

March 4, 2020

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments to Docket No. FDA-2020-N-0025, “Testing Methods for Asbestos in Talc and Cosmetics Products Containing Talc”

The U.S. Chamber Institute for Legal Reform (“ILR”), an affiliate of the U.S. Chamber of Commerce (“the Chamber”), respectfully submits these comments regarding recent “Preliminary Recommendations” by an FDA-organized working group, the Interagency Working Group on Asbestos in Consumer Products (“IWGACP”), regarding procedures for testing talcum powder for asbestos.¹ As set forth below, these recommendations – which were created by a small subset of staff from the agencies represented on the IWGACP – are overly broad, unsupported by science and likely to adversely affect significant segments of the American economy.

The IWGACP’s recommendations chiefly propose that laboratories that test talc for asbestos no longer attempt to distinguish between true asbestos and “cleavage fragments,” which are essentially tiny pieces of ordinary rock that can resemble asbestos fibers in size and shape.² While we appreciate the IWGACP’s intent to provide clarity in an area where analytical techniques continue to be proposed and refined, it has swept too broadly in essentially deeming asbestos and cleavage fragments to be equivalent. As set forth below, scientific studies have not shown that cleavage fragments have the same harmful effects as asbestos. Yet, the IWGACP’s recommendations proceed from the hypothesis that the two are “suspected” of having similar biological effects.³

Although the IWGACP’s recommendations are characterized as “preliminary” and do not purport to “represent proposed changes to any regulations of the U.S. Government,”⁴ they may significantly impact American industry. As the FDA is aware, myriad consumer and industrial

¹ See generally FDA, IWGACP, *Executive Summary: Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc* (“IWGACP Recommendations”), Jan. 6, 2020.

² See *id.* at 4-5. The IWGACP uses the term “elongate mineral particle” or “EMP” to refer to asbestos structures or cleavage fragments with aspect ratios of at least 3:1. *Id.* at 4. For the purposes of this letter, the terms “cleavage fragments” and “nonasbestiform EMPs” are used interchangeably to refer to structures that are *not asbestos* but would be counted as “EMPs” under the IWGACP’s proposed approach.

³ See *id.* at 3.

⁴ See *id.* at 1 n.1.

products contain talc, including cosmetics, pharmaceuticals, automotive parts, plastics and certain food items.⁵ In addition to these industries, some of which have already been impacted by the recommendations, other industries that use different minerals that must be examined microscopically potentially will be affected.

Given the recommendations' lack of scientific underpinning and broad potential impact, we urge the FDA and other agencies whose staff comprise the IWGACP to withdraw them until they are subject to notice-and-comment rulemaking and the review procedures enumerated in Executive Order No. 13,891. This would allow the FDA and other agencies represented on the IWGACP (not just isolated staff) to thoroughly review the science and to better understand the recommendations. It would also give interested stakeholders the opportunity to engage with the FDA regarding the potential far-reaching implications of the recommendations.

Section I below summarizes our primary concerns with the recommendations. Section II explains how the recommendations would likely impact a broad range of industries whose interests the Chamber represents.

I. The IWGACP's Recommendation That Cleavage Fragments Be Treated As Equivalent To Asbestos Is Scientifically Unsupported.

The principal problem with the IWGACP's recommendations is that they treat true asbestos and cleavage fragments (non-asbestos structures that can resemble asbestos) as one and the same. Going as far as to call "the distinction" between these types of particles "irrelevant," the IWGACP directs laboratories that test talc to count *all* such structures under a single category, which it generally terms "EMPs."⁶ This approach is overly broad and scientifically unjustified.

It is well-recognized that exposure to *asbestos* is harmful to human health,⁷ but the term "asbestos" refers only to the rare, "asbestiform" variety of the serpentine mineral chrysotile and the amphibole minerals amosite, actinolite, anthophyllite, crocidolite and tremolite.⁸ The published literature has explained that these minerals more commonly are "nonasbestiform," in

⁵ Talc, FDA, <https://www.fda.gov/cosmetics/cosmetic-ingredients/talc>; *see also* U.S. Geological Survey ("USGS"), National Minerals Information Center, Talc and Pyrophyllite Statistics and Information, <https://www.usgs.gov/centers/nmic/talc-and-pyrophyllite-statistics-and-information> ("Major markets for talc are ceramics, paint, paper, and plastics."); *see also, e.g.*, IWGACP Recommendations at 1 ("Talc . . . is used in a wide variety of consumer products including cosmetics, foods, dietary supplements, drugs, medical devices, ceramics, and art materials.").

⁶ IWGACP Recommendations at 3-5. Specifically, the IWGACP broadly defines "EMP" as "any mineral particle with a minimum aspect ratio of 3:1." *Id.* at 5 (emphasis omitted). It recommends that any EMP longer than 0.5 µm be reported when testing talc for asbestos, and that "test methods specify reportable EMPs identified as amphibole or chrysotile particles as covered minerals." *Id.*

⁷ *See, e.g., id.* at 1-2.

⁸ *See, e.g.*, 29 C.F.R. § 1910.1001(b) & App. J (OSHA stating that "[f]or the purpose of regulation," the six covered minerals must "be in the asbestos growth habit").

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which case they are essentially ordinary rock.⁹ However, nonasbestiform minerals can fracture into particles known as “cleavage fragments” that can be relatively long and thin and thus resemble asbestos in some respects, but continue to lack other characteristics of asbestos, such as high tensile strength and flexibility.¹⁰

Although the IWGACP asserts that there are “many definitions of ‘asbestos,’” it identifies no authority that includes nonasbestiform mineral structures in the definition of asbestos.¹¹ In fact, federal statutes and regulations uniformly exclude the nonasbestiform varieties of the relevant minerals in defining asbestos.¹²

U.S. regulators – including the agencies whose members comprise the IWGACP – have continually recognized that there is a lack of evidence that nonasbestiform EMPs are as harmful as asbestos. For example, OSHA concluded as part of its rulemaking in 1992 that “substantial evidence is lacking to conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos” and that there is no credible link between exposure to nonasbestiform minerals and cancer.¹³ As a result, OSHA excluded nonasbestiform EMPs from the definition of “asbestos” and from the scope of its asbestos regulation.¹⁴ Similarly, the U.S. Department of the Interior has stated 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.”¹⁵

⁹ See, e.g., Int’l Agency for Research on Cancer, World Health Org., *Talc Not Containing Asbestiform Fibres*, in 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 277, 277 (2010).

¹⁰ See Asbestos Exposure Limit, 73 Fed. Reg. 11,284, 11,285 (Feb. 29, 2008) (MSHA explaining that “[w]hen pressure is applied, the nonasbestiform crystals fracture into prismatic particles, which are called cleavage fragments because they result from the particle’s breaking or cleavage. Cleavage fragments may be formed when nonfibrous minerals are crushed, as may occur in mining and milling operations.”). Asbestos fibers’ long and thin dimensions, tensile strength and flexibility are all thought to contribute to their potential to navigate the body’s defenses, persist in the body and eventually cause disease.

¹¹ See IWGACP Recommendations at 2. The IWGACP observes that a “[l]ack of consensus concerning what should be called ‘asbestos’ has persisted since the first reports indicating that asbestos might be present in talc.” *Id.* at 3. We believe that disagreement in this area has chiefly been driven by the plaintiffs’ bar, which has sought to impose an extremely broad definition of asbestos to bolster its position in litigation against talc defendants.

¹² See, e.g., 15 U.S.C. § 2642(3) (Toxic Substances Control Act defining asbestos as the “asbestiform varieties” of the six minerals); 40 C.F.R. § 763.163 (similar by EPA); 29 C.F.R. § 1910.1001(b) (similar by OSHA); 73 Fed. Reg. at 11,292 (MSHA’s definition of asbestos “does not include nonfibrous or nonasbestiform minerals”) (citation omitted).

¹³ Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite, 57 Fed. Reg. 24,310 (June 8, 1992).

¹⁴ See *id.* at 24,311.

¹⁵ U.S. Dep’t of the Interior, USGS, *Some Facts About Asbestos* 2 (2001) (emphasis omitted) (quoting 57 Fed. Reg. 24,310). In addition, the National Institute for Occupational Safety and Health (“NIOSH”) published a bulletin in 2011 discussing health issues surrounding asbestos and cleavage fragments. Although it decided to include

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The approach these agencies have taken is supported by the scientific literature. For example, a 2008 study examining human populations determined that “the weight of evidence fully supports a conclusion that non-asbestiform amphiboles do not increase the risk of lung cancer or mesothelioma.”¹⁶ A different 2008 survey of relevant in vitro studies concluded that “[t]he available studies show that cleavage fragments are less bioreactive and cytotoxic than asbestiform fibers.”¹⁷ And a third notable 2008 study explained that five experimental animal studies did not link prolonged exposure to nonasbestiform tremolite to an increased risk of disease.¹⁸

The IWGACP appears to have ignored these and other studies¹⁹ that undermine the basis for its recommendations.²⁰ Moreover, it appears that the few studies cited by the IWGACP do not support the allegation that nonasbestiform EMPs have similar pathological outcomes as asbestos.²¹ Ultimately, the IWGACP concludes only that nonasbestiform EMPs “*could* pose a

cleavage fragments in its recommended exposure limit for workers under an explicit “precautionary approach,” it ultimately found that evidence on the carcinogenicity of cleavage fragments is “inconclusive.” See NIOSH, U.S. Dep’t of Health & Human Servs., Current Intelligence Bulletin 62, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* (NIOSH 2011 Bulletin) at 19, 30 (2011). NIOSH specifically noted that animal studies, although limited, “suggest that nonasbestiform amphiboles might pose different risks than asbestos,” and that the results of in vitro studies are in accord. See *id.* at 31-32. For its part, the FDA has previously indicated that it recognizes the distinction between asbestos and nonasbestiform EMPs. For example, in a 2014 letter denying a citizen petition requesting that cosmetic talc bottles bear a cancer warning label, the FDA discussed only “talc containing asbestos fibers such as *tremolite asbestos* or chrysotile” – indicating awareness of the distinction between tremolite asbestos and ordinary, nonasbestiform tremolite. Letter from Steven M. Musser, Ph.D., Deputy Dir. For Sci. Operations, Ctr. for Food Safety & Applied Nutrition, to Samuel S. Epstein, M.D., Cancer Prev. Coalition, Univ. of Ill. – Chi. School of Pub. Health, at 2 (Apr. 1, 2014) (emphasis added). In addition, the testing protocols used by the FDA’s contract laboratory for testing cosmetic talc products provide procedures for detecting “asbestos,” defined to exclude nonasbestiform particles. See, e.g., NY ELAP 198.6 at 1-2 (protocol used by AMA Analytical Services, Inc., which tested talc products for the FDA in 2009-2010 and 2019).

¹⁶ Gamble & Gibbs, *An Evaluation of the Risks of Lung Cancer and Mesothelioma From Exposure to Amphibole Cleavage Fragments*, 52 Regul. Toxicol. Pharmacol. S154, S154 (abstract) (2008).

¹⁷ Mossman, *Assessment of the Pathogenic Potential of Asbestiform vs. Nonasbestiform Particulates (Cleavage Fragments) in In Vitro (Cell or Organ Culture) Models and Bioassays*, 52 Regul. Toxicol. Pharmacol. S200, S200 (abstract) (2008).

¹⁸ Addison & McConnell, *A Review of Carcinogenicity Studies of Asbestos and Non-Asbestos Tremolite and Other Amphiboles*, 52 Regul. Toxicol. Pharmacol. S187, S189-S190 (2008).

¹⁹ See, e.g., Roggli, *The So-called Short-Fiber Controversy: Literature Review and Critical Analysis*, 139 Arch. Pathol. Lab. Med. 1052, 1052 (abstract) (2015) (literature review concluding that “[t]here is no convincing evidence for a pathogenic effect for fibers that are 5 µm or less in length” and that “[s]imilar observations have been reported for nonasbestos mineral fibers”).

²⁰ As one presenter at the IWGACP’s public meeting put it, the studies the IWGACP relied on were “somewhat selective.” Commenter Presentation: Dr. Eric Chatfield, Chatfield Technical Consulting Limited, FDA Public Meeting, Feb. 4, 2020, at 2, <https://www.fda.gov/media/135059/download>.

²¹ Several of these studies conclude only that the possibility that cleavage fragments are harmful cannot be ruled out. See ANSES, Opinion of the French Agency for Food, Environmental and Occupational Health & Safety on ‘Health Effects and the identification of cleavage fragments of amphiboles from quarried minerals,’ at 7 (Dec. 4, 2015) (“[I]t is not possible to rule out a risk to health linked to exposure to cleavage fragments”); Dodson et al., *Asbestos Fiber Length as Related to Potential Pathogenicity: A Critical Review*, 44 Am. J. Indus. Med. 291, 293

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health concern” and “are *suspected* of having biological activity with similar pathological outcomes” as asbestos.²² This tepid conclusion should not have been the premise for a sweeping recommendation to treat all asbestos fibers and cleavage fragments as the same, even if it had been based on a thorough review of the literature.

II. The IWGACP’s Recommendations Have And Will Continue To Affect The Talc Industry And Related Industries.

The IWGACP’s recommendations have the potential to affect numerous sectors of the American economy, rendering it all the more important that they be based on sound science rather than unsupported hypotheses.

The U.S. talc industry itself is highly economically significant; as the USGS has put it, “talc is a part of everyday life” in the U.S.²³ The USGS reports that in 2019, “[t]otal sales (domestic and export) of talc by U.S. producers were estimated to be 570,000 tons valued at \$120 million,” while an additional estimated 310,000 tons of talc were imported to the U.S., principally from Canada, China and Pakistan.²⁴ The talc produced and sold in the U.S. in 2019 was used in the following industries: paint (23%); ceramics (including automotive parts) (20%); paper (15%); plastics (12%); rubber (4%); roofing (3%); and cosmetics (2%).²⁵ Based on these data alone, the IWGACP’s recommendations should be considered a “[s]ignificant guidance document” under Executive Order No. 13,891 – a designation that applies to regulatory guidance that “may reasonably be anticipated to . . . lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety.”²⁶ Notably, Executive Order No. 13,891 generally requires agencies promulgating such documents to provide for notice and

(2003) (“Thus while not a ‘regulated fiber’ these structures may well pose significant health risks.”). Others conclude only that “short, thin *asbestos* fibers” can cause disease, saying nothing about whether cleavage fragments should be deemed similarly harmful. See Suzuki et al., *Short, thin asbestos fibers contribute to the development of human malignant mesothelioma: pathological evidence*, 208 Int’l J. Hyg. Environl.-Health 201, 208 (2005) (emphasis added) (principally discussing chrysotile asbestos).

²² See IWGACP Recommendations at 3-4 (emphases added). Illustrating this, the IWGACP essentially adopted findings set forth in the NIOSH 2011 Bulletin, which, as noted above, deemed the evidence of cleavage fragment carcinogenicity “inconclusive.” NIOSH 2011 Bulletin at 30 (cited in IWGACP Recommendations at 4).

²³ USGS, Industrial Minerals of the United States, U.S. Talc – Baby Powder and Much More at 2 (Sept. 2000), <https://pubs.usgs.gov/fs/fs-0065-00/fs-0065-00.pdf>.

²⁴ USGS, Mineral Commodity Summaries, Talc and Pyrophyllite at 162 (Jan. 2020), <https://pubs.usgs.gov/periodicals/mcs2020/mcs2020-talc.pdf>.

²⁵ *Id.* The USGS reports that “[t]he remaining 21% was for export, insecticides, refractories, and other miscellaneous uses.” *Id.*

²⁶ Promoting the Rule of Law Through Improved Agency Guidance Documents, Exec. Order No. 13,891, 84 Fed. Reg. 55,235, 55,236 (Oct. 9, 2019). The IWGACP’s recommendations should also be considered a “significant guidance document” because they conflict with other agencies’ determination that nonasbestiform particles should not be regulated as asbestos equivalents, as explained above. See *id.* (“[s]ignificant guidance document[s]” may be those that “create a serious inconsistency or otherwise interfere with an action taken or planned by another agency”).

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comment; respond to “major concerns raised in comments”; obtain “approval on a non-delegable basis by the agency head or by an agency component head”; and submit the document for review by the Office of Information and Regulatory Affairs before issuing it publicly.²⁷

Companies that manufacture and sell talc products will certainly be adversely affected if the IWGACP’s recommendations are not withdrawn, and especially if they are formally adopted without modification and finalized in a white paper, as the FDA has suggested it may do.²⁸ If the recommendations are deemed authoritative by courts, talc companies will face additional litigation driven by plaintiffs’ attorneys seeking to premise liability on alleged exposure to mineral structures that the scientific community does not deem harmful. Indeed, one prominent plaintiffs’ attorney has already committed to “us[ing] the recommendations in future trials” against talc manufacturer defendants to attempt to argue (in the face of science) that cleavage fragments are regarded as asbestos equivalents.²⁹ Likewise, a laboratory manager who frequently serves as a plaintiffs’ expert was recently quoted as stating: “It’s helpful . . . to understand what [labs] should be counting – whether it’s for the courtroom or for a client in industry.”³⁰ This indicates that laboratories are already looking to change their testing procedures to conform to the IWGACP’s recommendations, despite those recommendations being explicitly “preliminary” and also contrary to existing science and notwithstanding the fact that the misguided test results reached under these new procedures may be used in court.

The recommendations could also have a domino effect on other, non-FDA-regulated industries that use talc (e.g., plastics, automobiles, rubber, ceramics, paint, paper and construction). If the talc used by those industries contains nonasbestiform EMPs, some may begin advocating for additional workplace or environmental controls that are unwarranted based on existing scientific research.

Finally, the IWGACP’s recommendations, particularly when coupled with statements made by members of the group at the FDA public meeting, could give rise to calls for testing and greater regulation of other minerals, without scientific basis.³¹ Other affected minerals could include

²⁷ See *id.* at 55,237. Moreover, significant guidance documents are subject to the same requirements that apply to rules as set forth under Executive Orders 12,866, 13,771, and 13,777, meaning that the IWGACP needed to perform a detailed examination of the costs and benefits of its chosen approach and otherwise justify its decision-making. See *id.*

²⁸ See Speaker Presentation: Wrap-Up and Next Steps by Linda M. Katz, M.D., M.P.H. from FDA, FDA Public Meeting, Feb. 4, 2020, at 8, <https://www.fda.gov/media/135012/download>.

²⁹ See Chad Terhune & Lisa Girion, *Government experts urge new talc testing standards amid asbestos worries*, Reuters (Jan. 10, 2020), <https://in.reuters.com/article/us-usa-fda-talc-testing-idINKBN1Z92I4> (plaintiffs’ attorney Mark Lanier stating that he believes the IWGACP’s recommendations “shot” the assertion that cleavage fragments are not equivalent to asbestos ““out of the water””).

³⁰ See *id.* (statement by Georgia laboratory manager and plaintiffs’ expert Steven Compton).

³¹ See Speaker Presentation: Mineral Fibers in the Lung – Exposure and Toxicity by Christopher P. Weis, Ph.D., D.A.B.T. from the National Institute of Environmental Health Sciences, FDA Public Meeting, Feb. 4, 2020, at 14, <https://www.fda.gov/media/135017/download> (suggesting that all EMPs – not just asbestos and nonasbestiform EMPs – can cause health issues).

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minerals that are co-located with non-asbestos amphibole EMPs, and minerals that, like talc, themselves can contain EMPs. The mining, farming and construction industries, among others, use such minerals. Further, hundreds of minerals contain EMPs, including barite, beryllium, magnesium, strontium and zirconium.³² Those minerals are important to the aerospace, oil and gas, and nuclear industries, as well as the military.³³ Indeed, the Department of the Interior and the Department of Defense recently designated those five minerals as being critical to the economic and national security of the United States.³⁴ Other critical minerals eventually could be affected as well.

* * *

We appreciate the IWGACP’s concern for public health and the need for guidance in an area that the IWGACP acknowledges is the subject of “scientific debate.”³⁵ Further, some of the IWGACP’s more general recommendations are warranted, including its call to improve the “reliability of the analytical methods for” testing talc for asbestos and the specific concerns it raises regarding laboratory accuracy.³⁶ We also agree with the IWGACP that efforts should be made “[t]o improve agreement in data interpretation among stakeholders and resolve inconsistencies in applying published methods.”³⁷

However, none of these goals is served by declaring the distinction between asbestos and cleavage fragments “irrelevant” and calling for it to be ignored moving forward. An agency should hesitate to make such sweeping proclamations without sound scientific support – which is sorely lacking here. Given the impact of the IWGACP’s recommendations on the talc and related industries, we urge the FDA to withdraw the recommendations in favor of formal notice-and-comment rulemaking and to follow the procedures for agency guidance set forth in Executive Order No. 13,891.

Sincerely,



Harold Kim
President, ILR

³² Gunter, *Elongate mineral particles in the natural environment*, 361 *Toxicol. and Applied Pharmacol.* 157, 163 (2018), <https://www.sciencedirect.com/science/article/pii/S0041008X18304307>.

³³ See generally USGS, Draft Critical Mineral List—Summary of Methodology and Background Information—USGS Technical Input Document in Response to Secretarial Order No. 3359, Open-File Report 2018-1021, <https://pubs.usgs.gov/of/2018/1021/ofr20181021.pdf>.

³⁴ See Final List of Critical Minerals 2008, 83 *Fed. Reg.* 23,295, 23,295 (May 18, 2018).

³⁵ IWGACP Recommendations at 1 n.1.

³⁶ See *id.* at 5-6 (discussing, *inter alia*, issues with sample representativeness, false positives/negatives and lab interference).

³⁷ *Id.* at 5.