

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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March 3, 2020

The Honorable Dr. Stephen M. Hahn  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

As Chairman of the Subcommittee on Economic and Consumer Policy, I am writing to commend the Food and Drug Administration (FDA) for reconsidering outdated and ineffective testing methods for the presence of asbestos in talc-containing products, which most recently resulted in FDA's public meeting on "Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc."

As you know, within a month of the Subcommittee's December 10, 2019, hearing on "Examining Carcinogens in Talc and the Best Methods for Asbestos Detection," FDA announced that it would hold an open meeting on that topic.<sup>1</sup> The meeting took place on February 4, 2020.<sup>2</sup>

FDA's Preliminary Recommendations by the Interagency Working Group on Asbestos in Consumer Products adopted many of the testing improvements that were highlighted in the Subcommittee's December hearing.<sup>3</sup> The Subcommittee supports the Preliminary Recommendations, particularly the requirements to use an analytical transmission electron microscope (TEM) and to test for elongate mineral particles with at least a 3:1 aspect ratio.

However, the Preliminary Recommendations fail to include one key reform: samples must be prepared using the heavy liquid-separation method (HLS).

If that requirement is added to the current recommendations, you will have the

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<sup>1</sup> Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining Carcinogens in Talc and the Best Methods for Asbestos Detection* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-carcinogens-in-talc-and-the-best-methods-for-asbestos-detection>).

<sup>2</sup> Food and Drug Administration, *Public Meeting on Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc* (Feb. 4, 2020) (online at [www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-testing-methods-asbestos-talc-and-cosmetic-products-containing-talc-02042020-02042020](http://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-testing-methods-asbestos-talc-and-cosmetic-products-containing-talc-02042020-02042020)).

<sup>3</sup> *Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc*, Interagency Working Group on Asbestos in Consumer Products (Jan. 6, 2020) (online at [www.fda.gov/media/134005/download](http://www.fda.gov/media/134005/download)).

Subcommittee's full support. If it is not, or if the Preliminary Recommendations are scaled back, the Subcommittee would be forced to consider whether legislation is necessary to address these problems.

### **FDA Must Require the Heavy Liquid–Separation Method for Sample Preparation**

For decades, manufacturers of talc products have reported negative asbestos tests. They did so by employing testing methods that were not sensitive enough to detect harmful amounts of asbestos in their products and by using sample-preparation methods that allowed dangerous asbestos particles to hide undetected. These practices have allowed companies to sell asbestos-containing products to unknowing consumers for decades. When proper testing methods are used, such as TEM and HLS, the results are vastly different: **65% of Johnson & Johnson samples of talc products sold between the 1940s and the present have tested positive for asbestos.**<sup>4</sup>

Finding asbestos in talc is difficult because it may be present in very low, yet quite lethal, concentrations. For every asbestos fiber in cosmetic talc, there are 600,000 talc particles. The presence of so many talc particles prevents certain detection methods from finding the asbestos that is present. Dr. William Longo testified before the Subcommittee:

[A]ny analytical method for the detection of asbestos in talc must have good sensitivity, but good sensitivity does you no good if your sample-preparation method doesn't allow you to see the asbestos in something that is 99 percent talc.<sup>5</sup>

He also testified that the heavy liquid–separation method “can separate and remove a substantial amount of the talc, leaving behind any amphibole asbestos that might be present, making it far easier and quicker analysis, along with substantially better sensitivity.”<sup>6</sup>

The use of HLS is revealing the presence of substantial asbestos in cosmetic talc that was previously undetected under the outdated industry methods. Using HLS, Dr. Longo has “detected amphibole asbestos in approximately 65 percent of all the cosmetic samples analyzed in the last 3 years.”<sup>7</sup>

### **Subcommittee Supports Preliminary Recommendation to Require Use of Transmission Electron Microscopes**

Current industry methods for detecting asbestos in talc primarily involve two testing methods: polarized light microscopy (PLM) and the use of an analytical transmission electron

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<sup>4</sup> Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, Testimony of William Longo, *Hearing on Examining Carcinogens in Talc and the Best Methods for Asbestos Detection* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-carcinogens-in-talc-and-the-best-methods-for-asbestos-detection>).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

microscope (TEM). TEM testing is more sensitive than PLM, but laboratories hired by industry test for asbestos in talc rely almost entirely on PLM.

The Subcommittee supports the Preliminary Recommendation to require TEM because it is more sensitive than currently used methods and is widely available.

**Subcommittee Supports Preliminary Recommendation Regarding Testing for Elongate Mineral Particles that Meet a Minimum Aspect Ratio of 3:1**

All elongate particles meeting a 3:1 aspect ratio are harmful to humans. However, industry has tried to avoid liability by creating meaningless distinctions among asbestos particles. It is time for FDA to reject industry's artificial distinction. As Dr. Jacqueline Moline testified to the Subcommittee:

Any particle of asbestos that's small enough to be inhaled and is three times longer than it's wide, can cause disease, including mesothelioma. Using terminology to somehow differentiate whether a particle is asbestiform or cleavage fragment obfuscates the issue and is just semantics. If it can be breathed into the lung, the body doesn't care how the fiber grew.<sup>8</sup>

The Subcommittee supports the Preliminary Recommendation to test for elongate mineral particles, which will capture both asbestiform and non-asbestiform particles. This eliminates an arbitrary distinction, since both are harmful to human health.

**The Need for More Accurate Testing is Highlighted by Johnson & Johnson's Brazen Attempts to Cover Up the Presence of Asbestos in its Consumer Products**

On October 18, 2019, FDA announced that it had detected asbestos in one lot of Johnson & Johnson's baby powder, and the company recalled nearly 33,000 bottles of baby powder in the United States.<sup>9</sup>

After the recall, Johnson & Johnson made multiple claims in the media attacking the integrity and accuracy of FDA's positive test results. On October 29, 2019, Johnson & Johnson announced that it had paid two labs to conduct additional tests on samples from the same bottle of baby powder from which FDA's sample that tested positive for asbestos came. The company reported that none of the tests it commissioned detected asbestos.<sup>10</sup> In fact, contrary to that

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<sup>8</sup> Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, Testimony of Dr. Jacqueline Moline, *Hearing on Examining Carcinogens in Talc and the Best Methods for Asbestos Detection* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-carcinogens-in-talc-and-the-best-methods-for-asbestos-detection>).

<sup>9</sup> *J&J Recalls 33,000 Bottles of Baby Powder as FDA Finds Asbestos in Sample*, Reuters (Oct. 18, 2019) (online at [www.reuters.com/article/us-johnson-johnson-talc/jj-recalls-33000-bottles-of-baby-powder-as-fda-finds-asbestos-in-sample-idUSKBN1WX1L3](http://www.reuters.com/article/us-johnson-johnson-talc/jj-recalls-33000-bottles-of-baby-powder-as-fda-finds-asbestos-in-sample-idUSKBN1WX1L3)).

<sup>10</sup> *J&J Says New Tests Find No Asbestos in Same Baby Powder Bottle That Sparked Recall*, Reuters (Oct. 29, 2019) (online at [www.reuters.com/article/us-johnson-johnson-talc/jj-says-new-tests-find-no-asbestos-in-same-baby-powder-bottle-that-sparked-recall-idUSKBN1X82FP](http://www.reuters.com/article/us-johnson-johnson-talc/jj-says-new-tests-find-no-asbestos-in-same-baby-powder-bottle-that-sparked-recall-idUSKBN1X82FP)).

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representation, one of Johnson & Johnson's paid labs did find asbestos in the product, but it retracted the finding when Johnson & Johnson attributed the asbestos to environmental contamination of a rogue air-conditioning unit.<sup>11</sup> Following this event, Johnson & Johnson released a statement announcing that its products were free from asbestos.<sup>12</sup>

FDA must use the most sensitive testing method to detect carcinogenic asbestos in consumer talc-based products. It should no longer use the preferred detection methods of Johnson & Johnson. The Subcommittee hopes that FDA will take this necessary step by adopting the Preliminary Recommendations and adding the requirement to utilize the HLS method of test sample preparation.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



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Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member

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<sup>11</sup> *J&J Rapidly Tested Its Baby Powder After Asbestos Finding—And the Results Were Complicated*, Wall Street Journal (Nov. 17, 2019) (online at [www.wsj.com/articles/j-j-rapidly-tested-its-baby-powder-after-asbestos-finding-and-the-results-were-complicated-11573986601](http://www.wsj.com/articles/j-j-rapidly-tested-its-baby-powder-after-asbestos-finding-and-the-results-were-complicated-11573986601)).

<sup>12</sup> *Company Investigation Confirms No Asbestos in Johnson's Baby Powder*, Johnson & Johnson (Dec. 3, 2019) (online at [www.jnj.com/company-investigation-confirms-no-asbestos-in-johnsons-baby-powder](http://www.jnj.com/company-investigation-confirms-no-asbestos-in-johnsons-baby-powder)).