Daubert Challenges to Novel Plaintiffs' Analytical Methods/FDA Counting Criteria

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Christopher S. Kozak has earned a reputation among his clients and colleagues for being well-prepared, thorough, and driven for amicable case resolution – and, if that does not work, aggressively defending his clients at Trial. In fact, he has tried cases to verdict in some of the most difficult jurisdictions in the Country, including New York City and Philadelphia. Christopher also is well known for his efficiency and desire to quickly move matters forward. He has more than 20 years of experience handling a broad range of civil litigation cases venued in federal and state courts located in New Jersey, New York, Pennsylvania and Connecticut.

I. Introduction

The most argued about issue in talc litigation is whether the product was derived from a source that grew as "asbestiform." Regardless of its source, talc used for pharmaceuticals and cosmetics usually includes minor amounts of accessory minerals, including: chlorite, magnesite, calcite, dolomite, and sometimes trace amounts of the amphibole minerals tremolite or anthophyllite. Notably, the tremolite and anythophyllite grow in either massive, non-asbestiform form (more common) or asbestiform form (rare).

In the World Health Organization's 2010 Talc Monograph, it concluded that there is inadequate evidence in humans for the carcinogenicity of inhaled talc not containing "asbestos" or "asbestiform fibers." It defined asbestiform as the pattern of growth of a mineral, that a mineral fiber can be elongated without being asbestiform, and that when tremolite and anthophyillite are asbestiform, they constitute asbestos and, when not asbestiform, they are referred to as mineral fragments or cleavage fragments. In sum, the WHO concluded that the carcinogenicity of talc depends on whether it contains contaminants that grew as asbestiform. Similarly, in 1992, OSHA noted the biological differences between the massive and asbestiform versions of anthophyllite, tremolite, and actinolite (collectively "ATA"), concluding after extensive review of the science that non-asbestiform ATA had not been found to be carcinogenic. As such, and relevant here, "tremolite asbestos" and "anthophllyite asbestos" would continue to be regulated, while non-asbestiform ATA would not because there was inconclusive evidence that those forms of the amphibole minerals were carcinogenic.

Of course, the factor that confounds the identification of asbestiform versus non-asbestiform ATA, and is the factor that allows Plaintiffs' experts to create the most confusion in litigation, is the fact that the talc at issue always has been ground up or milled into very small particles. Moreover, depending on the sample preparation method being used, the sample may have been further ground up, sonicated, centrifuged, frozen, or otherwise manipulated, making it impossible to determine how the particle formed in nature. In the absence of direct evidence from the mines, Plaintiffs are forced to argue circumstantially through post-milled testing of samples, that the talc must have formed with "tremolite asbestos" or "anthophyllite asbestos." This article will discuss the tests used to attempt to identify and count the minerals that could have grown in asbestiform habits.

II. Generally Accepted Methods to Test Talc for the Presence of Asbestos

As background, for decades, the pharmaceutical and cosmetic talc industries have been testing their talcs by using the methods commonly known as the C.T.F.A. J4-1 method and/or the USP / NF monograph for talc. These methods were developed over the course of years, and were recommended by industry scientists as being the most reasonable for reliably screening large quantities of material. Under either method, the initial step determined whether the minerals at issue, *e.g.*, tremolite or anthophyllite, were present in the first place. If present, the methods required the use of a microscope to determine the morphology or shape of the particles in the sample. By viewing at lower magnifications, the analyst could more easily see fiber groupings that might be indicative of its formation or growth in nature.

Both of the generally accepted methods for testing talc had very clear definitions of the characteristics needed to categorize the material as being fibrous or meeting a post-milled definition of appearing to have been formed in an "asbestiform" way. For example, the J4-1 method required the following:

1. Particles must appear to be fibrous rather than as crystals or slivers
2. The maximum diameter of a fiber to be counted is 3 microns
3. The maximum length of a fiber to be counted is 30 microns
4. The length to width ratio must be 5 or more to 1, that is, 5 times or more longer than wide
5. The separate or individual fibers must contain fibrils or the "bundle of sticks" effect unless they are as a nondivisible stage. A fibril cannot be subdivided and would be counted if it meets the other criteria. The length to width ratio of 5 or more to 1 is not meant to imply that other particles are not hazardous.

And the USP / NF called (and still calls) for:

1. A range of length to width ratios of 20:1 to 100:1, or higher for fibers longer than 5µm
2. If there is a capability of splitting into very thin fibrils
3. If there are 2 or more of the following 4 criteria:
   a. parallel fibers occurring in bundles
   b. fiber bundles displaying frayed ends
   c. fibers in the form of thin needles
   d. matted masses of individual fibers and/or thin fibers showing curvature

It is clear that these methods seek to identify evidence of fibers in bundle form, which, if present, would be circumstantial evidence of how they grew. This is important because when it comes to the ultimate issue of causation, the most important factor for the jury to determine is whether the talc at issue contained minerals that came from an asbestiform habit.

III. Plaintiffs' Methods & Counting Criteria

In attempting to characterize particles as asbestos or asbestiform, the Plaintiffs' experts gravitate towards methods that are generally accepted for asbestos identification in bulk materials (not talc, which has mineralogical interferences), that count the smallest units of particles (as small as 0.5µm), and that allow characterization of "bundles" based on shape and analyst discretion. Specifically, Plaintiffs' experts have relied on non-talc methods such as 1987 AHERA, the "Blount" method (a heavy liquid separation PLM method from a 1991 article written by Alice Blount), various I.S.O. methods (*e.g.*, 10312, 22262-1), and a modified "Blount" method for TEM with heavy liquid separation. There is at least one expert that even uses I.S.O 22262-2, which has a protocol for talc, but is a method not even followed precisely by the expert.

Notably, the methods being used are either not specified for talc (and, thus, do not account for the interferences and difficulties inherent in analyzing a milled talc sample) or are protocols that have been modified / manipulated to the point where the sample may not represent the product

"as used" by the consumer and certainly retains none of the characteristics to prove how the minerals formed in nature.

IV. Challenging Those Methods & Criteria

It's these "thumb on the scale" issues involving the methodology selection and modification that need to be addressed with the Court at the earliest stage possible, so that it can make a "gatekeeper decision" whether to allow the testimony or preclude it because the risk of misleading the jury is too great. Even if the application is not expected to be successful, it is worth making these motions or submitting Trial briefs on these issues to educate the Court, and, for appellate purposes, establish a well-developed Record. In federal court, the parties have F.R.E. 702 and *Daubert* factors to filter the type of expert opinions that will be allowed at Trial. Nearly all state courts have similar evidential rules for the foundation an expert will need to demonstrate in order to give an opinion, which include the mandate that the expert's methods be generally accepted and properly, predictably applied.

On April 27, 2020, the District Court of New Jersey, Chief Judge Freda Wolfson issued a 141 page decision, addressing various experts proposed by the parties in ovarian cancer litigation. *See In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices And Products Litigation,* ---F. Supp.3d ---, 2020 WL8968851 (D.NJ 2020). Though specific to ovarian litigation, the Court squarely addressed the admissibility of the testing methods offered by one of the Plaintiffs' testing experts. After extensive hearings and briefing by the parties, the Court rejected defendants' arguments that the testing expert had used AHERA and ISO testing methods, had failed to use generally accepted talc testing methods, or that the methods were incompletely applied or lacking data. She explained that defendants did not prove that the methods were not reliable for their purposes, did not offer competing methods, and/or that the issues raised went to the weight the jury would give the expert's opinions.

The problem with this and other Court decisions approving the expert's cocktail of methods is that when used in the manner proffered, the plaintiffs' methods inevitably give the same result - an opinion that asbestos or asbestiform amphibole is present in the samples . . . at trace levels (though extrapolated out to the 1,000s, 100,000s, or even millions). And, when challenged, these experts all admit that their counts do not distinguish between asbestiform growth and non-asbestiform growth. In sum, the testing method does not show asbestiform growth.

Defendants' motions to preclude portions of the testing experts' testimony must illustrate to the court how the test selected is misleading, how the expert has identified a method not specific for talc, that the method was not followed, and/or that necessary data from the testing was not provided. Indeed, in her April 27th decision, Judge Wolfson granted the defense motion to preclude opinions related to I.S.O. 22262-1 because it was not specific for talc, certain data was not provided, and the expert himself had previously testified that it was not a sufficient method. Similarly, in discovery, regardless of the testing method selected, defendants are encouraged to explore why the method was selected, whether all the steps were followed precisely (if not, why - and, if not, whether the chosen route had the capability of altering the results), whether the method accounted for interferences / errors / subjectivity, and any data that might be missing.

V. Conclusion

Particle identification and counts are the most contentious issues at talc Trials. By carefully crafting Motions *in Limine*, and cross examinations (if necessary), defendants can demonstrate to the Court that the Plaintiffs' experts' methods and counting criteria are designed to identify particles as "asbestos" or "asbestiform," that such characterizations are always misleading or often cannot be duplicated, and ultimately fail to provide any evidence probative of the ultimate issue . . . whether the tremolite or anthophyllite, if identified in trace amounts, grew in the asbestiform (rare) or non-asbestiform (common) habit.

The reality is NO METHOD can conclusively answer the question of "how the mineral formed" after the talc has been milled.