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MDL JUDGE'S TEXTBOOK ASSESSMENT OF EXPERT EVIDENCE DOOMS PLAINTIFFS' CLAIMS

by Evan M. Tager, Craig A. Woods, and Jonathan S. Klein

The U.S. Supreme Court made clear in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), that experts must offer a reasoned explanation of why they believe the data underlying their opinions support their conclusions. In accord with *Daubert's* gatekeeping duty, the courts should exclude a conclusion "that is connected to existing data only by the *ipse dixit*" of the expert. *Id.* at 146. A recent decision from Judge Seeborg of the Northern District of California in the *Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation* MDL illustrates how the courts should treat a results-oriented expert who offers conclusions but no reasoned and reliable explanation why the data support those conclusions. 2020 WL 204115 (N.D. Cal. Jan. 13, 2020).

Former users of Pfizer's Viagra and Eli Lilly's Cialis sued the two manufacturers, alleging that Viagra and Cialis caused or exacerbated the growth of melanomas. Success on their claims requires the plaintiffs to prove general causation (that Viagra and Cialis are biologically capable of causing or exacerbating melanoma in general) and specific causation (that the drugs caused or exacerbated a particular plaintiff's melanoma). To prove general causation, the plaintiffs offered three experts who purported to apply the well-established Bradford Hill criteria, a set of nine factors that the scientific community uses as a framework for assessing whether an observed association between an exposure and a disease is likely causal. The Bradford Hill criteria examine: (1) the strength of association between exposure to a substance and the claimed harm, (2) consistency of association, (3) specificity of association, (4) the length of time between the exposure and the claimed harm, (5) the dose response, (6) biological plausibility, (7) coherence with other scientific knowledge, (8) experimental evidence, and (9) analogy to other substances.

In concluding that the scientific evidence showed that Viagra and Cialis caused or exacerbated melanoma, the plaintiffs' experts relied on a series of scientific studies that purported to show an association between exposure to PDE5 inhibitors and melanoma. PDE5 is an enzyme involved in intercellular signaling, and Viagra and Cialis act as PDE5 inhibitors in treating erectile dysfunction. Notably, the studies expressly disclaimed any conclusion that PDE5 inhibition causes melanoma progression and warned that "further research would have to be done before anyone should reach a conclusion that PDE5 inhibitor use does or could contribute to melanoma progression." *Id.* at *1-4, *13.

Pfizer and Eli Lilly moved to exclude the experts' opinions as unreliable, and after scrutinizing the experts' reasoning, the district court excluded all the general causation opinions offered by the plaintiffs' experts. Emphasizing that the expert conclusions appeared "unduly results-driven," Judge

Evan M. Tager is a Partner with Mayer Brown and is the *WLF Legal Pulse* blog's Featured Expert Contributor on Judicial Gatekeeping of Expert Evidence. **Craig A. Woods** is a Partner, and **Jonathan S. Klein** is an Associate, with Mayer Brown LLP.

Seeborg held that the experts failed to explain cogently how they could reliably conclude that Viagra and Cialis cause melanoma when the studies on which they relied showed nothing more than a weak association between PDE5 inhibitors and melanoma. *Id.* at *10-11.

One expert, Dr. Ahmed, testified that her causation opinion placed “significant weight” on the strength of the association between Viagra/Cialis and melanoma progression documented in the studies. *Id.* As the court noted, “the stronger the association between exposure to a substance and a particular outcome, the more likely it is that the relationship is causal.” *Id.* But as several metaanalyses (which pool the results of the studies together into a combined “risk estimate”) showed, the risk estimate between the two drugs and melanoma was only “somewhere around 1.2.” *Id.* A relative risk of 1.2 implies that PDE5 inhibition increases the risk of melanoma progression by only 20% over background risks—an amount the district court characterized as “undeniably... not a strong association.” *Id.* Pressed on why she attributed “significant” weight to the strength of association, Dr. Ahmed “was unwilling to identify what she perceived the strength of association to be.” *Id.* As often happens, the expert instead resorted to the “totality of the evidence.”

Judge Seeborg also noted two other indicia of unreliability: First, Dr. Ahmed failed to account for the lack of a dose-response between PDE5 inhibition and melanoma progression in the studies on which she relied—which is another Bradford Hill factor. The dose response factor examines whether increases in exposure generally increase the likelihood of disease. However, the studies at issue showed that melanoma progression remained approximately the same even as exposure to the PDE5 inhibitor increased. *See id.* at *10. Second, Dr. Ahmed, a practicing physician, had never warned any of her patients that Viagra or Cialis causes or exacerbates melanoma. The disparity between Dr. Ahmed’s decision not to warn her own patients about causation and her opinion as a hired expert in the MDL “further buttress[ed] the conclusion that Dr. Ahmed’s opinion on causation is not sufficiently reliable for admission.” *Id.* at *10 n.5. At bottom, the district court found Dr. Ahmed’s analysis “unduly resultsdriven” and consequently unreliable because it offered no clear and reliable explanation why the underlying data supported her conclusions. *Id.* at *10.

Like Dr. Ahmed, another of the plaintiffs’ experts, Dr. Singh, based his causation opinion on a purported “strength of association” between the drugs and melanoma progression. To support his claim, Dr. Singh relied heavily on one study, Li 2014, which reported a higher “risk factor” of 1.84 between PDE5 inhibition and melanoma progression. However, Dr. Singh conceded that he could not characterize even this association as “strong,” that the study was “small,” and that “its results have not been duplicated.” *Id.* at *11. Judge Seeborg concluded that Dr. Singh offered no persuasive reason to rely more heavily on Li 2014 than on other studies that showed a weaker association. In finding Dr. Singh’s opinion unreliable, the district court explained that “Dr. Singh could not reasonably conclude, and did not conclude, that the association was strong. His decision to weigh that factor relatively heavily... therefore appears untethered to the evidence.” *Id.*

The opinion of the plaintiffs’ final causation expert, Dr. LiuSmith, suffered from many of the same defects as the other experts’ opinions. To support her causation opinion, Dr. LiuSmith relied heavily on the purported consistency of findings across different studies, noting that all but one study involving Cialis found a statistically significant association with melanoma progression. But as the district court explained, Dr. LiuSmith’s analysis improperly conflated the strength of association (*i.e.*, the relative risk, which ranged somewhere around an “undeniably weak” 1.2) and the consistency of association (*i.e.*, the fact that several studies conducted at different times by different researchers involving different populations all found an association). *Id.* at *11. Dr. LiuSmith’s failure to account for the acknowledged weakness of the association in her analysis and her blurring of the difference between the strength and consistency of association led Judge Seeborg to hold that “Dr. LiuSmith’s

application of the Bradford Hill factors appears resultdriven” and consequently unreliable. *Id.*

In closing, Judge Seeborg expressly noted what defendants regularly experience in other actions: “[T]here simply is no interpretation by anyone other than plaintiffs’ experts that supports general causation.” *Id.* at *12. The absence of any unbiased corroborating evidence led the district court to remark that “[t]he unavoidable conclusion is that [the plaintiffs’ experts’] weighing of the Bradford Hill factors does not represent a faithful application of an accepted methodology.” *Id.*

Too often, district courts elect not to exclude (or even scrutinize) expert conclusions when an expert blurs several factors and then purports to draw conclusions from “the totality of the evidence” or “the record as a whole.” Like several other key decisions we chronicled in the Washington Legal Foundation’s recent Monograph (Evan M. Tager *et al.*, *Admissibility of Expert Testimony: Manageable Guidance for Judicial Gatekeeping* (Washington Legal Foundation 2020)), Judge Seeborg’s decision in the MDL deserves praise for faithfully applying *Daubert*’s gatekeeping requirement and rejecting expert conclusions supported by little or nothing but the *ipse dixit* of the expert.