Legal Opinion Letter

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AVOIDING THE SIDESHOW:
ONE TRIAL JUDGE'S TEXTBOOK APPLICATION OF *DAUBERT* TO EXCLUDE DUBIOUS TESTIMONY

by
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Properly applied, the federal rules offer formidable protection against junk science and paid advocates. One federal court recently got it right by excluding purported expert testimony, including that of widely-used plaintiffs' expert Suzanne Parisian, due to its "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." *Hogan v. Novartis Pharmaceuticals Corp.*, 1:06-cv-BMC-RER, 2011 WL 1533467, *5 (E.D.N.Y. Apr. 24, 2011).

The Stakes. Novartis Pharmaceuticals Corporation ("NPC") manufactures the intravenous bisphosphonate drug Zometa®, which is approved by the Food and Drug Administration (FDA) for the prevention of bone destruction in cancer patients suffering from metastatic bone disease. The drug is still on the market, and in fact remains the "standard of care" for treatment of patients with metastatic bone disease. Although NPC prevailed in opposing certification of a class action, *In re Aredia and Zometa Products Liability Litigation*, No. 3:06-MD-1760, 2007 WL 3012972 (M.D. Tenn. Oct. 10, 2007), NPC has been served with numerous individual lawsuits alleging that Zometa® causes osteonecrosis of the jaw.

One such case was filed by Karleen Hogan on behalf of her late husband, Timothy Hogan. After the completion of discovery, the federal MDL court remanded the *Hogan* case to the United States District Court for the Eastern District of New York for trial before Judge Brian M. Cogan. Led by lead trial counsel Bruce J. Berger, lawyers from Hollingsworth LLP and Rivkin Radler LLP tried the *Hogan* case, and on May 25, 2011, a jury returned a complete defense verdict.

Plaintiff's "Superlawyer" Experts. Plaintiff's claims essentially hinge on whether NPC provided adequate warnings to Mr. Hogan's prescribing physicians. Plaintiff hired Dr. Suzanne Parisian, a purported expert on FDA regulations and warnings, and Dr. Robert Marx, an oral surgeon, to offer expert testimony on her behalf. NPC filed motions to exclude plaintiff's case-specific experts under Federal Rules of Evidence 702 and 403 and *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Just weeks before jury selection was scheduled to begin in *Hogan*, Judge Brain M. Cogan excluded Dr. Parisian's testimony in its entirety, and limited the proposed testimony of Dr. Marx.

Dr. Parisian has testified dozens of times on regulatory, corporate conduct, and warnings issues on behalf of plaintiffs asserting personal injury claims against pharmaceutical and medical device manufacturers. Courts have struggled to rein her in once she takes the stand. *See, e.g., In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008), *aff'd in part, rev'd in part*, 586 F.3d 547 (8th Cir. 2009).

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In her 120-page report in *Hogan*, Dr. Parisian criticized NPC's corporate conduct in connection with its evaluation, marketing, and labeling of Zometa®. Despite the substantial length of her report, Judge Cogan was "[u]nclear . . . where Dr. Suzanne Parisian's testimony fits." 2011 WL 1533467 at 1. Judge Cogan noted that there was no evidence that NPC had violated any specific FDA regulations. Judge Cogan accordingly 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. Therefore, her personal opinions that NPC somehow failed to abide by the regulations were irrelevant and unhelpful to the jury. *Id.* at 2-3

The court then analyzed "whether Dr. Parisian is qualified to testify" on the topic of pharmacovigilance, *i.e.* "what pharmaceutical companies do to anticipate and prevent adverse drug reactions." *Id.* at 3-4. Judge Cogan noted that Dr. Parisian had never worked for a pharmaceutical company, and in her short "stint" at FDA she was never involved in the regulation of pharmaceuticals (instead, she worked in the medical devices division). *Id.* at 3. "Given this background," the court held, "I find that she is unqualified to opine on the potentially relevant testimony she offers in her report regarding pharmaceutical companies' internal operating procedures and other standards with which she claims manufacturers voluntarily elect to comply." *Id.* at 4. Because her proposed testimony was "mostly irrelevant," and she was unqualified to render her only potentially relevant opinions, Judge Cogan held that "if the Court allowed Dr. Parisian to testify, the side show would turn into the main event." *Id.* Dr. Parisian was plaintiff's only expert on regulatory or warnings issues; her exclusion leaves plaintiff with no retained expert to address these issues.[1]

Judge Cogan also precluded plaintiff's oral surgeon expert, Dr. Marx, from opining that NPC had allegedly engaged in "bad faith," and from criticizing NPC's design of its clinical trials. Judge Cogan held that Dr. Marx's proposed "bad faith" testimony was irrelevant, and that such testimony would be more akin to argument by a "superlawyer" rather than the reasoned opinions of an expert witness. 2011 WL 1533467 at 5. Moreover, the court excluded his criticisms of NPC's clinical trial designs because "Dr. Marx admitted in his deposition that he has never planned or managed any clinical trials intended to study the effect of any drugs on humans." *Id.* at 6.

Takeaways:

- A successful pre-trial challenge rests on a powerful testimonial record. Dr. Parisian's exclusion in *Hogan* was made possible in large part because the defendant invested considerable time and upfront expense to build a record through extensive cross-examination of her in various depositions, hearings, and trials in the Zometa® litigation.
- Rule 702 and its state analogs offer protections that reach beyond *Daubert*. Dr. Parisian's 120-page report in *Hogan* included dozens of pages where she simply quoted, out of context, internal company documents. She then speculated about NPC's alleged state of mind, knowledge, and corporate intent. But as Judge Cogan recognized, such speculation is not testimony premised on the "specialized knowledge" required by Fed. R. Evid. 702 and is not helpful to the jury.
- With no expert available to turn the regulatory "side show" into the main event, some courts may assess that regulatory issues should drop out altogether. Judge Cogan's exclusion of Dr. Parisian rested, in part, on his conclusion that "the FDA is mostly irrelevant to this action," since plaintiff could not produce evidence that NPC had violated any FDA regulations. *Hogan* Order at 4.

[1]Plaintiff had previously disclosed another purported warnings expert, Dr. Vogel, but dropped him before the court issued its *Daubert* ruling. After Dr. Parisian's exclusion, plaintiff tried to reinstate Dr. Vogel as a testifying expert just days before the start of trial. Judge Cogan again got it right, excluding Dr. Vogel's proposed testimony because, like Dr. Parisian's and Dr. Marx's, it "reveal[ed] the type of advocacy and narration that this Court has precluded other experts from offering." *Hogan v. Novartis Pharms. Corp.*, No. 06 Civ. 0260 (BMC) (RER) (E.D.N.Y. May 3, 2011).

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