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EASTERN DISTRICT OF PA SOLIDIFIES RULE 702 REQUIREMENTS FOR MEDICAL CAUSATION – PART I

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An Eastern District of Pennsylvania [summary judgment decision](#) the court issued just before Christmas reinforces a number of basic tenets relating to a plaintiff's burden to prove both general and specific causation by a preponderance of the evidence.

In this first of a two-part commentary, we review the court's gatekeeping approach on "general" medical causation, which focuses on "ruling in" potential causes. Part II will examine the court's treatment of the experts' opinions on "specific" medical causation, i.e., ruling out potential causes that lack a scientific basis given the facts of the case.

The facts were straightforward. Plaintiff Hoeftling alleged his 40-year use of Red Man chewing tobacco and Skoal moist snuff caused him to develop squamous cell cancer of the tonsil. All experts in the case agreed there are three main risk factors for this type of cancer: (1) HPV, (2) smoking, and (3) alcohol. Hoeftling hired well-credentialed oncologists who posited a new fourth risk factor: smokeless tobacco use.

The experts on both sides not only agreed on the three main risk factors, they also agreed on the state of the medical literature relating to this new fourth risk factor of smokeless tobacco use. Indeed, all experts, including Hoeftling's, agreed there was—at a minimum—a lack of epidemiological evidence that smokeless tobacco was a cause of tonsil cancer. In light of this reality, Hoeftling's oncologists focused on biological plausibility, one of the Bradford-Hill criteria.

Defendants challenged these expert opinions under Rule 702 and prevailed. Summary judgment followed.

Practitioners should keep the following rules in mind to achieve more consistent application of Rule 702:

1. General Causation – Cancer risks are measured by human reaction to the product at issue, not the product's individual components. Opinions about the risks of other, dissimilar products normally will not "fit" the case facts.

The court resisted the urge to treat all tobacco products the same, recognizing that smoking has been well-established as a risk factor for tonsil cancer over numerous epidemiological studies. In contrast, the court noted the lack of association between smokeless tobacco products and tonsil cancer, citing *Wells v. SmithKline Beecham Corp.*, [601 F.3d 375, 377-78](#) (5th Cir. 2010)) and *Paoli*, 35

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F.3d at 752 (explaining plaintiffs must show the product “can cause the types of harm they suffered, and that the [product] in fact did cause them harm”).

Reviewing the variable risks of different categories of tobacco products (i.e. cigarettes, dry snuff, moist snuff, chewing tobacco) the court reinforced common sense and the best gatekeeping practice under Rule 702. Just as sports cars carry different risk profiles from sedans and SUVs, the different cancer risks from “tobacco” products depend on the dose and the unique characteristics of the product consumed.

2. General Causation – Different types of cancer have different risk factors and causes.

The court rightly looked to evidence of risks for tonsil cancer, not cancers in other sites, such as the gum or lip. Hoefling urged the court to treat both smokeless tobacco products as general “carcinogens,” meaning any type of cancer could be attributed to use of the products because they contained carcinogenic compounds. The court declined to assume that regulatory assessments of tobacco components as “carcinogenic” equates to causing cancer of every type in every organ.

The sources Dr. Busse relies on do not support his opinion that smokeless tobacco, including Skoal and Red Man, can in general cause tonsil cancer. This violates Daubert’s requirement that his opinion rest upon “good grounds.” Paoli, [35 F.3d at 742](#) (quoting Daubert, [509 U.S. at 590](#)). The IARC did not conclude smokeless tobacco causes tonsil or oropharyngeal cancer. (Busse Dep., ECF 71-3 at 113:7-23, 115:2116:16; Chabner Dep., ECF 71-4 at 83:1-20; Tomar Dep., ECF 70-2 at 184:1-185:24). It found a causative link only to oral-cavity, esophageal and pancreatic cancer. (Id.) Moreover, the 1986 Surgeon General report pointed to evidence that using snuff can cause cancer, with the “strongest” evidence for oral-cavity cancer. (ECF 71-2, ¶ 2.) But it did not conclude smokeless tobacco causes oropharyngeal cancer. (Id.) In fact, it stated there was “sparse” evidence of any association between “smokeless tobacco use and cancers outside of the oral cavity.”

3. General Causation – Experts must take account of the relevant literature as a whole. Experts can’t simply cherry pick studies that support their opinion.

In forming his general causation opinion, Dr. Busse relied on the authorities he cites in his report, case specific documents like Hoefling’s medical records and a 1981 article based on a study of 255 women in North Carolina. (Busse Dep. at 59:1-17; Busse Rpt. at 2; Winn Art., ECF 71-9.) He did not do an “in depth” review of any epidemiological research published after 1981. (Busse Dep. at 55:22-24.) Nor did he independently review the epidemiological research cited by the Surgeon General report or IARC. (Id. at 58:2024.) Dr. Busse did not review the 2016 Wyss study, which Dr. Chabner described as one of the “more complete” articles on smokeless tobacco products and Dr. Tomar characterized as the most “on point” for his work on this case.

It is insufficient for an expert to merely criticize studies contradicting their opinion.

Expert causation testimony “generally should be supported by positive and replicated epidemiological studies.” In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig., [26 F.Supp.3d 466, 475](#) (E.D. Pa. 2014) (Zolof II). When an expert’s causation opinion is “equivocal or inconsistent with” epidemiological research, the expert must “thoroughly analyze” its “strengths and weaknesses.” Id. Dr. Busse did not do so. He attempts to reconcile his general causation opinion with existing research by pointing to the

difficulty of distinguishing smokeless tobacco's role from those of confounders. But this fails to sufficiently explain why the existing research-or lack thereof-"does not contradict or undermine" his opinion.

4. General Causation – Bradford-Hill's criteria do not apply with equal weight. Biological plausibility is too subjective to override epidemiology studies showing no statistical association between an exposure and an outcome.

Dr. Busse's belief that it is biologically plausible for smokeless tobacco products like Red Man or Skoal to cause tonsil cancer does not account for the absence of data to support general causation.

As to the Bradford-Hill criteria, the court correctly pointed out that the criteria are irrelevant to general causation analysis when epidemiological studies have been conducted and not yielded a statistical association.

*Nor would it have been appropriate to apply them here: scientists are to do so only after an epidemiological association is demonstrated. Id. at 678 (explaining Hill used as the "starting point" of his analysis "'an association between two variables' that is 'perfectly clear-cut and beyond what we would care to attribute to the play of chance'" (quoting Bradford Hill, *The Environment and Disease: Association or Causation*, 58 *Proc. Royal Soc'y Med.* 295, 295-300 (1965))). That has not happened in this case.*

In part II, we'll review the court's treatment of the plaintiff's specific causation opinions.