Johnson & Johnson Responds To Recent News Coverage on Talc

December 16, 2018

THE FACTS ABOUT THE DECEMBER 14, 2018 REUTERS ARTICLE

On Friday, December 14, 2018, Reuters published a story about Johnson & Johnson (J&J) baby powder that misrepresented J&J, our product, our actions, and the science about talc. Reuters misled its readers by printing inaccurate statements, withholding crucial information that otherwise undermines its thesis. Reuters published this story even though it was advised that it had the facts wrong.

Prior to publication, Reuters was supplied with substantial amounts of information that demonstrated the following that was ultimately omitted from the final article:

1. J&J's baby powder is safe and does not cause cancer. Studies of tens of thousands of women and thousands of men show that talc does not cause cancer or asbestos-related disease.
2. For decades, J&J's baby powder has repeatedly been tested for asbestos and been found not to contain asbestos.
3. J&J has cooperated fully and openly with the U.S. Food & Drug Administration and other global regulators, providing them with all the information they requested over decades. We have also made our cosmetic talc sources and processed talc available to regulators for testing. Regulators have tested both and found no asbestos. To say we hid anything is false.

The information Reuters relied upon has been publicly available for years. It is unfortunate that while Reuters was provided with many of these detailed facts, they elected not to report them.

Below are the facts. More can be found at www.factsabouttalc.com.

I. Reuters's story ignored the overwhelming science showing that talc does not cause cancer.

Reuters declined to report on the critical, dispositive science conducted by independent, leading health researchers that examined the carcinogenic effects of cosmetic talc products and concluded that talc is safe and does not cause ovarian cancer or mesothelioma.

- **Ovarian Cancer Studies.** Reuters did not mention the scientific studies of tens of thousands of women who use talcum powder, which show no increased risk of ovarian cancer.

The Nurses' Health Study
The study followed over 78,000 women for 24 years (over 31,000 used talc). The study showed *no overall increase in the risk of ovarian cancer.*

The Women's Health Initiative Study
The study followed over 61,000 women for 12 years (over 32,000 used talc). The study showed *no overall increase in the risk of ovarian cancer.*

The Sister Study
The study followed over 41,000 women for 6 years (over 5,500 used talc). The study showed *no overall increase in the risk of ovarian cancer.*

- These studies were conducted by scientists at institutions including Harvard Medical School, Harvard School of Public Health, the University of Massachusetts Amherst, and the National Institute of Environmental Health Sciences.

- **Talc Miners and Millers Studies.** Reuters deemphasizes the multiple peer-reviewed studies of thousands of miners and millers from the areas where J&J historically sourced its talc. These are the best people to study since they were working the closest with the talc every day, and *no cases* of mesothelioma were found. Reuters mentions the study of Vermont miners and millers without mentioning that the study found *no cases* of mesothelioma.

- **Other Studies.** Reuters also omits that other studies of cosmetic or pharmaceutical talc have established that talc does not cause mesothelioma. Large-scale reports on patients who had a medical procedure done in which talc was actually injected into the linings of the lungs found that none developed mesothelioma. Animal studies in which rodents were injected with talc sourced from the deposits J&J used did not result in mesothelioma.

- There is not a single, sound study showing that talc causes mesothelioma. Again, Reuters was informed of this and omitted these facts.

II. Reuters misinformed its readers about the facts showing J&J talc does not contain asbestos.

A. Although Reuters received dispositive information showing that today's talc – mined in China for the last 15 years – does not contain asbestos. Reuters chose not to inform its readers of this fact.

- Reuters was requested to clearly report this fact so consumers would know there has been no asbestos in talc on the market over the last 15 years, and Reuters chose not to do so in its article. In fact, routine J&J testing records go back at least to the 1970s and show no asbestos in talc used in baby powder.

- *After* the article came out, the Reuters reporter appeared on CNBC's "Power Lunch," MSNBC's "Velshi & Ruhle," and NBC's "Nightly News" programs on Friday, December 14, 2018, and made this very point. In the "Power Lunch" interview, she said, "There's no evidence that what [J&J is] selling today [] has any asbestos in it" but claimed she hadn't looked at the evidence. On the "Nightly News," however, it was disclosed that the Reuters reporter acknowledged that J&J had provided test reports for the last 15 years that showed no asbestos was found in J&J talc.

- Reuters knows that plaintiffs' lawyers in the recent *Henry* trial, where the jury ruled in favor of J&J, agreed that "[t]he China mines don't have asbestos in them." *Yet, Reuters did not include this in its article.*

B. For decades, independent tests of thousands of samples of our talc mines and processed talc by the world's leading labs, regulators, and most prominent universities have found that our talc does not contain asbestos. *Nevertheless, Reuters failed to disclose to its readers the independent institutions, laboratories, and universities that tested J&J's cosmetic talc and concluded it did not contain asbestos.*

- **The U.S. National Institute for Occupational Health and Safety (NIOSH)**. NIOSH and Harvard School of Public Health jointly published a scientific study of J&J's mines in Vermont. They concluded that "geological studies dating from the early 1900s have shown that the Vermont talc deposits contain no asbestos"

- They also tested talc by "petrographic microscope analysis, transmission electron microscopy, and x-ray diffraction with step-scanning" which "revealed no asbestos" in these samples."

This information was supplied to Reuters and they omitted it from their story.

- **Other Entities.** In additional to NIOSH and the Harvard School of Public Health, Reuters knows numerous other entities tested J&J talc and found it did not contain asbestos, *yet Reuters did not fully inform its readers about these tests*:

    - Illinois EPA
    - Massachusetts Institute of Technology
    - Mount Sinai Hospital
    - Princeton University
    - Colorado School of Mines
    - Dartmouth University
    - Geological Society of the United States
    - Atomic Energy Commission at Harwell (England)
    - Cardiff University (Wales)
    - Mining Institute of Torino (Italy)
    - RJ Lee Group (an outside laboratory retained by J&J)
    - McCrone Associates (founded by two of the world's leading microscopists)

    - EMV Associates
    - ES Laboratories

- Reuters reported that in the 1970s, Dr. Arthur Langer found a "relatively small" amount of chrysotile in J&J's talc. While Reuters noted that he did not find any asbestos in a subsequent test of the same sample, they neglected to mention that independent microscopists tested the same lot that Dr. Langer used. They all found that he was mistaken about his findings of chrysotile and that the samples tested did not contain asbestos.

- Reuters suggested that the "concentration method", an experimental method evaluated to test talc purity, was the most advanced method and that J&J should have used it.

Yet, although Reuters was informed of the following information, it elected not to disclose it:

    - Regulatory bodies around the world have not adopted any form of a concentration method to date, despite such methods being public knowledge since the 1970's.
    - The U.S. Food and Drug Administration (FDA) itself tested a concentration method over 40 years ago (from 1974-1976) and rejected it as inadequate because it *could not detect the most widely used commercial asbestos*.

- J&J used more sensitive and reliable methods than a concentration method to test its talc: a combination of x-ray diffraction, polarized light microscopy, and transmission electron microscopy. Use of this testing method exceeded the industry standard.

- Experts actually used a concentration method on J&J's talc and did not find any asbestos. Both Dr. Frederick Pooley of Cardiff University and the Colorado School of Mines tested J&J's talc with the concentration method (Dr. Pooley used the concentration method and TEM) and did not find any asbestos.

C. Reuters acknowledges that the minerals which can in rare instances form to create asbestos can also form to create what Reuters calls "unremarkable" rocks which are not asbestos or "non-asbestiform." This is like the difference between graphite and diamonds. Both are made of the same element (carbon), but they have very different properties; you can't cut glass with graphite. Yet Reuters proceeds to treat these "unremarkable" rocks like asbestos. There is no scientific evidence that finding infinitesimal amounts of non-asbestiform minerals, which are "ubiquitous in the earth's crust" according to the United States Geological Survey, means you find asbestos, which is rare. *It neglected to tell its readers* that there is no evidence that exposure to minute amounts of non-asbestiform minerals has carcinogenic effects.

- Reuters misleadingly said that government agencies have treated these minerals known as "cleavage fragments" as asbestos, even though they are not asbestos. *Reuters did not inform its readers* that the *majority* of health and safety regulatory bodies and organizations have recognized this distinction, including:

    - International Agency for Research on Cancer
    - U.S. Occupational Safety and Health Administration
    - U.S. Mine Safety and Health Administration
    - U.S. Environmental Protection Agency
    - The National Institute for Occupational Safety and Health
    - U.S. Agency for Toxic Substances and Disease Registry
    - U.S. Geological Survey
    - U.S. Consumer Product Safety Commission

- Reuters does mention two of these entities—Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA)—but does so in a misleading way.

- **OSHA.** Reuters acknowledges that OSHA decided after extensive study not to regulate cleavage fragments as asbestos. But the article goes on to make the inaccurate claim that OSHA nevertheless still recommends to count cleavage fragments as asbestos. These OSHA counting rules are not about determining whether asbestos is present somewhere. They are only applicable to estimating the quantity of those fibers once you have already determined asbestos is there.
- **EPA.** Reuters misleadingly reports that the U.S. EPA does not distinguish between asbestiform and non-asbestiform minerals even though EPA does. In its article, it referenced a position once stated by a regional EPA office that has now been archived by the EPA. Current Federal EPA regulations do not hold that position, yet, Reuters reported that it does.

D. Reuters failed to explain the meaning of background levels of asbestos.

- Plaintiffs' own witnesses have admitted that over a lifetime, everyone accumulates millions and billions of fibers in their lungs just from "background asbestos" in the air without increasing health risk.

- In the 1986 response to a citizen petition, the FDA determined that even in "a worst-case estimate of exposure to asbestos from cosmetic talc," the risk would be "less than the risk from environmental background levels of exposure to asbestos (non-occupational exposure) over a lifetime."

E. Reuters erroneously reported there were "asbestos fibers in samples taken from the Vermont operation" in the 1980s. *But it actually cited five test results that were indeed industrial talc samples from a California mine (Red Hill)—not Vermont—that was never used for cosmetic purposes.*

F. Reuters misleadingly reported that X-ray scanning is the primary method that J&J used and that J&J only periodically tested its talc with transmission electron microscopy (TEM). In fact, since the 1970s, J&J has had in place a rigorous program of routine testing that requires that it or its supplier take hourly samples of its cosmetic talc production and test composites of those samples using X-ray Diffraction (XRD), Polarized Light Microscopy (PLM), and TEM. Indeed,

J&J had tested on a regular basis both the source talc and composites of its samples with TEM. When performing these tests, J&J always used the state-of-the-art methods and technology for testing talc. This testing concluded that there was no asbestos in J&J's cosmetic talc.

G. Reuters then criticizes J&J's TEM testing because it only tested "a tiny fraction of what was sold." Reuters completely dismisses the scientific validity of composite sampling. That is why when you go for a blood test, your doctor doesn't remove all of your blood to test it, just a sample.

Even though J&J's outside experts tested samples of talc with TEM, it ensured that these samples were representative of its total supply by combining hourly samples taken during each shift and then randomly testing those composites by TEM.

Reuters was apprised of these facts.

H. Reuters Gives A One-Sided View Of The Testing Conducted During Litigation.

- Reuters reports on what plaintiffs' experts claimed to have found from testing J&J's talc. But they tell only one side of the story. For example, Reuters did not mention that one of these people admitted that he would call something he found asbestos "even though it's not."

- The article mentions that one of J&J's expert geologist has agreed to be a witness in up to 100 trials. But the article doesn't mention that the expert who plaintiffs typically hire will be a witness the same number of times, if not more. Nor did Reuters tell its readers that a court determined his lab produced "junk science," and that his company has been paid over $30 million by plaintiffs' attorneys over 30 years.

- When discussing testing in litigation, Reuters reports that a lab "found asbestos in Shower to Shower talc from the 1990s, according to an Aug. 11, 2017, court report." Reuters did not tell its readers plaintiffs' lawyers did not put this report before a jury because it was so fraught with errors.

- Reuters asserted that in the middle of one case, "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." Reuters withheld from its readers facts that show why that geologist's statement was unreliable.

The actual evidence shows that the sample she tested was most likely *not* J&J's talc, and further, that she refused to allow J&J to run its own tests on the sample.

I. Against the independent tests of thousands of samples using state of the art methods, the articles point to a handful of outlier results that were either retracted, proven false by subsequent testing, or shown to be unreliable. This issue is not open to dispute. The science has been clear that our talc does not and did not contain asbestos.

J. In the 1970s, J&J experienced a similar event of false information in the media, when reports surfaced, based on preliminary and erroneous test results, that J&J's talc was found to contain asbestos. Testing after those inaccurate reports confirmed, yet again, that our talc does not contain asbestos.

III. <u>Reuters has received information showing that J&J has shared any information sought by global regulators, including the FDA, and that the company has been transparent about it.</u>

A. J&J has consistently provided the FDA access to the company's processed talc and independent labs' testing results. Not only did J&J not hide anything, it has provided substantial documentation of test records and methodologies to help inform the FDA on these matters.

This information was supplied to Reuters and they chose not to report it.

B. Reuters reported that J&J withheld information from the FDA without noting that J&J provided extensive testing information to the FDA, disclosing many of the issues Reuters claims that J&J hid, even though disclosure was not legally required. For example:

- J&J gave McCrone labs, its main outside testing laboratory in the 1970s, written permission to disclose all test results on J&J's consumer talc samples.

- The test results J&J provided to the FDA almost 50 years ago disclosed that there was non-asbestiform amphibole in certain fringe areas and trace amounts of non-asbestiform tremolite found in talc deposits. This is not and was not new information.

- Dr. Pooley from Cardiff University, speaking as a disclosed J&J consultant, openly discussed his work on experimental concentration methods with an FDA panel in 1975.

- J&J provided open access to its experts who engaged in an open and constructive dialogue with FDA in the early 1970s.

C. Reuters reports that J&J pressured the FDA to allow it to use a testing methodology that would only detect 1% of asbestos. This is misleading.

- J&J tests its own talc with methods that go far above and beyond that requirement. J&J uses step-scanning XRD, which has a detection limit of 0.1%, and employs methods with TEM that have an even lower level of sensitivity.

- Furthermore, since the 1970s, J&J has exceeded the industry standard by using not just XRD and PLM, but also TEM.

D. *Reuters also failed to mention that J&J was just one source of information to the FDA.*

- The FDA was also receiving information from its own independent testing of J&J's product and source over four years in the 1970s, continued monitoring through the 1980s, and testing over two years in 2009-2010.

- Although Reuters claims the FDA tests in the 1970s did not use "the most sensitive methods," it omitted that, during that time period, FDA was also receiving information from scientists at Mount Sinai Hospital, which tested J&J's talc using transmission electron microscopy and similarly confirmed that it did not contain asbestos.

E. Reuters falsely reported that many of the documents "were shielded from public view by court orders that allowed J&J to turn over thousands of documents it designated as confidential," and claimed that the contents of these documents were reported in the article for the first time. *In fact, every single company document Reuters falsely claims is new has been listed on an exhibit list at a trial, several of which J&J won.* J&J documents shown to juries at trial, by either J&J or plaintiffs, are publicly hosted on J&J's website www.factsabouttalc.com.

Nor is the reporting anything new. Far from a new theory or insight, Reuters has *resurrected* a disproven argument about asbestos in J&J's talc that dates back to news reports from the 1970s. These recent allegations were covered by other outlets in January, which linked to the same documents that were allegedly new nearly a year ago. A Bloomberg article called the story "deja vu for some investors" citing its own article on the topic from over a year ago.

F. Reuters also distorted the meaning of numerous internal documents. Here are just some examples:

- Reuters cites an April 9, 1969 memo to imply that J&J knew that tremolite caused cancer at that point. *That document is not about any talc deposit used in baby powder.*

- Reuters mischaracterizes a memo that "talc purity was a pipe dream." This comment does not relate to asbestos, but "respirable particles" of *talc*. In other words, the memo's author was discussing the difficulty of making every single *talc* particle large enough so it could not be breathed in.

- Reuters grossly misrepresents a phrase a J&J employee wrote: "we cannot say always" asbestos free. In addition, Reuters withholds from its readers that all this person meant was that, given that J&J sold baby powder since the 1890s when modern microscopes did not exist, it should not be suggested that J&J had tested for asbestos during that very early period.

- Reuters was provided with testing records showing that talc samples were tested going back to 1949, but did not mention this.

- The Wilson Nashed letter is another example of Reuters cherry-picking certain phrases to imply that J&J found asbestos, when in fact we did not. Even though the letter references "fibrous minerals," the testing attached to the letter by three separate laboratories *ultimately found no asbestos*.

- Reuters reports about documents destroyed from a Vermont mine, and quotes outside counsel as saying those documents did not relate to testing records. Reuters did not mention J&J provided them with an affidavit from the J&J geologist who wrote a memo discussing the documents who swore to that.

G. Reuters misreported the circumstances of the discovery of J&J's documents in the Coker case.

- J&J feels sympathy for Ms. Coker and her family, along with all those who have suffered from mesothelioma and ovarian cancer. But J&J is not responsible for these diseases. Ms. Coker's tissue was tested, and the presence of amosite was detected. Amosite is a form of asbestos that is found in other commercial products, but has *never* been associated with talc.

- Ms. Coker's own can of baby powder was tested and no asbestos was detected in it.

- At that point it was clear her mesothelioma came from another source, so no further discovery was warranted. And all that discovery would have shown is J&J's decades of testing detecting no asbestos.

- The suggestion that J&J hindered Ms. Coker's pursuit of her case or that somehow discovery that Ms. Coker's counsel elected not to pursue would have made any difference is not what happened in the case.

- Plaintiff's counsel sought to extend discovery deadlines in the case so that lung tissue testing could be completed. J&J was amenable to plaintiff's numerous extension requests, including a Rule 11 "Standstill" Agreement that gave plaintiff's expert time to test plaintiff's tissue samples. When the expert report was finally completed (well after the deadline listed in the agreement) plaintiff moved for a continuance to again push back the court-mandated deadline to respond to J&J's Motion for Summary Judgment. When plaintiff was unable to meet the new deadline, J&J again agreed to allow the plaintiffs to extend their deadline.

- In the end, with her own expert test results related to her tissue and her can of baby powder, plaintiff filed a Notice of Nonsuit within days after the final extended deadline to respond to the Motion for Summary Judgment.

H. Reuters withheld from its readers that no jury verdict in a talc case against J&J has been upheld on appeal, and every one that has been through the appellate process has been overturned.

I. Reuters claims that "J&J declined to comment further for this article" even though Reuters was provided with extensive documents—most of which were not included in the article. J&J offered numerous times to meet with Reuters in person to discuss with appropriate experts all of its allegations, and each time Reuters refused.

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