Johnson & Johnson Responds To The December 10, 2019, Hearing Of The Subcommittee On Economic And Consumer Policy, Committee On Oversight And Reform, U.S. House Of Representatives

On December 10, 2019, the House of Representative's Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform held a hearing on "Examining Carcinogens in Talc and the Best Methods for Asbestos Detection." In light of the questions and statements at the hearing, Johnson & Johnson is providing this information to the public.

How does Johnson & Johnson test its cosmetic talc to make sure it is safe?

Johnson & Johnson uses an industry-leading suite of testing methods including those the FDA recently called "the most sensitive techniques available." Johnson & Johnson is careful at every stage of its process to ensure that the cosmetic talc used in its products is not contaminated with asbestos. At the time the allegations first arose, it asked a number of independent institutions, laboratories, and universities to test its talc. Those institutions include the U.S. FDA, the Harvard School of Public Health, MIT, Mt. Sinai Hospital, McCrone Associates, and Cardiff University, among others, and these tests confirmed that Johnson & Johnson's cosmetic talc products were free of asbestos.

Dr. William Longo testified at the hearing. Who is he?

Dr. Longo is a paid litigation witness for plaintiffs' lawyers. His lab has made tens of millions of dollars testifying for plaintiffs in asbestos litigation. Approximately 95% of the time Dr. Longo is in court, it is on behalf of plaintiffs. However, not all courts have reacted favorably to his testimony. Some courts have said that Dr. Longo's methods are "junk science," his studies are "pseudo-science at best," and his testimony is "disingenuous, not credible and unsupported by any respectable community of scientists."

Before he began testifying against Johnson & Johnson, Dr. Longo swore under oath that he was "very familiar" with the issue of asbestos in cosmetic talc, and that the presence of asbestos in cosmetic talc was nothing but an "urban legend." In other words: folklore that people talk about that isn't true. He repeatedly testified that he did not detect any asbestos in cosmetic talc. In another case, he testified: "We've looked. We have not found it." As recently as 2010, Dr. Longo testified that talc sourced from places other than New York are "clean." Johnson & Johnson never sourced its cosmetic talc from New York. Now, only when being paid to testify against Johnson & Johnson, does Dr. Longo say its talc was contaminated with asbestos.

Dr. Longo talked about the heavy liquid separation method to test for asbestos. Is this a new technique?

No. The focus of Dr. Longo's testimony—the heavy liquid separation preparation method—is a red herring. This method is neither novel nor is it a secret. The technique has been known in the scientific community for decades. As far back as the 1970s, independent experts, including scientists at the FDA, rejected the technique for its unreliability and failure to detect the most prevalent type of asbestos—chrysotile. *In fact, no regulatory agency anywhere in the world has adopted Dr. Longo's heavy liquid separation technique.*

Dr. Longo said that testing without the heavy liquid separation method is not sensitive enough to routinely detect asbestos in talc. Is that correct?

No, it is wrong. Johnson & Johnson's expert Dr. Matthew Sanchez can see the same things that Dr. Longo can see. Dr. Sanchez has *also* found amphibole mineral particles in the *same bottles* of Johnson's Baby Powder *without using* heavy liquid separation. Although they can see the same thing, Dr. Sanchez has demonstrated that those mineral particles are not asbestos. They are the much more common non-asbestiform varieties of certain minerals. Sensitivity is **not** the issue. The issue is accurately characterizing what is detected.

Dr. Longo claimed at the hearing that 65% of the bottles of Johnson & Johnson's cosmetic talc he tested were positive for asbestos. He is mischaracterizing the mineral particles he is finding. Dr. Longo testified that if one of his "analysts who is conducting the test sees a non-asbestiform amphibole cleavage fragment" of a certain size and shape (i.e., not asbestos), "the analyst will count that as an asbestos structure" anyway.

Dr. Jacqueline Moline testified at the hearing. Who is she?

Dr. Moline is a paid litigation witness for plaintiff lawyers. Her testimony has changed since she started testifying against Johnson & Johnson. Before she was being paid to testify against Johnson & Johnson, Dr. Moline recognized that studies of talc miners and millers who were exposed to large quantities of talc did not find that the miners and millers were at increased risk of contracting asbestos-related diseases, including mesothelioma. Those studies demonstrated that those mines did not contain asbestos, including mines that supplied Johnson & Johnson its talc. Now, when testifying against Johnson & Johnson, Dr. Moline says those studies were inadequate.

Dr. Moline said there are no health differences between asbestiform and non-asbestiform minerals. Is this correct?

No, it is wrong. Numerous well-respected scientists have concluded that trace amounts of non-asbestiform minerals do not present a health risk.

- OSHA is a U.S. government agency with responsibility for ensuring safety at work. The agency announced in 1992 that its asbestos regulations will exclude non-asbestiform amphiboles because "substantial evidence is lacking to conclude that… [they] present the same type or magnitude of health effects as asbestos."

- The United States Geological Survey ("USGS") states that "when it comes to health risk," it "matter[s] whether an amphibole is asbestiform," and that "available evidence supports a conclusion that exposure to nonasbestiform cleavage fragments is not likely to produce a significant risk of developing asbestos-related disease."

- NIOSH – OSHA's scientific and research arm – has similarly declared that "nonasbestiform minerals are not 'asbestos' or 'asbestos minerals,'" and only "exposure to fibers from the asbestos minerals" is credibly linked to adverse health effects in epidemiological studies.

Dr. Rod Metcalf testified at the hearing. Who is he?

Dr. Metcalf is a paid litigation witness for plaintiff lawyers. He has a general background in geology, but his testimony did not relate to Johnson & Johnson's talc specifically.

What did Dr. Metcalf say about whether talc can be free of asbestos?

Dr. Metcalf disagreed with the suggestion that "talc cannot reliably be asbestos free." And while acknowledging talc deposits can be asbestos-free, he provided no information specific to the mines Johnson & Johnson actually used in the past or uses now.

What have independent scientists and organizations said about the mines J&J used?

Numerous independent scientists and organizations have concluded that the mines Johnson & Johnson used in Vermont and Italy contain no asbestos. For example:

- NIOSH and the Harvard School of Public Health evaluated Johnson & Johnson's Vermont talc mine and concluded that "analysis by NIOSH, which included petrographic microscope analysis, transmission electron microscopy, and x-ray diffraction with step-scanning, revealed *no asbestos* in these samples." They also recognized that "studies dating from the early 1900's have shown that the Vermont talc deposits contain *no asbestos*."

- The American Conference of Governmental Industrial Hygienists (ACGIH) stated there was no asbestos in Johnson & Johnson's Vermont and Italian talc mines.

- The International Agency for Research on Cancer (IARC) concluded, "The type of talc that is currently used for cosmetic purposes in the USA does not contain detectable levels of amphibole, including asbestos."

Some witnesses seemed to suggest that Johnson & Johnson's internal documents showed positive tests for asbestos. What were they referring to?

Plaintiffs' witnesses routinely misuse and misrepresent the contents of Johnson & Johnson's internal documents. Sometimes test results are cited that find non-asbestiform amphibole minerals, which are not asbestos. Sometimes test results are cited that were from sources never used for Johnson & Johnson's cosmetic talc products. Other times, documents are cited involving samples intentionally spiked with asbestos to evaluate testing procedures. And sometimes documents are cited that purport to find asbestos but were subsequently proven inaccurate.

Why didn't Johnson & Johnson CEO Alex Gorsky testify?

Mr. Gorsky is the CEO of Johnson & Johnson and, in that role, he is responsible for broad oversight of the Company's 264 operating businesses in 60 countries. As would be expected for leading a multinational company, Mr. Gorsky is not involved in the day-to-day decision-making process regarding cosmetic talc products and relies on others to keep him informed, as necessary. On an issue of such specialty and complexity—the best methods for testing talc—he regularly relies on the expertise of scientists and other subject matter experts.

The hearing concerned highly technical and scientific matters. For example, a geologist testified about highly specialized terms and concepts known to geologists including the hydrothermal alteration of protoliths, metosomatism, and carbonate protolithologies.

Given the focus of the hearing, Johnson & Johnson offered to have two other, more suitable witnesses appear at the hearing: Dr. Matthew Sanchez and Ms. Kathleen Widmer. Dr. Sanchez received a Bachelor of Science degree, a Master of Science degree, and a Ph.D. in Geology. And he is deeply experienced in the testing of Johnson's Baby Powder—his company has tested Johnson & Johnson's talc for more than a decade. Kathleen Widmer is a senior executive directly responsible for North America's consumer products, including Johnson's Baby Powder. The Subcommittee declined both witnesses.

Has Johnson & Johnson cooperated with Congress?

Yes. For nearly a year, Johnson & Johnson has cooperated with the Subcommittee on the safety of cosmetics, including by providing briefings, written submissions, and documents. Earlier this year, in response to the Subcommittee's request for documents and information regarding a wide variety of topics—including asbestos, asbestos testing methods, test results, sales figures, marketing materials, and more—Johnson & Johnson provided nearly 10,000 pages of materials. Johnson & Johnson also offered to provide more than 300,000 additional pages of materials related to the testing of talc. Johnson & Johnson is currently responding to the Subcommittee's additional requests after the hearing and will be producing additional documents and materials to the Subcommittee. Johnson & Johnson remains committed to working with all Members of Congress to address these significant and important public policy issues.

Has Johnson and Johnson cooperated with the FDA?

Yes. Johnson & Johnson has worked constructively and cooperatively with FDA and will continue to do so. On October 16, 2019, Johnson & Johnson was advised by FDA that, for the first time, it had detected asbestos in a single bottle of Johnson's Baby Powder. This lone finding stood in stark contrast to the thousands of tests over the past 40 years that have confirmed that Johnson & Johnson's cosmetic talc does not contain asbestos, including FDA's own findings over the same course of time, including as recently as September 2019. Nonetheless, out of an abundance of caution, Johnson & Johnson voluntarily recalled the lot at issue.

In parallel, Johnson & Johnson immediately initiated a rigorous, thorough examination into the matter. Johnson & Johnson contracted two third-party laboratories to expedite a large number of tests of the recalled lot of Johnson's Baby Powder. Over the course of the investigation, a total of 155 tests were conducted by the two labs using four different testing methods on samples from the same bottle tested by the lab the FDA used, the recalled lot of Johnson's Baby Powder, as well as three lots manufactured before the recalled lot and three lots manufactured after the recalled lot. All results confirm there is no asbestos in Johnson & Johnson's talc.

Johnson & Johnson shared its exhaustive 2,100+ page investigation with FDA that specifically enumerated the possible internal and external causes which could lead to FDA's finding. These issues included, for example, the chronological inconsistencies in the report of the lab hired by FDA which suggest that cross-contamination may have occurred during sample preparation. Johnson & Johnson hopes to work collaboratively with the FDA to get to the bottom of these discrepancies.

To access supporting documents, click here.