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ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM
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December 10, 2019

Mr. Alex Gorsky
Chairman of the Board and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Gorsky:

The Subcommittee is writing to request documents and information concerning recent public statements made by Johnson & Johnson casting doubt and sowing consumer confusion about the detection of asbestos by the Food and Drug Administration (FDA) in talc-based Johnson & Johnson Baby Powder.

On October 18, 2019, FDA announced that it had detected asbestos in one lot of your company's baby powder and that Johnson & Johnson would voluntarily recall the product. FDA warned consumers to discontinue the use of bottles from the tested lot.[1] FDA's announcement resulted in Johnson & Johnson recalling nearly 33,000 bottles of baby powder in the United States.[2]

On October 24, 2019, Walmart, CVS, and Rite-Aid removed all Johnson & Johnson baby powder from their shelves in addition to the lot identified by FDA.[3]

Since the recall, Johnson & Johnson has made multiple claims in the media that appear to cast doubt about the integrity of FDA's positive test results. Your company challenged the accuracy FDA's test results, stating that it needs to "determine the integrity of the tested sample and the validity of the test results." The company has also made the claim that "thousands of

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[1] Food and Drug Administration, *Baby Powder Manufacturer Voluntarily Recalls Products for Asbestos* (Oct. 18, 2019) (online at www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos).

[2] *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).

[3] *Walmart, CVS & Rite Aid Cart Off J&J Baby Talc as FDA Finds Asbestos Trace*, Financial World (Oct. 26, 2019) (online at www.financial-world.org/news/news/business/3723/walmart-cvs-amp-rite-aid-cart-off-jampj-baby-talc-as-fda-finds-asbestos-trace/).

tests over the past forty years repeatedly confirm that [your] consumer talc products do not contain asbestos."[4]

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 tested positive for asbestos. The company reported none of the Johnson & Johnson-commissioned tests detected asbestos.[5] However, we are concerned that this claim is not entirely accurate.

RJ Lee Group (RJ Lee), an independent contracting lab hired by Johnson & Johnson to test additional samples of the bottle from which FDA's independent lab detected asbestos, also detected asbestos in samples of Johnson & Johnson's talc-based baby powder. The company retracted this positive finding, attributing the asbestos to environmental contamination of an air-conditioning unit.[6]

On December 3, 2019, Johnson & Johnson released a statement announcing that the results of its investigation into FDA's positive asbestos findings "revealed that the testing protocol at AMA [AMA Analytical Services, Inc.] deviated from standard practice and that AMA did not execute a full asbestos confirmation as required by their lab's test method."[7]

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."[8]

However, on November 25, 2019, during a briefing with Subcommittee staff, FDA disclosed that in its normal course of testing confirmation, 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.

To better understand Johnson & Johnson's public statements and its defense of the safety of its talc-based baby powder, I request that you produce by December 24, 2019, all documents, including memoranda and communications, referring or relating to:

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[4] *Johnson & Johnson Recalls Baby Powder Over Asbestos Worry*, New York Times (Oct. 18, 2019) (online at www.nytimes.com/2019/10/18/business/johnson-johnson-baby-powder-recall.html).

[5] *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).

[6] *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-findingand-the-results-were-complicated-11573986601).

[7] *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).

[8] *Id.*

1. Johnson & Johnson's decision to limit the scope of its October 18, 2019, announced recall of bottles specific to Lot #22318RB, including rationale behind leaving Johnson & Johnson's baby powder on the market;

2. The decisions by Wal-mart, CVS, and Rite-Aid's on October 24, 2019, to remove all Johnson & Johnson's baby powder from their stores;

3. Johnson & Johnson's strategy to respond to FDA's October notification to the company that FDA's independent contractor detected asbestos in samples of Johnson & Johnson's baby powder;

4. RJ Lee's initial finding of asbestos in a sample testing conducted within the course of Johnson and Johnson's investigation into FDA's asbestos detection results, internally and with RJ Lee;

5. The December 5, 2019, letter sent by the Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy to FDA requesting that FDA publish results of tests it commissioned by OSHA to confirm its October 18, 2019, findings of asbestos in a sample of Johnson & Johnson's talc-based baby powder, including when and how the company became aware of the letter and by whom;

6. Public statements by Johnson & Johnson related to FDA's October 18, 2019, asbestos detection announcement including analyses, studies, data, or marketing materials utilized in crafting a public response to FDA's October 18, 2019, asbestos detection announcement;

7. The owners and locations of mines and manufacturing facilities that mined and/or processed all talc contributing to recalled Lot #22318RB and all other Lot numbers originating from those mines and manufacturing facilities;

8. Johnson & Johnson's decision not to disclose on the front label of its talc-based baby powder bottles any representation that the contents contain talc, including any discussion of findings with the 2009 Research International consumer survey commissioned by Johnson & Johnson;

9. Johnson & Johnson's decision to include cornstarch as an ingredient on the front label of its cornstarch-based baby powder, including any discussion of findings with the 2009 Research International consumer survey commissioned by Johnson & Johnson;

10. Any new warning labels to inform consumers of any risks, including but not limited to ovarian cancer and mesothelioma;

11. Side-by-side historical annual sales figures for Johnson & Johnson's talc-based baby powder and Johnson & Johnson's cornstarch-based baby powder since 1984; and

12. Whether Johnson & Johnson should pursue a phase out of its talc-based baby powder from the market;

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.

An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Thank you for your attention to this matter.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member

Responding to Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committees.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committees' preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committees should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committees should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committees' letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee on Oversight and Reform, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a

part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term "including" shall be construed broadly to mean "including, but not limited to."

5. The term "Company" means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; (b) the individual's business or personal address and phone number; and (c) any and all known aliases.

7. The term "related to" or "referring or relating to," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term "employee" means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term "individual" means all natural persons and all persons or entities acting on their behalf.