

Women's use of talc powder may be tied to ovarian cancer

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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 the information 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 reviewed the <u>risk factors</u>, finding just one that could apply: regular use of talcum powder for feminine hygiene.

Talc powder might be a cause ovarian cancer - who knew? Berg was stunned to learn that about 20 medical journal studies dating to the early 1980s 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. 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."

"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 Johnson & Johnson in federal court in her hometown of Sioux Falls, S.D. In a mystifying verdict in October 2013, the jury found Johnson & Johnson Consumer Cos. guilty of negligence for failing to warn of the ovarian cancer risk but awarded zero damages to Berg.

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 Johnson & Johnson, the suits name Imerys Talc America Inc., part of the global mining concern that supplies talc to Johnson & Johnson. Other marketers of talc powder and the Personal Care Products Council, a Washington trade group for cosmetics makers, are named in some cases.

"We use this on children ... and it had to be a good thing, right?" said plaintiff Deborah Giannecchini, 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."

Imerys and the Personal Care Products Council wouldn't comment.

Johnson & Johnson refused interview requests but said in a statement: "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. Since talc does not cause ovarian cancer, they argue, warnings were unnecessary.

Most of the lawsuits have been filed in New Jersey, Johnson & Johnson's headquarters, or in state court in St. Louis. 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 1 woman in 70. Studies showing a higher rate of the disease with talc use typically found an increased risk of about 35 percent - which puts the odds at about 1 in 50.

Talc, the softest of minerals, is used in a multitude of products, including in 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 because of impurities, rather than talc itself. Over the years, talc suppliers have paid settlements or judgments to talc miners or factory workers, such as tire makers, who contracted asbestos-related illnesses following exposure to industrial grade talc.

Johnson & Johnson 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 Johnson & Johnson with failing to take the precaution



of replacing talc with corn starch, which has similar skin-soothing properties but has not been linked to health risks. While defending the safety of talc, Johnson & Johnson has offered powders with cornstarch or cornstarch-talc blends.

In October 2012, for reasons neither company would discuss, Johnson & Johnson sold North American marketing rights to Shower to Shower to Valeant Pharmaceuticals.

Suspicions 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 of numerous reports of a statistical link between genital talc use and ovarian cancer.

A 1999 report said talc use could be the cause of about 10 percent of ovarian cancers in the United States - 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."

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 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," the agency said, "but chance, bias or confounding factors cannot be ruled out with reasonable confidence."

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

Her first husband had died of lung cancer from smoking, and her two daughters now feared they would lose their mom, too.

"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 Department of Veterans Affairs hospital in Sioux Falls.

In researching 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.

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."

In its head-scratching verdict, the jury found the Johnson & Johnson subsidiary, Johnson & Johnson Consumer Cos. Inc., guilty of negligence for failing to warn of the <u>ovarian cancer</u> risk. Although Berg 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.

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



Contacted by FairWarning, jury forewoman Christina Wilcox explained the compromise verdict. Jurors decided that "the actual medical proof (that talc caused Berg's cancer) was not there," she said. Berg "just got handed a bad deal."

"However, we also felt that Johnson & 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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