Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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December 5, 2019

Dr. Brett Giroir Acting Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Dear Dr. Giroir:

The Subcommittee on Economic and Consumer Policy is examining consumer concerns regarding the safety of personal care products that contain tale, including Johnson & Johnson's tale-based baby powder.

I am troubled by allegations that Johnson & Johnson has made questioning the integrity of the finding by the Food and Drug Administration (FDA) that samples of Johnson & Johnson's baby powder contain asbestos. Johnson & Johnson's allegations appear to be without scientific merit.

The positive test result came from an FDA contract lab, AMA Analytical Services Inc. (AMA). FDA also contracted with AMA to conduct its 2009-2010 Talc Survey, in which asbestos was not detected in Johnson & Johnson's talc-based baby powder.¹ At that time, Johnson & Johnson did not question the integrity of the test or the laboratory. In fact, the Director of AMA is a former paid expert witness for Johnson & Johnson.²

On December 3, 2019, Johnson & Johnson issued a statement announcing the results of its own investigation into FDA's positive asbestos findings. Johnson & Johnson claimed that its investigation "revealed that the testing protocol at AMA deviated from standard practice and that AMA did not execute a full asbestos confirmation as required by their lab's test method."³

¹ Food and Drug Administration, *Talc* (Oct. 25, 2019) (online at www.fda.gov/cosmetics/cosmetic-ingredients/talc).

² Exclusive: J&J's Own Expert, Working for FDA, Found Asbestos in Baby Powder, Reuters (Oct. 30, 2019) (online at www.reuters.com/article/us-usa-health-j-j-expert-exclusive-idUSKBN1X912O).

³ Company Investigation Confirms No Asbestos in Johnson's Baby Powder, PR Newswire (Dec. 3, 2019) (online at www.prnewswire.com/news-releases/company-investigation-confirms-no-asbestos-in-johnsons-baby-powder-300968701.html).

Dr. Brett Giroir Page 2

Johnson & Johnson also alleged that "the most probable root causes for the FDA's reported results were either test sample contamination and/or analyst error at the AMA lab."⁴

However, on November 25, 2019, during a briefing with Subcommittee staff, FDA disclosed that it utilized laboratories at the Occupational Safety and Health Administration (OSHA) to confirm AMA's test results. FDA also stated that it is currently in possession of OSHA's test results.

Since Johnson & Johnson has impugned the integrity of FDA's test results, I strongly urge you to make public the results of the OSHA confirmation test. It is not uncommon for FDA to publicly release test results from OSHA. In fact, FDA utilized OSHA laboratories to successfully detect asbestos in children's make-up kits earlier this year and made those results public.⁵

Scientific studies are inconclusive as to whether talc or talcum powder are safe, even in their purest forms.⁶ But talc is carcinogenic when it contains asbestos—a mineral that is known to cause cancer and mesothelioma.⁷

The integrity of FDA's processes has been publicly challenged in a manner detrimental to the trust Americans have in agencies of government. When FDA warns consumers about a product's hazards, it is important that Americans trust that FDA's findings truly prioritize public health. It is paramount to your agency's credibility to release the results of OSHA's confirmation testing of AMA's original results. I urge you to do so expeditiously.

If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Paya Tyusens

Raja Krishnamoorthi Chairman

⁴ Id.

⁶ Johnson & Johnson Accused of Hiding the Asbestos in Its Baby Powder for Decades, Vox (Dec. 14, 2018) (online at www.vox.com/the-goods/2018/12/14/18141265/johnson-johnson-talc-asbestos-lawsuits-cover-up-stock-price).

7 Id.

⁵ Food and Drug Administration, *FDA Advises Consumers to Stop Using Certain Cosmetic Products* (Mar. 5, 2019) (online at www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products).

Dr. Brett Giroir Page 3

cc: The Honorable Michael Cloud, Ranking Member Subcommittee on Economic and Consumer Policy