty of scientific integrity.”

Rich Zazenski, Luzenac’s director of environment and safety, declared in the Feb. 27, 2006 [email to a J&J official](#): “I can’t believe the arrogance and insolence of this ‘U.N. agency.’”

Talc and Ovarian Cancer: *A Slow-Building Controversy*

- 1971** — Study by British researchers finds talc particles “deeply embedded” in 10 of 13 ovarian cancer tumors.
- 1982** — First study showing statistical link between genital talc use and ovarian cancer. Over next 30 years, about 20 more epidemiological studies will also show modest increase in risk of ovarian cancer among talc users.
- 1992** — Cosmetics industry trade group forms Talc Interested Party Task Force to develop talking points and find experts to rebut studies linking talc to ovarian cancer.
- 1994** — Food and Drug Administration rejects petition by Cancer Prevention Coalition, an advocacy group, to require a warning against using talc for genital hygiene, citing lack of evidence.
- 2005** — U.S. National Toxicology Program rules existing data insufficient to list talc as a cancer-causing agent.
- 2006** — International Agency for Research on Cancer, a branch of the World Health Organization, classifies talc as a 2B agent, “possibly carcinogenic to human beings.”
- 2013** — Cosmetic Ingredient Review, an industry funded group, issues finding that talc “is safe in the present practices of use and concentration.”
- 2013** — In first-of-its-kind lawsuit, jury finds unit of Johnson & Johnson guilty of failing to warn of ovarian cancer risk, but awards plaintiff Deane Berg zero damages.
- 2015** — Johnson & Johnson and its talc supplier Imerys face about 700 claims by ovarian cancer victims who say they contracted the disease through regular use of Johnson’s Baby Powder and Shower to Shower.

MICHELLE ZIOMEK/FAIRWARNING

“Rest assured, we (I) will explore all possible avenues of challenge—not necessarily expecting a retraction—but to see what sort of political heat (with financial ramifications) that could and should be brought down upon IARC and WHO,” the email said. Zazenski died in 2008, and it’s uncertain if there was an effort to carry out the threat.

In 2013, the industry cheered the findings of an expert panel of the [Cosmetic Ingredient Review](#), a group that is funded by cosmetics manufacturers but says its reviews are independent. The panel declared that talc “is safe in the present practices of use and concentration.”

A coveted image

J&J was founded in the 1880s by the brothers Robert Wood, James Wood and Edward Mead Johnson. First aid kits, dental floss, sanitary napkins and baby powder were among their first products. Today, J&J is [a \\$74 billion-a-year colossus](#) with a workforce of nearly 129,000, more than 275 operating companies in over 60 countries, and a huge footprint in pharmaceuticals and medical devices, along with consumer health aids.

Yet the Johnson & Johnson name still evokes cherubic infants and adoring moms, burnishing an image that most big companies can only envy. Fortune Magazine’s 2015 list of most admired companies ranks J&J first in the pharmaceutical industry and 11th of 668 companies worldwide. In December, the website CareerBliss.com, ranked J&J number one on its list of the [50 Happiest Companies in America](#), which honors businesses with the most contented workers.

J&J last year won kudos for vowing to share clinical trial data with researchers, and for announcing it was testing an Ebola vaccine. In December, a 3 1/2 minute [infomercial](#) with singer-actor Jennifer Hudson on ABC’s “The View” touted one of J&J’s charitable endeavors.

“What a great company they are!” enthused Rosie O’Donnell, then co-host of The View. “They’re a wonderful company that America’s believed in for so long.”

Legal battles that have engulfed the company leave a different impression, however.

Last month, J&J’s McNeil Consumer Health Care division [pleaded guilty](#) to a criminal charge of selling adulterated medicines, including children’s Tylenol and Motrin that were contaminated with bits of metal. The plea deal with the Justice Department, which included a criminal fine and forfeitures of \$25 million, capped a series of recalls and enforcement actions stemming from quality control breakdowns at McNeil’s Fort Washington, Pa., plant.

In November 2013, J&J and two subsidiaries, Janssen Pharmaceuticals and Scios, Inc., agreed to pay more than \$2.2 billion to the U.S. and 45 states [to settle criminal and civil charges](#) of illegally promoting Risperdal and other anti-psychotic drugs for unapproved uses. They had also been accused of paying kickbacks to doctors and a major



pharmacy to prescribe the drugs. As part of the settlement, Janssen pleaded guilty to a criminal misdemeanor. J&J settled the remaining civil allegations [without admitting wrongdoing](#).

The same month, J&J's DePuy Orthopaedics unit announced an agreement to pay [about \\$2.5 billion to compensate 8,000 patients](#) who had surgery to replace allegedly defective DePuy hip joints. Earlier this year, the company reached a similar settlement with another 1,400 patients—yet it still faces thousands of injury claims related to the DePuy implants.

By [J&J's count](#), at the end of 2014 it faced 56,300 personal injury claims in the U.S. involving three product lines: hip implants, Risperdal and pelvic mesh devices made by its Ethicon Inc. subsidiary.



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- Attorney Ted Meadows

The talc litigation, on the other hand, wasn't even get mentioned in J&J's 2014 annual report. Still, the challenge has not been taken lightly. J&J has retained as lead counsel the firm of Shook, Hardy and Bacon, a go-to corporate defender that has represented tobacco companies, drug and auto makers in high-stakes litigation.

In this together

Deane Berg recalls her sense of shock and dread when she heard her diagnosis. Both she and her husband Jim broke down and wept.

She got chemotherapy through a port in her chest. It was painful, nauseating—“to put it point blank, holy hell. ... It put my family through a lot, too,” Berg said. Her first husband had died of lung cancer from smoking, and her two daughters now feared they would lose their mom, too. One called Berg from college every day to make sure she was all right.

“Once you get a cancer diagnosis ... it never goes away,” Berg said. “There’s always that ultimate fear that it’s going to come back.” So far it hasn’t. Berg eventually returned to work as a physician’s assistant at the VA hospital in Sioux Falls. She figures her ordeal has made her better at the job.

“It has definitely taught me how important it is to take time with cancer patients, to give them concern and caring, and to say ‘I know what you’re going through,’” she said in an interview. “I give them a hug and say we’re in this together.”

In studying the risk factors that might have led to her cancer, Berg mostly came up empty. Family history of ovarian cancer? No. Previous cancers? No. Mutations in the BRCA 1 or BRCA 2 genes? No. Use of fertility drugs; never having been pregnant; eating a high-fat diet—no, no and no. But some literature cited another possibility—genital use of talc.

Berg posted a question on the website of the [National Ovarian Cancer Coalition](#), asking if anyone had used talc and contracted ovarian cancer. Soon she was contacted by a Mississippi lawyer named Allen Smith. After checking him

out “to make sure he was legit,” Berg said, she authorized Smith to order an analysis of her tumor tissue. Talc particles were found inside. Explaining her decision to file a lawsuit, Berg told FairWarning: “I don’t want other women to suffer like I did if this could be prevented.”

Her case was tried in fall 2013. Medical experts for J&J dismissed the idea that talc caused her cancer as biologically implausible. They explained the discovery of talc particles in the tumor tissue as probably due to contamination, a common problem in hospitals. Berg’s lawyers sought to discredit the defense experts as hired guns, noting that two had testified on behalf of tobacco companies.

In its head-scratching verdict, the jury found the J&J subsidiary, Johnson & Johnson Consumer Cos., Inc., guilty of negligence for failing to warn Berg of the ovarian cancer risk. Though she had suffered losses—months of lost work time, permanent hearing loss and numbness in her hands and feet from chemotherapy; and the endless fear of her cancer coming back—the jury awarded no damages.

Berg said her lawyers were “dumbfounded,” and that she attributed the result to South Dakota being “a very conservative state.”

It tempers her anger to consider the big picture. “I’m lucky to be alive—really, really lucky,” she said. “I count my lucky stars, let’s put it that way, that I’m not gone.”

Contacted by FairWarning, jury foreperson Christina Wilcox explained the compromise verdict. Jurors decided that “the actual medical proof [that talc caused Berg’s cancer] was not there,” she said. “She [Berg] just got handed a bad deal.”

“However, we also felt that Johnson and Johnson should consider putting...something on the product to alert the consumers of the possible injury and the possible risk,” Wilcox said. “Let the consumer decide what they want to do.”

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