

[Experts Offering Evidence of Corporate Intent, Ethics, And The Like](#)

Thursday, May 19, 2011

Returning from the ALI meeting, Bexis had sitting in his inbox the final hard copies of update 14 for his Drug/Device [products liability book](#). For those of you that use Bexis' book, that means there's more to use, but for Bexis that means that it's time to start on update 15. A legal author's work is never done. This time he's planning to update the chapter on evidence.

It's also time for our Thursday long post - time to kill two birds with one stone.

Right now the book has a short subsection on corporate intent evidence in drug and device cases. That section states simply that corporate motive and intent evidence (usually offered by some purported "expert") has generally been found inadmissible by courts trying drug and medical device product liability cases. There's one footnote, citing four cases from three jurisdictions: [Smith v. Wyeth-Ayerst Laboratories Co.](#), 278 F. Supp.2d 684, 700 (W.D.N.C. 2003); [Figueroa v. Boston Scientific Corp.](#), 2003 WL 21488012, at *4 (S.D.N.Y. June 27, 2003); [In re Diet Drugs Products Liability Litigation](#), 2001 WL 454586, at *2 (E.D. Pa. Feb. 1, 2001); [In re Diet Drugs Products Liability Litigation](#), 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

We think Bexis can do better than that with this update – and we think we can make a blog post out of it as well. So let's take a look. What have courts held about corporate motive and intent evidence lately?

Probably the best treatment of the subject, of the cases coming down since this part of the book was updated, is in [In re Rezulin Products Liability Litigation](#), 309 F. Supp.2d 531 (S.D.N.Y. 2004). There, three purported corporate ethics "experts" were excluded for a variety of reasons. First, their ethics opinions were "speculative" in the sense that they were based upon "subjective belief." Id. at 543-44. Second, ethical matters were not relevant to product liability litigation, as it was unrelated to the alleged defects being claimed. "While the defendants may be liable in the court of public opinion, or before a divine authority . . . , expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits." Id. at 544. Third, ethics evidence was argumentative and prejudicial. Id. at 545. Fourth, expert witnesses aren't really qualified at divining corporate intent, which is something that lay jurors

are equally competent to judge, should it be relevant to anything. Id. at 546-47.

Other cases have also considered and rejected ethics/intent-related testimony for one or more of the reasons articulated by the Rezulin court. In re Trasyolol Products Liability Litigation, 2010 WL 1489793, at *7-9 (S.D. Fla. Feb. 24, 2010), largely followed Rezulin in excluding disguised business ethics evidence:

Despite Plaintiffs' argument that the opinion at issue is not an ethical opinion because [the witness] does not use the word "ethical" or "unethical" in his Report . . . , this Court will consider [its] substance. . . . Much of the testimony in dispute relates to [defendant's] responsibilities, the studies that [it] should have done to comply with drug safety principles, and the issues that [defendant] should have addressed earlier than it did. The Court finds that this proffered testimony is akin to the ethics testimony found to be inadmissible in Rezulin. . . . The Court finds this testimony inadmissible because it is a reflection of [the witness'] own subjective beliefs and personal views and does not rest on knowledge as required by Rule 702.

Id. at *8; see id. at *9 ("speculation about [the defendant's] subjective motivations . . . is not a proper subject for expert testimony"). See also In re Trasyolol Products Liability Litigation, 709 F. Supp.2d 1323, 1347 (S.D. Fla. 2010) (witness lacked expertise "to infer . . . knowledge and intent and present those inferences to the jury"); In re Trasyolol Products Liability Litigation, 2010 WL 4052141, at *8 (S.D. Fla. Feb. 24, 2010) (opinion concerning defendant's "knowledge, motive, intent, and state of mind . . . are inadmissible . . . because they have no basis in any relevant body of knowledge or expertise and lie outside the proper bounds of expert testimony"); In re Trasyolol Products Liability Litigation, 2010 WL 4259332, at *8 (S.D. Fla. Feb. 24, 2010) ("[t]he question of intent or motive is a classic jury question and not one for experts").

The court in Deutsch v. Novartis Pharmaceuticals Corp., ___ F. Supp.2d ___, 2011 WL 790702 (E.D.N.Y. Mar. 8, 2011), also found corporate intent evidence to be improper on multiple grounds, relying primarily on Rezulin:

[The witness] scatters improper personal opinions, speculation, and state of mind inferences throughout the narratives in her report. Such opinions are inadmissible insofar as the opinions of expert witnesses on the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise. In addition, "bad company" opinions that are not based on any FDA regulation or other applicable standard are similarly inadmissible.

Id. at *45. In addition, the witness was found generally unqualified to testify about corporate ethics, and to have no basis beyond subjective personal opinion for any assertion that “ghostwriting” (preparation of scientifically accurate articles for others to claim authorship) was unethical or otherwise improper. Id. at *46.

Essentially the same result occurred in In re Fosamax Products Liability Litigation, 645 F. Supp.2d 164 (S.D.N.Y. 2009), with vague and conclusory ethics testimony being excluded:

To the extent [defendant] challenges testimony about purported general ethical standards . . . [its] motion is GRANTED [A]uthorities such as the 1964 Declaration of Helsinki [] providing generally accepted international standards such as “The health of my patient will be my first consideration” . . . [and] that “[t]rust and honesty are essential virtues that permeate all aspects of human life, including the drug approval process” . . . are so vague as to be unhelpful to a fact-finder.

Id. at 194 (quoting Rezulin); see id. at 192 (“the knowledge, motivations, intent, state of mind, or purposes of [defendant and] its employees . . . is not a proper subject for expert or even lay testimony”); 195 (same).

Likewise, the court in In re Baycol Products Litigation, 532 F. Supp. 2d 1029 (D. Minn. 2007), blew out corporate ethics evidence as “only marginally relevant’ and not a proper subject for expert testimony:

Personal views on corporate ethics and morality are not expert opinions. Further, expert testimony that is merely speculation or pure conjecture based on the expert’s impressions of the physical evidence must be excluded as not based on any reliable methodology or scientific principle.

Id. at 1053; see id. at 1054 (“testimony . . . that [] speculates as to [defendant’s] motive, intent or state of mind, or speculates as to motives of the FDA or what other drug companies would do is excluded”); 1058 (ethics opinion concerning “preclinical and clinical testing not only lacks foundation, but is also speculative and will not assist the fact-finder”); 1067 (ethics opinion “is legal argument that does not qualify as expert testimony”); 1069 (“an expert may not testify as to ethical issues or to his personal views”).

Corporate ethics testimony also bit the dust in In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation, 2010 WL 1727828 (M.D. Ga. Apr. 27, 2010). An author of a

general business ethics textbook was found unqualified to testify about what it was “appropriate” for a medical device company to do:

[The witness] has no expertise in the fields that would qualify a witness to testify about what scientific information should be reported to the FDA or to testify about medical device industry standards for warning physicians and patients about potential adverse effects of a medical device. Therefore, she is not qualified to offer an opinion about the appropriateness of [defendant’s] conduct.

Id. at *4. The “code of ethics” that the witness purported to interpret was such that “anyone who reads and understands the English language can interpret and apply [its] principles.” Id. at *4 n.3.

Corporate ethics testimony was excluded as unscientific and unduly prejudicial in Wolfe v. McNeil-PPC, Inc., 2011 WL 1673805 (E.D. Pa. May 4, 2011):

Simply because [the witness’] subjective views of ethics are informed by well-known principles does not convert them into objective, reliable, scientific knowledge. . . . Whatever benefit could be derived from his opinions about [defendant’s] social responsibility and ethical obligations is vastly outweighed by the tendency of such testimony to encourage the jury to impose liability on an improper basis.

Id. at *8-9.

In In re Prempro Products Liability Litigation, 554 F. Supp. 2d 871 (E.D. Ark. 2008), aff’d in pertinent part, rev’d in part on other grounds, 586 F.3d 547, 571 (8th Cir. 2009), a purported expert ran amok at trial. Among other things, the witness’ “editorial about pharmaceutical companies putting sales and marketing before science” should have been excluded. Id. at 881. Similarly, in Lopez v. I-Flow Inc., C.A. No. 08-1063, slip op. at 19-20, 2011 WL _____ (we’ve sent this to Westlaw; there will be a cite in a few days) (D. Ariz. Jan. 26, 2011), the court rejected intent testimony for lack of personal knowledge, helpfulness to the jury, and as outweighed by prejudice, confusion, etc. See also In re Heparin Product Liability Litigation, 2011 WL 1059660, at *7 (N.D. Ohio March 21, 2011) (witness must “not express any views as to Defendants’ intent, motives, or state of mind”); In re Gadolinium-Based Contrast Agents Products Liability Litigation, 2010 WL 1796334, at *13 (N.D. Ohio May 4, 2010) (“[n]or may [the witness testify as to [defendant’s] knowledge, motivations, intent or purposes”); Lofton v. McNeil Consumer & Specialty Pharmaceuticals, 2008 WL 4878066, at *6-7 (N.D. Tex. July 25, 2008) (opinions “regarding Defendants’ ethical obligations, motive, state of mind, asserted

knowledge, and alleged conduct” excluded as “personal opinions or legal conclusions based on Defendants’ alleged behavior”); In re Guidant Corp. Implantable Defibrillators Products Liability Litigation, 2007 WL 1964337, at *8 (D. Minn. June 29, 2007) (witness “not allowed to testify as to [defendant’s] knowledge” or “whether Guidant’s conduct was ethical”); Bessemer v. Novartis Pharmaceuticals Corp., 2010 WL 2300222 (N.J. Super. L.D. April 30, 2010) (“state of mind, intent, motive, or ethics” “are not the proper subject of expert opinion testimony” and would be “speculative”).

Rezulin also demonstrates that there are really two types of evidence at issue in most of these sorts of cases. Not only is there the kind of thing that first attracted our attention – that is, the giving of outright opinions about whether a defendant acted properly – but there’s also the broader issue of bringing in an expert to review documents s/he had nothing to do with preparing and/or knows nothing about and then, in effect, giving the lawyer’s closing argument from the witness stand, in some sort of narrative casting the defendant in the worst possible light. So there’s really a distinction between “ethics” evidence and “conduct” evidence. Rezulin excluded this sort of “narrative” evidence as well:

[The] “history of Rezulin” is merely a narrative of the case which a juror is equally capable of constructing. . . . Such material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence. . . . [T]he glosses that [the witness] interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs’ theory of the case. As plaintiffs’ Rezulin “historian,” therefore, [the witness] does no more than counsel for plaintiff will do in argument, *i.e.*, propound a particular interpretation of defendant’s conduct. Accordingly, [the witness’] testimony relating to the “history of Rezulin” is inadmissible.

309 F. Supp.2d at 551 (various citations omitted).

So one thing that will be happening is the division of the one existing paragraph in the book into two, one involving corporate ethics/intent directly and the other the sort of “narrative” held inadmissible in Rezulin.

Other cases (mostly the same cases, actually) similarly exclude narrative-type evidence in drug/device cases. For instance, in Prempro the court reversed its own rulings at trial and held:

If an expert does nothing more than read exhibits, is there really any point in her testifying as an expert? . . . [T]he use of the “regulatory expert” to deal with large volumes of documents is subject to abuse. The expert did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony. [The witness] did not provide analysis, opinion, or expertise.

554 F. Supp.2d at 886. See Heparin, 2011 WL 1059660, at *8 (witness “may not give a narrative history . . . which must be presented through direct evidence”); Deutsch, 2011 WL 790702, at *45 (excluding a “a factual narrative of events” because it lacked “analysis, opinion, or expertise” and because it included “personal opinions, speculation, and state of mind inferences throughout”); Lopez, [slip op.](#) at 18-19 (excluding “report [that] simply presents a narrative of selected regulatory and corporate events and quotations”); Gadolinium, 2010 WL 1796334, at *13 (witness “may not provide a narrative history of [the product], which must be presented through direct evidence”); Trasylo, 709 F. Supp.2d at 1346-47 (excluding “pure factual narrative regarding [the drug’s] regulatory history”); Trasylo, 2010 WL 4259332, at *8 (a “narrative . . . is lay matter that is not a permissible subject of expert testimony”); In re Viagra Products Liability Litigation, 658 F. Supp.2d 950, 967 (D. Minn. 2009) (“there is no evidence that the jury could not be presented with these same documents and draw from them the relevant regulatory history”); Fosamax, 645 F. Supp.2d at 192 (“[a]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence”); Prempro, 554 F. Supp. 2d at 880 (testimony that “simply read and summarized the documents, as any layperson could have done” should have been stricken); 887 (“an expert witness simply summariz[ing] a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony”).

Whew!

Yup, we’d have to say that this part of [Bexis’ book](#) requires updating. It will be, but blog readers just got a sneak preview.