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Experts Cannot Serve as "Superlawyers" Advocating Conclusions That Plaintiff Wants the Jury to Reach

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This past May, Novartis Pharmaceuticals Corporation secured a significant defense verdict in a products liability lawsuit concerning the company's drug, Zometa, pending in the Eastern District of New York. *Hogan v. Novartis Pharmaceutical Corp.*, No. 06-civ-260 (E.D.N.Y. May 25, 2011). *Hogan* was one of several cases filed against Novartis alleging that Zometa caused plaintiffs to develop osteonecrosis of the jaw (ONJ) that was consolidated for pre-trial proceedings in a multi-district litigation in the United States District Court for the Middle District of Tennessee. After completion of discovery, the MDL court remanded *Hogan* to the United States District Court for the Eastern District of New York for trial before Judge Brian M. Cogan.

Zometa is an FDA-approved intravenous bisphosphonate drug prescribed to patients with metastasizing cancer to prevent bone damage. It is still on the market, and remains the standard of care for treatment of patients with metastatic bone disease. In *Hogan*, plaintiff alleged that her late husband developed ONJ as a result of using Zometa, which he was prescribed in March of 2003 to prevent bone loss during treatment for multiple myeloma, a cancer that affects blood plasma cells. In December 2003, decedent had eight teeth extracted, and in July 2004, an X-Ray showed a non-healing lesion and a soft tissue mass in the area where the teeth had been extracted. Necrotic tissue was removed and decedent was diagnosed with ONJ. Mr. Hogan died of multiple myeloma in 2005.

Plaintiff's claims stemmed from whether Novartis adequately warned of the risk of developing ONJ from use of Zometa. Plaintiff retained Dr. Suzanne Parisian, the ever-present plaintiff's expert, to testify about FDA regulations and warnings, and Dr. Robert Marx, an oral surgeon. Successfully using *Daubert*, the defense was able to exclude Dr. Parisian's testimony in its entirety and limit the proposed testimony of Dr. Marx. Without this testimony, plaintiff was left with no expert to address regulatory and warning issues, contributing greatly to the eventual defense verdict.

The Underlying Daubert Decision

Judge Cogan began his discussion of Dr. Parisian's proposed testimony by stating that it was "[u]nclear...where Dr. Suzanne Parisian's testimony fits." *Hogan v. Novartis Pharmaceutical Corp.*, 2011 WL 1533467, at *1 (E.D.N.Y. Apr. 24, 2011). Dr. Parisian was offered as a regulatory expert to opine on regulatory and labeling issues, including the role and function of the FDA; defendant's conduct in obtaining approval for Zometa; Novartis' relationship with the FDA; and finally, what defendant communicated to physicians about ONJ. Dr. Parisian admitted that she was not there as "the expert in Aredia and Zometa," but rather "as the expert on FDA issues involving Aredia and Zometa." *Id.* Plaintiff, however, did not assert any FDA regulation violations in her Complaint. As such, the court held that "plaintiff cannot have her cake and eat it too; she cannot bring common law claims not grounded in FDA regulations only to present an expert to opine on whether defendant violated those regulations." *Id.* at *2. Any testimony suggesting that Novartis failed to comply with FDA regulations was thus irrelevant. *Id.* at *2 – *3. Indeed, there was no evidence whatsoever that Novartis had violated any specific FDA regulations. *Id.* at *4.

Further, Dr Parisian was unqualified to testify on the topic of pharmacovigilance, *i.e.* "what pharmaceutical companies generally do to anticipate and prevent adverse drug reactions." *Id.* at *3. Dr. Parisian never worked for a pharmaceutical company, and was therefore "unqualified to opine on the potentially relevant testimony she offers in her report regarding pharmaceuticals companies' internal operating procedures and other standards with which she claims manufacturers voluntarily elect to comply." *Id.* at *3. Ultimately, the court excluded Dr. Parisian's testimony in its entirety because it was mostly irrelevant, and "if the Court allowed Dr. Parisian to testify [about the FDA's role in this litigation], the side show would turn into the main event." *Id.* at *4.

Plaintiff also sought to introduce the testimony of Dr. Robert Marx, a board-certified oral and maxillofacial surgeon, who was among the first to identify ONJ in one of his textbooks, and has treated many patients with ONJ. The court limited the testimony of Dr. Marx as it related to his analysis of Novartis' corporate documents and his proposed testimony explaining how these documents established causation. *Id.* at *6, citing *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) ("While an expert must of course rely on facts or data in formulating an expert opinion, an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence."). Nor was Dr. Marx qualified to assess the defendant's clinical trials. *Id.* at *5-6 ("He would not, for instance, have the expertise to opine on the level of probability for developing a certain medical condition that pharmaceutical companies should tolerate before including specialists to monitor it during their trials"). The court also struck Dr. Marx's testimony to the extent it related to defendant's supposed bad faith in manipulating publication of an article discussing ONJ, particularly because plaintiff did not seek punitive damages. Dr. Marx's opinion on whether participants in defendant's clinical trial developed ONJ, however, was deemed relevant and reliable.

Finally, in perhaps the most astute statement made by Judge Cogan in his opinion, the court expressed concern that "all of plaintiff's experts, to some degree, are being proffered as 'superlawyers' to serve as scientifically informed advocates of conclusions that plaintiff wants the jury to reach and which belong only in summation, not expert testimony." *Id.* at *5. This is the gate-keeping role of *Daubert* at its best. In fact, the defense might view it as the icing on this opinion's cake.

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