The Metropolitan
Corporate Counsel®

www.metrocorpcounsel.com

Volume 17, No. 11 November 2009

Effective Use Of A Regulatory Expert In Product Liability Litigation

Beth S. Rose and Vincent Lodato

SILLS CUMMIS & GROSS P.C.

Regulatory issues are often front and center in complex pharmaceutical and medical device product liability litigation. Plaintiffs' complaints routinely focus on product labels and claim that they do not adequately reflect risks which were known or learned during pre-clinical testing, clinical trials or through post-marketing adverse event reporting. In order for a manufacturer of a prescription drug or medical device to combat these charges, it must have a strategy to educate the jury about the role the Food and Drug Administration ("FDA") plays in evaluating new drugs and medical devices and how the agency regulates these products through their entire life cycle. While company witnesses from regulatory and safety are useful in this regard, they are no substitute for the testimony of an FDA/regulatory expert – typically, a former FDA employee with the experience to explain the context in which the manufacturer's conduct should be evaluated.

Like all witnesses, expert testimony is governed by and subject to the applicable rules of evidence. The challenge for the trial lawyer is to craft a direct examination that withstands evidentiary objections that the expert's testimony is invading the province of the jury or is nothing more than a legal conclusion. This is no easy feat inasmuch as the regulatory expert's opinion is often based on the relationship between a complex set of facts and applicable law. This article describes the principal areas in which testimony by a regulatory expert has been offered, allowed or disallowed and offers best practices to maximize the admissibility of such testimony at trial.

Beth S. Rose *is Chair of the Firm's Product Liability Practice Group and Co-Chair of the Firm's Litigation Practice Group.* ***Vincent R. Lodato*** *is an Associate in the Firm's Litigation Practice Group. The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of Sills Cummis & Gross P.C.*

Beth S. Rose

Vincent Lodato

Explaining The General Framework Of The FDA And Its Regulations

Testimony explaining how the FDA and its regulations operate is the most traditional and least controversial area for a regulatory expert. For instance, an expert may testify about the structure of the FDA, the education and experience of agency reviewers, and how the FDA goes about evaluating a New Drug Application ("NDA") or Pre-Market Application ("PMA") to determine the safety and efficacy of a pharmaceutical or medical device not yet on the market. The expert may explain to the jury the circumstances under which a drug or device manufacturer must provide post-market adverse event data to the FDA. This type of testimony is almost always permitted because it fulfills the traditional role of an expert – aiding the jury in understanding specialized evidence and helping it determine a fact in issue. *See, e.g., Federal Rule of Evidence 702; In re Fosomax Products Liability Litigation*, 2009 U.S. Dist. LEXIS 64661, *68 (S.D.N.Y. 2009) ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry.").

Providing A Factual Summary Of The Regulatory History Of A Product Or The Defendant's Actions

A party may utilize an FDA expert to provide a summary or narrative of the

Please email the authors at brose@sillscummis.com or vlodato@sillscummis.com with questions about this article.

regulatory history of a product. In the prescription drug context, the testimony may include an explanation of the animal testing the manufacturer conducted before human testing was initiated. Likewise, in a medical device case, the expert may explain why the manufacturer submitted a supplemental pre-market application to initiate a label change. This type of expert testimony is traditionally admissible provided that the expert is "adding" something to the evidence he or she is summarizing. For example, it is permissible for an FDA expert to discuss a letter the manufacturer received from the FDA approving a label change and explaining the significance this letter has under FDA regulations. Courts are much more likely to allow an expert to summarize a product's regulatory history where the expert is explaining the regulatory significance of the evidence, defining complex or specialized terms or drawing inferences from the documents that are only apparent because of the expert's specialized knowledge or experience. *See In re Fosomax*, 2009 U.S. Dist. LEXIS 64661 at *72-73. Parties tend to face admissibility problems where the expert is merely quoting, summarizing or regurgitating documents without providing an additional commentary or analysis beyond the text of the documents themselves. *See generally, In re Prempro Products Liability Litigation*, 554 F. Supp. 2d 871 (E.D. Ark. 2008) (striking an FDA expert's testimony where it consisted solely of summarizing and quoting documents without any expert commentary or analysis).

Evaluating And Opining On The Defendant's Compliance With FDA Regulations

Having an expert discuss the FDA framework and comment on the significance of the regulatory evidence can be very helpful. Most parties, however, want the expert to take the next logical step, and evaluate whether the manufacturer "complied" with or "violated" FDA regulations. The admissibility of such testimony can be dicey especially where the expert uses certain buzzwords such as "complied," "violated" or "adequate." Many courts have balked at allowing FDA experts to express these types of opinions because they view them as legal conclusions or an invasion of the province of the jury. *See, e.g., In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Such testimony usurps the role of the trial judge in instructing the jury as to the applicable law and the role of the jury in applying that law to the facts before it."). Some courts, however, have allowed FDA experts to opine as to the "reasonableness" of the defendant's conduct in the context of the applicable FDA regulations. *See, e.g., In re Guidant*, 2007 WL 1964337, *7 (D. Minn. June 29, 2007) (holding that plaintiff's FDA expert could testify as to whether the defendant's actions were "reasonable and appropriate"). Attorneys planning to use an FDA expert to give this type of opinion testimony should try to use phrases such as "reasonable," "appropriate" and "properly" during their direct examination so as to increase the likelihood that the testimony will be admitted.

Interpreting And Opining On Regulations

While regulatory experts are generally precluded from providing testimony that amounts to a legal conclusion, the difficulty often lies in determining what type of testimony actually constitutes a legal conclusion. The context of the expert's testimony is critical to this determination. In *Steele v. DePuy Orthopaedics, Inc*., 295 F. Supp. 2d 439 (D.N.J. 2003), the Court was asked to determine whether the FDA's approval of the product at issue pre-empted plaintiff's claims. In opposition to the defendant's motion, plaintiffs submitted an affidavit of a regulatory expert who concluded that the "Real Time Review" procedure that the FDA used to evaluate and approve the product was more akin to the 510(k) process (which the Supreme Court found does not pre-empt state tort claims) than the PMA process. The court struck the expert's affidavit because his opinion addressed a purely legal issue – pre-emption – and was not designed to aid the jury in understanding the evidence or determine an issue in dispute. *Steele*, 295 F. Supp. 2d at 445-46. Courts have also precluded FDA experts from opining on an FDA regulation where the judge believes that the expert's interpretation is inconsistent with the FDA's guidance on an issue. *McDarby v. Merck & Co., Inc*., 949 A.2d 223, 262-65 (N.J. App. Div. 2008).

Opining On How The FDA Would React To Regulatory Submissions

To rebut a plaintiff's claim that the manufacturer should have warned about an alleged side effect, it would be helpful to show that the FDA would have rejected the language plaintiffs propose. An argument can be made that an FDA expert who has considered label changes during his or her tenure at the agency has the requisite training and experience to offer such an opinion. Most courts, however, have rejected such an argument, finding that the opinion lacked a proper evidentiary foundation and was speculative. *See McDarby*, 949 A.2d at 263 (precluding an FDA expert from testifying that had Merck submitted a label change for Vioxx pursuant to the CBE process, the FDA would have rejected it). Likewise, FDA experts are prohibited from giving an opinion on the intent, motives and state of mind of FDA reviewers and officials, or their anticipated reactions to regulatory submissions. According to one court, the specialized knowledge and training of an FDA expert does not qualify him or her to read the minds of FDA employees. *See In re Fosomax Products Liability Litigation*, 2009 U.S. Dist. LEXIS 64661 at *72-73.

Nevertheless, depending on the subject matter and assuming that the regulatory expert is a former FDA employee, it may be possible to lay a sufficient foundation and elicit the desired testimony. For example, in a trial last year in federal court, the judge initially sustained an objection to questions regarding whether a document prepared for a foreign regulatory agency should have been submitted to FDA. After the expert testified that she was familiar with foreign regulatory submissions and had reviewed them while at FDA, the court allowed her to offer the opinion that the company acted reasonably by not submitting the document to the agency.

Conclusion

Retention and development of a well-qualified, credible regulatory expert in complex product liability litigation is essential to a successful defense. A carefully constructed direct examination will help maximize the expert's utility at trial. While the evidentiary issues are challenging, anticipating and addressing potential objections prior to trial is well worth the effort.