BNA, INC.

TOXICS LAW REPORTER

BNA Employee-Owned Since 1947

EXPERT ADMISSIBILITY

PRODUCT LIABILITY

Plaintiffs in product liability cases often seek admission of expert testimony as to the defendant company's ''bad conduct'' in support of negligence and punitive damages claims. Courts, however, often exclude such testimony on grounds of lack of qualifications, failure to meet *Daubert* reliability and relevance requirements, and failure to satisfy other evidentiary rules, say attorneys Frank Leone and Mark A. Miller in this BNA Insight. The authors set forth the bases for seeking exclusion of corporate conduct expert opinions, and discuss specific challenges to narrative, state of mind, regulatory, and failure to warn testimony.

A Defense Perspective on Excluding Corporate Conduct Experts in Product Liability Litigation

BY FRANK LEONE AND MARK A. MILLER

In pharmaceutical and other products liability cases, plaintiffs often attempt to present ''bad company'' expert testimony about a defendant's corporate conduct. These experts seek to opine that the defendant company endangered public safety by misrepresenting or not disclosing information; it misled or otherwise ''bamboozled'' regulatory agencies; it did not perform scientific studies; and/or if it did studies, it hid, or mischaracterized, their results. These experts also purport to testify that the defendant acted with malice or evil intent, violated regulations (or the spirit thereof), and that regulatory agencies, prescribing physicians, and/or the public would have acted differently if the defendant, in short, had been honest. For example, such experts have tried to offer opinions that a defendant company was ''driven by its desire to increase profits,''[1] it ''decided to focus on the incomplete and inaccurate approval data and to minimize the troubling post-approval data,''[2] it ''failed to provide the [] studies'' to the government,[3] or it ''violated [government] regulations in its develop-

[1] *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *2 (E.D. Pa. June 20, 2000).

[2] *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 545 n.38 (S.D.N.Y. 2004).

 ISSN 0887-7394

ment and marketing of [its product], and thus was not a reasonable . . . manufacturer.''[4]

Typically, these experts reach their opinions after a limited review of internal corporate documents and fact testimony that plaintiffs' counsel have selected, and their opinions often are based only on vague and personal notions of appropriate corporate ethical behavior. Plaintiffs rely on these opinions to support their claims that the defendant acted negligently and, furthermore, its actions were reckless, malicious, or intentional, and a jury, therefore, should award punitive damages. Defendants may seek to exclude such corporate conduct expert testimony on a motion under *Daubert*, its state counterparts, and evidentiary rules, which require that experts be qualified and that their opinions be reliable, relevant, the product of specialized knowledge, based on sufficient facts and data, helpful to the trier of fact, proper subjects of expert opinion, and not unfairly prejudicial.

I. Grounds for Challenging Plaintiffs' Expert Corporate Conduct Testimony

Because jurors give great weight to expert testimony, courts need to act as gatekeepers to separate legitimate scientific inquiry from subjective speculation.[5] Specifically, to be admissible, expert testimony must comply with Federal Rule of Evidence 702 (or its state counterparts) and the standards of *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993), which require that the expert's methodology must be reliable (*e.g.*, it can be tested) and relevant to the issues at hand.[6] Federal Rule of Evidence 702 gives the party challenging corporate conduct expert testimony most of the tools it needs:

> If scientific, technical, or other *specialized knowledge* will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness *qualified as an expert* by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon *sufficient facts or data*, (2) the testimony is the *product of reliable principles and methods*, and (3) the witness has *applied* the principles and methods *reliably to the facts of the case*. Fed. R. Evid 702 (emphasis added).

As set forth below, courts have often held that corporate conduct witnesses fail to meet one or more of Rule 702's requirements, and have excluded their expert testimony.

A. Experts Typically Lack Qualifications To Testify about Acceptable Corporate Conduct

In general, Federal Rule of Evidence 702's requirement that an expert witness be qualified ''by knowledge, skill, experience, training, or education'' does not pose a high threshold to admissibility, but plaintiffs' corporate conduct experts may still not cross that threshold.[7] Although the witnesses may be qualified to discuss various subjects (*e.g.*, regulations, medicine, toxicology, or other scientific disciplines), rarely do they have the qualifications to opine as to the nature or appropriateness of a defendant's corporate conduct.[8]

Courts have excluded corporate conduct-related expert testimony based on the expert's admission that he lacks any real world experience with the product or industry practice at issue. An expert may never have worked for a company in the relevant industry,[9] or studied, published about, designed, developed, manufactured, marketed, or prepared warnings for the prod-

[3] *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1330 n.5 (S.D. Fla. 2010).

[4] *Id.* at 1332.

[5] *See generally Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993); *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

[6] Several states do not apply *Daubert* in reviewing expert testimony and some states that employ the *Frye* standard, for example, limit challenges to general acceptance of novel scientific opinions. *See, e.g.*, *Grady v. Frito-Lay, Inc.*, 839 A.2d 1038, 1044 (Pa. 2003) (''the *Frye* rule will continue to be applied in Pennsylvania''). Subjective corporate conduct opinions likely do not qualify as ''scientific'' and, thus, are not subject to a *Frye* exclusion. *See, e.g.*, *Revis v. State*, No. CR-06-0454, 2011 WL 109641, at *32 (Ala. Crim. App. Jan. 13, 2011) (''this Court specifically noted . . . that Rule 702 alone, and not . . . *Frye* . . . governed the admissibility of nonscientific expert testimony''); *People v. Gordon*, 881 N.E.2d 563, 570 (Ill. App. Ct. 2007) (discussing cases that ''deemed HGN test results to be nonscientific evidence that did not need to satisfy the *Frye* standard'' (internal quotations and citations omitted)). Corporate conduct opinions may nevertheless be challenged under state Rule 702 analogues.

[7] *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (''In keeping with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to ''opinion'' testimony,' . . . the standard for qualifying expert witnesses is liberal.'' (quoting *Daubert*, 509 U.S. at 588-89)).

[8] A party may not qualify an expert as to a specific issue by showing that the expert has specialized knowledge or training that would permit him to opine on some other issue. *See, e.g.*, *In re Rezulin*, 309 F. Supp. 2d at 546 n.40 (plaintiffs' expert ''acknowledged that he was not an expert in corporate intent, just someone who is 'able to draw inferences' ''); *id.* at 549 (plaintiffs' experts with backgrounds in various medical disciplines ''are not qualified to render opinions describing or interpreting FDA regulations, or commenting on [the defendant's] adherence to those regulations''); *In re Diet Drugs*, 2000 WL 876900, at *9 (expert who was a pharmacoepidemiologist and pharmacoeconomist was not qualified to opine on corporate conduct issues). A witness's admission of his lack of expertise in the relevant areas is helpful in obtaining his exclusion. *See, e.g.*, *Rasmussen v. City of New York*, No. 10 Civ. 1088(BMC), 2011 WL 744522, at *3 (E.D.N.Y. Feb. 23, 2011) (the courts ''will not qualify a witness as an expert in an area if that witness does not even consider himself to be an expert'').

[9] *See, e.g.*, *In re Heparin Prod. Liab. Litig.*, MDL No. 1953, 2011 WL 1059660, at *10 (N.D. Ohio Mar. 21, 2011) (excluding plaintiff's expert on pharmaceutical manufacturing procedures and corporate compliance with FDA regulations as unqualified because, *inter alia*, ''[h]e has never been hired by a pharmaceutical company and has no first-hand experience with the pharmaceutical industry''). *Cf. In re Prempro Prods. Liab. Litig.*, No. 4:03CV1507-WRW, 2006 WL 5217764, at *5 (E.D. Ark. Sept. 13, 2006) (finding expert witness qualified to testify regarding whether defendant pharmaceutical company met the standard of care for drug promotion where the witness was a practicing physician in internal medicine, held a Masters in Public Health, taught at a university, and ''conducted independent social science research and written evidence-based reviews and editorials'' on pharmaceutical marketing, and thus ''has a knowledge of pharmaceutical marketing that is beyond a juror's common understanding'').

  TXLR ISSN 0887-7394

uct at issue or a similar product.[10] For example, in *In re Diet Drugs Products Liability Litigation*, MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000), plaintiffs offered two experts (one a pharmacoepidemiologist and pharmacoeconomist, and the other an expert on primary pulmonary hypertension and its alleged relationship to diet drugs) to testify about the defendant company's product labeling decisions.[11] Although the court acknowledged that the plaintiffs' experts were well-qualified in their respective fields, it nevertheless found them unqualified to discuss corporate decision-making.[12] The court observed that the experts' respective disciplines ''do not include knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion.''[13]

Products liability cases often involve regulatory compliance issues, but courts have found experts to be unqualified to testify about such issues if they have never worked for the relevant regulatory authority or, if they have had regulatory experience, it is not with the specific type of product at issue.[14] Thus, courts have excluded testimony from doctors who lacked expertise in U.S. Food and Drug Administration (''FDA'') regulations, and, therefore, could not opine that a defendant withheld information from FDA.[15] Courts also have found that experts lacked expertise on product labeling, and, thus, could not offer testimony that a company should have included additional warnings on its product label.[16]

Even if a court admits testimony as to regulatory requirements and the defendant's compliance therewith, the court may find an expert is not qualified to discuss ethical or industry standards.[17] In one recent case, a plaintiff sought to avoid a qualifications challenge by offering a bona fide business ethics expert.[18] The university business ethics professor intended to testify that a medical device manufacturer failed in its ethical duty to protect patients and disclose information to the public and FDA. In so doing, the expert relied on the ''Consumer Bill of Rights'' (taken from a 1962 speech by President John F. Kennedy) and a trade association standard. The court excluded the testimony, finding that the witness was not qualified in medical ethics, FDA, or medical industry standards, and lacked any special expertise regarding the industry code of ethics.[19]

B. Experts Often Lack Personal or Specialized Knowledge About Defendant's Corporate Conduct

Even if a witness is found to be qualified, courts may exclude plaintiffs' corporate conduct experts because they lack personal knowledge of the facts underlying their opinions. For example, in *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, the plaintiffs' FDA regulatory consultant opined as to whether the FDA ''approved'' the use of a certain poly-

[10] *See, e.g.*, *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998) (unpublished table decision) (pharmacist/toxicologist was unqualified to testify as to adequacy of drug warning where he had ''never been involved with the drafting, regulation, or approval of product labeling for any prescription medication'' and that ''experience as a pharmacist, reading prescription labels and dispensing drugs, [did] not qualify him to testify about the adequacy of drug warnings''); *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir. 1997) (metallurgic expert could testify about properties and characteristics of metal safe, but was not qualified to testify about industry standards for design of safes because ''[h]e had never before analyzed a safe, engaged in the manufacture or design of safes, or received any training regarding safes,'' and, ''[e]ven more importantly, he was not personally familiar with the standards . . . used in the safe industry''); *see also Moore v. P & G-Clairol, Inc.*, No. 09 C 1723, 2011 WL 1002958, at *7 (N.D. Ill. Mar. 18, 2011) (excluding plaintiffs' expert on warning labels because, although expert had ''laboratory experience'' the expert had ''no background or training in psychology or any field related to the design of warnings to consumers . . . and no experience in how a consumer interprets a warning or self-test instructions''); *Danaher v. Wild Oats Markets, Inc.*, No. 08-cv-2293-DJW, 2011 WL 768106, at *5 (D. Kan. Feb. 28, 2011) (excluding plaintiffs' expert in ''ear candle'' product liability case as unqualified because the expert had no training or experience in the design, manufacture, or construction of the candles, had never performed any tests on the candles, had never seen the particular candle burn, and had little knowledge of the components of the specific candle). *But see DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 719 (7th Cir. 1998) (''a judge does not automatically abuse his discretion in concluding that an expert can offer useful information without having dealt previously with the product at issue in the case'').

[11] *Id.* at *1-4.

[12] *Id.* at *9.

[13] *Id.*

[14] *See, e.g.*, *Hayes ex rel. Hayes v. MTD Prods., Inc.*, 518 F. Supp. 2d 898, 901 (W.D. Ky. 2007) (excluding opinion of former Commissioner of Consumer Product Safety Commission because generic regulatory expertise is not expertise on the product at issue, i.e., lawn mowers); *In re Diet Drugs*, 2000 WL 876900, at *11 (excluding corporate conduct experts who had never worked for the FDA because although ''fully qualified within their specialties, that does not qualify them to speak as experts in the field of the requirements of the federal regulations regarding labeling and warnings for FDA approved drugs''). *But see, In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 190 (S.D.N.Y. 2009) (''Dr. Parisian's time at the FDA, though primarily spent on medical devices, included sufficient experience with various aspects of the regulation of pharmaceutical drugs.'').

[15] *See, e.g.*, *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489725, at *8 (S.D. Fla. Mar. 29, 2010); *In re Diet Drugs*, 2000 WL 876900, at *11.

[16] *In re Trasylol*, 2010 WL 1489725, at *7; *see also, e.g.*, *Wehling*, 162 F.3d at 1158; *Moore*, 2011 WL 1002958, at *7.

[17] *See, e.g.*, *Deutsch v. Novartis Pharms. Corp.*, No. 09-CV-4677 (ADS)(WDW), 2011 WL 790702, at *46 (E.D.N.Y. Mar. 8, 2011) (''Dr. Parisian is not qualified to opine on the ethical standards in the pharmaceutical industry, nor is she qualified to testify as to any obligations [the defendant] may have had to the medical community in addition to the FDA requirements.''); *see also Hogan v. Novartis Pharms. Corp.*, 06 Civ. 0260 (BMC) (RER), 2011 WL 1533467 at *3 (E.D.N.Y. Apr. 24, 2011), (excluding plaintiff's corporate conduct expert, who never worked for a pharmaceutical company and was employed at FDA medical device division, as 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'').

[18] *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004 (CDL), 2010 WL 1727828, at *3-4 (M.D. Ga. Apr. 27, 2010).

[19] *Id.*

mer in the defendant's medical device.[20] The court excluded the testimony as failing to meet Federal Rule of Evidence 104 foundation requirements because the expert ''lacks personal knowledge'' on what the ''FDA did and did not approve . . . . The proper person that could testify as to what the FDA did and did not approve as to the use of polyimide in the header of the Prizm 2 based on Guidant's submissions to the FDA would be the person responsible for approving the Prizm 2 for distribution in 2000.''[21]

Similarly, in *In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, the plaintiffs' experts sought to opine about FDA standards and that the defendant failed adequately to disclose material facts about the drug to the FDA.[22] The court excluded the testimony because the experts lacked any experience with FDA regulations, and ''are unqualified also to testify about the *facts* of [the defendant's] disclosures to the FDA because they lack first-hand knowledge.''[23]

An expert witness need not have personal knowledge of a subject, of course, but Federal Rule of Evidence 702 requires ''specialized knowledge,'' which ''connotes more than subjective belief or unsupported speculation.''[24] Corporate conduct experts who provide testimony based on personal opinions or speculation fail to meet the specialized knowledge requirement. In *In re Trasylol Products Liability Litigation*, No. 08-MD-01928, 2010 WL 1489793 (S.D. Fla. Feb. 24, 2010), for example, the plaintiff's corporate conduct expert opined that the pharmaceutical company defendant breached ''ethical standards'' by failing to respond to ''safety signals'' involving the drug at issue.[25] The expert conceded that he lacked objective criteria (no ''guideline written on stone tablets'') and he relied on ''you know, common sense.''[26] The court excluded the testimony, finding that the expert's opinions were founded on the expert's ''own subjective beliefs and personal views and do[] not rest on knowledge as required by Rule 702.''[27]

C. Corporate Conduct Expert Opinions Are Not Helpful to the Trier of Fact

Whether or not a state has adopted *Daubert*, corporate conduct testimony may be excluded on the ground that it is not helpful to the trier of fact under Rule 702 and state analogues. For example, in *In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, the court excluded a clinical trials expert's opinions on industry ethics, finding that ''the witnesses' opinions regarding ethical standards for reporting or analyzing clinical trial data or conducting clinical trials articulate nothing save for the principle that research sponsors should be honest. Even if charitably viewed as a 'standard,' the testimony nevertheless is 'so vague as to be unhelpful to a fact-finder.' ''[28]

Moreover, as noted above, corporate conduct experts often base their opinions on little more than their review of counsel-selected internal company documents. Courts have consistently excluded expert witness commentary on internal corporate documents that is not based on any scientific, technical, or other specialized knowledge that can assist the jury. In *In re Prempro Products Liability Litigation*, 554 F. Supp. 2d 871 (E.D. Ark. 2008), for example, plaintiffs argued that their regulatory expert's ''testimony and use of internal company document[s] [would] educate the jury, not merely duplicate counsel's closing argument.''[29] The court, after first admitting the expert's testimony, subsequently struck much of it, finding that the witness ''generally, did *not* give the jury the tools they need to look at those documents, [to] understand them in the context of a regulatory background—she simply read the documents to the jury.''[30] The court further observed: ''If an expert does nothing more than read exhibits, is there really any point in her testifying as an expert? . . . The expert did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony. [The expert] did not provide analysis, opinion, or expertise.''[31] Indeed, the court concluded, the jury

[20] No. MDL 05-1708 (DWF/AJB), 2007 WL 1964337, at *7 (D. Minn. June 29, 2007).

[21] *Id.*

[22] *Id.* at 547.

[23] *Id.* at 549; *see also In re Trasylol*, 2010 WL 1489725, at *8 (excluding expert's testimony re company's alleged failure to disclose information to FDA under Fed. R. Evid. 702 because plaintiff had not shown that expert had reviewed company's submissions and his testimony therefore was ''purely speculative'').

[24] *Daubert*, 509 U.S. at 590; *see also In re Rezulin*, 309 F. Supp. 2d at 543.

[25] *Id.* at *7.

[26] *Id.* at *9.

[27] *Id.* at *8; *see also In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007) (''Personal views on corporate ethics and morality are not expert opinions''); *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2001 WL 454586, at *10 (E.D. Pa. Feb. 1, 2001) (purported expert testimony about ethics is inadmissible because it is ''inherently susceptible to subjective personal influence and lacking indicia of reliability'').

[28] *Id.* at 543 (citation omitted). The *Rezulin* court further stated that it would not permit the clinical trials expert to testify about ''the principle of non-maleficence'' (no one should cause harm to others) any more than it would ''permit a priest to testify about the Sixth Commandment under the guise of giving evidence of pharmaceutical industry standards.'' *Id.* at 543, 558 & n.102; *see also In re Fosamax*, 645 F. Supp. 2d at 194 (same expert's testimony that ''[t]rust and honesty are essential virtues that permeate all aspects of human life, including the drug approval process,'' are too vague to be helpful to the trier of fact); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, MDL 1535, 2005 WL 1868046, at *20-*21 (N.D. Ohio Aug. 8, 2005) (business ethics professor's testimony about ethical standards ''in excess of what the law requires'' excluded as unhelpful to the jury); *Concord Boat Corp. v. Brunswick Corp.*, No. LR-C-95-781, 1998 WL 35254137, at *2 (E.D. Ark. Mar. 2, 1998) (business ethics expert's opinions ''essentially deal with the ethical nature of the conduct and about whether it was right or wrong. The jury, by application of common sense and drawing on its own collective experience, can resolve those issues without the assistance of expert testimony.''); *Paley v. Fed. Home Loan, Mortg. Corp.*, No. Civ. A. 93-5801, 1994 WL 327659, at *4 (E.D. Pa. July 7, 1994) (disallowing testimony of putative experts about business ethics because the subject was ''well within the knowledge, experience, and understanding of the ordinary jury'').

[29] *Id.* at 886 (internal quotations omitted; second alteration in original); *see also id.* at 880 (''The testimony was simply a regurgitation of an exhibit, absent any expert analysis or opinion.'').

[30] *Id.* (internal quotations omitted; alteration in original). The 8th Circuit upheld the trial court's ruling striking the corporate conduct witness's testimony. *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009).

[31] *In re Prempro*, 554 F. Supp. 2d at 886; *see also In re Rezulin*, 309 F. Supp. 2d at 551 (excluding an expert's ''glosses''

  TXLR ISSN 0887-7394

could hear the evidence and draw its own conclusions about the defendant's conduct without the need for ''expert'' testimony.[32]

D. Corporate Conduct Experts Use Methodologies That Are Not Reliable

The primary methodological flaw found in many plaintiffs' corporate conduct opinions is that the experts have not applied any objective standards to reach their conclusions. Under a *Daubert* analysis, a reliable methodology requires the application of objective (*i.e.*, testable) standards. Absent an objective frame upon which to build opinions, the expert's testimony is ''inherently susceptible to personal influence and lacking indicia of reliability.''[33] In fact, courts have recognized that '' 'bad company' opinions that are not based on any FDA regulation or other applicable standard are . . . inadmissible.''[34]

In *In re Prempro Products Liability Litigation*, No. 4:03CV01507-WRW, 2010 WL 5663003 (E.D. Ark. Sept. 16, 2010), plaintiff put forth corporate conduct experts to testify that defendants violated various standards of care, including an alleged FDA ''standard of reasonable care'' and the Pharmaceutical Manufacturer's Association Code.[35] In excluding the experts, the court stated, ''Plaintiff's counsel admitted the standard could be different in every circumstance—and therein lies the rub—there is no set standard.''[36] The court added that the ''witnesses' proposed expert testimony is not expert in nature because Plaintiff is unable to point to the existence of a reasonable standard of care or a custom and practice established by either industry or governmental standards . . . . [Plaintiff's experts] cannot be qualified as experts simply to testify what they believe Defendants could have done versus what they should have done.''[37] The court concluded by holding that, ''[b]ecause Plaintiff cannot show some objective validation, [the plaintiff's experts] should not be permitted to testify as experts.''[38]

E. Corporate Conduct Testimony Constitutes Irrelevant Personal Opinions

Moreover, to be admissible under *Daubert*, expert opinion must be relevant as well as reliable (*i.e.*, it must ''fit'' with the facts of the case).[39] When experts fail to offer testimony based upon objective standards, and instead provide personal opinions, the testimony should be excluded as irrelevant.

First, personal and subjective ethical views are irrelevant because they do not make any facts at issue more or less likely. For example, in *In re Rezulin Products Liability Litigation*, 309 F. Supp 2d 531, the court found that the experts' corporate ethics testimony ''based on their personal, subjective views'' was irrelevant (as well as unreliable) because, ''[w]hile the defendants may be liable in the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits.''[40]

Second, courts view corporate conduct testimony as lacking fit because it is not derived from an objective methodology.[41] Expert testimony based upon ''common sense'' or the expert's ''personal opinion'' on corporate ethics and ''without any scientific or regulatory support'' only ''invites the jury to leap to the same conclusions as he'' without grounding such conclusions in the scientific method.[42] Thus speculative testimony, including speculation about motives and intent, is irrelevant.[43]

Third, courts have held that where plaintiffs do not assert regulatory violations, expert testimony about regulatory standards is inadmissible as irrelevant. In *Hogan v. Novartis Pharms. Corp.*, for example, the court in a pharmaceutical product liability case excluded plaintiff's expert who proposed to testify on the role of the FDA and the defendant's interactions with the FDA as irrelevant because ''Plaintiff has not asserted a federal claim for violating FDA regulations and fails to mention them anywhere in her pleading. . . . 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.''[44]

---

on a pharmaceutical manufacturer's internal corporate documents because they represented the expert's ''simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case'' and do ''no more than counsel for plaintiff will do in argument, *i.e.*, propound a particular interpretation of [defendant]'s conduct'').

[32] *See, e.g.*, *In re Prempro*, 554 F. Supp. 2d at 886 (''I did not anticipate that documents would be admitted via [expert] so that she could simply engage in recitation of those exhibits; jurors are capable of reading documents.'').

[33] *In re Diet Drugs*, 2001 WL 454586, at *10.

[34] *Deutsch*, 2011 WL 790702, at *45; *see also In re Trasylol*, 709 F. Supp. 2d at 1338 (excluding expert opinions that ''are personal 'bad company' opinions not based on any FDA regulation or other applicable standard'').

[35] *Id.* at *2.

[36] *Id.* at *3.

[37] *Id.* at *2-3.

[38] *Id.* at *3.

[39] *See Daubert*, 509 U.S. at 591 (''Rule 702 further requires that the evidence or testimony assist the trier of fact to understand the evidence or to determine a fact in issue. This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.'' (Internal quotations and citations omitted)).

[40] *Id.* at 543-44; *see also Halcomb v. Wash. Metro. Area Transit Auth.*, 526 F. Supp. 2d 24, 29 (D.D.C. 2007) (''The Court concludes that much of [expert's] report . . . impermissibly relies on personal opinions rather than general standards'' and is ''irrelevant.''); *In re Prempro Prods. Liab. Litig.*, No. 4:03CV1507-WRW, 2007 WL 5521248, at *3 (E.D. Ark. Nov. 9, 2007) (granting defendant's motion to exclude testimony of economics expert in a product liability case where the expert ''simply offers a factual summary of sales information and personal opinion, both of which are irrelevant and of no help to the jury'').

[41] *See, e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 155 (1997) (Stevens, J., concurring in part and dissenting in part) (''[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district judge to reject an expert's conclusions and keep them from the jury when they fit the facts of the case and are based on reliable scientific methodology.'').

[42] *Alderman v. Clean Earth*, No. 04C-06-181-FSS, 2007 WL 1334565, at *7 (Del. Super. Ct. Apr. 30, 2007), *aff'd*, 954 A.2d 909 (Del. 2008).

[43] *See, e.g.*, *In re Guidant Corp.*, 2007 WL 1964337, at *8 (excluding expert testimony about the defendant's knowledge as irrelevant).

[44] 2011 WL 1533467, at *2; *see also id.* at *4 (''even if the FDA's role in this litigation were properly described, it would be a side show; if the Court allowed [expert] to testify, the side show would turn into the main event'').

Finally, in, e.g., strict products liability cases (where punitive damages are not at issue), ''corporate ethics'' opinions may be viewed as irrelevant because the claims focus on the product, not the defendant's conduct in relation to the product.[45]

F. Corporate Conduct Expert Opinions Rarely Are Based on Adequate Facts and Data

Admissible expert testimony must be ''based upon sufficient facts or data.''[46] Courts have found that corporate conduct experts may fail to meet this requirement because of their reliance on selected documents that do not provide a full and accurate representation of the facts. To illustrate, in *In re Baycol Products Litigation*, 532 F. Supp. 2d 1029, the court excluded a plaintiff's expert who opined that the defendant acted unethically by, *inter alia*, not conducting studies or submitting appropriate data to the FDA, but who ''admitted at his deposition that he did not review the information provided to the FDA by [the defendant] prior to its approval, and that he did not review the FDA medical officer's review of Baycol after its new drug application was approved.''[47] The court held that: ''Without knowing definitively what preclinical or clinical studies were conducted, [the expert] was not in the position to offer the opinion that [the defendant] did not conduct or publish certain studies. His opinion in this regard thus lacks foundation.''[48]

G. Corporate Conduct Opinions Are Typically Litigation-Driven Advocacy

An additional methodological flaw in much of the plaintiffs' experts' corporate-conduct testimony is that the testimony is litigation-driven. That is, the expert has created the ''research'' and testimony solely for the purpose of advancing the plaintiff's case in court.[49] An expert, whether basing testimony upon professional studies or personal experience, must employ in the courtroom ''the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.''[50] In contrast, where the ''[plaintiff's expert] was not in fact an expert . . . when he was hired by the plaintiffs, but that he subsequently attempted, with dubious success, to qualify himself as such by a selective review of the relevant literature,'' the opinions are litigation-driven and inadmissible.[51] Indeed, courts have rejected opinions based on ''spoon-fed'' information from plaintiffs' counsel because they are ''simply too unreliable to be trusted.''[52]

Some experts go beyond litigation-driven opinions and become the plaintiff's advocate. *Daubert* recognizes that, when an expert becomes an advocate, he no longer offers reliable opinions.[53] For example, in excluding a corporate conduct witness, a court stated that ''[n]ormally bias is a matter for the jury. Here, however, it appears that [expert] is so biased it affects his objectivity and his ability to give an honest opinion.''[54] Another court determined that the same expert ''set aside the mantle of the scientist and replaced it with that of the zealot.''[55]

In *In re Trasylol Products Liability Litigation*, 709 F. Supp. 2d 1323, plaintiffs proffered an expert to testify about regulatory matters relating to the defendant's pharmaceutical product.[56] At a *Daubert* hearing, the court stated that, ''when efforts were made to establish the foundation of her opinions, [expert] retreated into obfuscation and referenced irrelevant FDA regulations while refusing to answer questions.''[57] The bulk of the expert's testimony, the court determined, ''did not involve any regulatory analysis and instead consisted of conclusions made from a review of the regulatory history and [defendant's] internal documents. . . . An instance [the court] found particularly egregious was [the expert's] apparent effort to construct a factual scenario, entirely divorced from any regulatory expertise, to support the Plaintiffs' theory as to [the defendant's] knowledge.''[58] Thus the court concluded that: ''[The expert] is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the

---

[45] *See, e.g., Rivera-Adams v. Wyeth*, No. 03-1713 (JAF), 2011 WL 346556, at *6 n.7 (D.P.R. Feb. 4, 2011) (''[plaintiff's expert's] failure to identify [an actual industry standard of care] proved immaterial, because the Plaintiff's strict-liability, failure-to-warn claim only required proof that the Defendant 'knew, or should have known of the risk inherent in the product.' '' (citation omitted)); *In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, MDL No. 1721, 2009 WL 1357234, at *3 (D. Kan. May 12, 2009) (expert opinions that defendant ''failed to act as a conscientious corporation, maintained a defective corporate culture, violated fundamental principles of ethics and compromised basic moral rights . . . would not assist the jury; they are not directly relevant to plaintiffs' product liability claims and they may tend to mislead or confuse the jury. Indeed, plaintiffs concede that [expert] opines not on the [product], but on the corporate conduct behind it.'' (internal quotations omitted)).

[46] Fed. R. Evid. 702.

[47] *Id.* at 1057-58.

[48] *Id.* at 1058; *see also In re Rezulin*, 309 F. Supp. 2d at 549 (''Plaintiffs experts are unqualified also to testify about the *facts* of Warner-Lambert's disclosures to the FDA because they lack first hand knowledge.'').

[49] *See, e.g., Lust ex rel. Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 597 (9th Cir. 1996) (expert was ''already a professional plaintiff's witness'' and it was ''not unreasonable to presume'' that his opinions were ''influenced by a litigation-driven financial incentive''); *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (''*Daubert II*'') (tailored-for-litigation opinions are not reliable); *Cottengim v. Mentor Corp.*, No. 05-161-DLB, 2007 WL 4553995, at *3 (E.D. Ky. Sept. 24, 2007) (excluding an expert's product defect opinions because they were ''developed with an eye toward litigation, if not solely for that end''). *But see Daubert II*, 43 F.3d at 1318 (that an expert's opinion may be obtained for purposes of litigation does not render it unreliable if otherwise supported by ''objective, verifiable evidence that the testimony is based on 'scientifically valid principles.' '')

[50] *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

[51] *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001) (quoting *Mancuso v. Consol. Edison Co.*, 967 F. Supp. 1437, 1443 (S.D.N.Y. 1997)).

[52] *See, e.g., Crowley v. Chait*, 322 F. Supp. 2d 530, 546-47 (D.N.J. 2004).

[53] *In re Rezulin*, 309 F. Supp. 2d at 538 (*Daubert* precludes ''engagement of 'expert' witnesses whose intended role is more to argue the client's cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit.'').

[54] *Johnson v. Baxter Healthcare Corp.*, No. CV-92-07501 (N.M. 2d Jud. Dist. Feb. 23, 1988).

[55] *Wilson v. Guichon*, [1990] B.C.W.L.D. 2056, para. 68 (Can. B.C.S.C.).

[56] *Id.* at 1329.

[57] *Id.* at 1339.

[58] *Id.* at 1342.

  TXLR ISSN 0887-7394

opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her 'takeaway' or 'take home message' with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise. Her testimony is unreliable and would not be of assistance to the jury.''[59] As a result, the court excluded the expert's testimony stating, among other things, that her ''major role in this litigation appears to be that of Plaintiffs' advocate rather than expert.''[60]

H. Corporate Conduct Opinions May Constitute Improper Legal Conclusions

Corporate conduct experts may purport to state ''ultimate opinions'' in a case (*e.g.*, the defendant was ''negligent''), and such testimony may constitute an improper legal conclusion.[61] The rationale for excluding ultimate opinion testimony is that such testimony will likely confuse the jury and usurp its role.[62] For example, courts have held that the question of whether defendants acted in ''good faith'' is an impermissible legal conclusion.[63]

As a general rule, however, expert testimony is not automatically improper if it ''embraces an ultimate issue to be decided by the trier of fact.''[64] Most courts will exclude testimony as improper if the expert is attempting ''to tell the jury what result to reach,''[65] if the testimony ''usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it,''[66] or if the testimony communicates ''a legal standard—explicit or implicit—to the jury.''[67] Moreover, courts will exclude experts who purport to testify as ''superlawyers''—''scientifically informed advocates of conclusions . . . which belong only in summation, not expert testimony.''[68] Finally, some courts will exclude testimony if the expert purports to use legal terms of art.[69] Expert testimony as to a company's compliance with legal requirements may be challenged as stating a legal conclusion, as addressed in Section III.C below.

I. Corporate Conduct Expert Testimony May Be Unfairly Prejudicial, Confusing or Misleading

Federal Rule of Evidence 403, and state analogues, bar even relevant testimony if its probative value is substantially outweighed by, *inter alia*, the dangers of unfair prejudice, confusing the issues, or misleading the jury.[70] Courts have invoked Rule 403 to exclude expert corporate conduct testimony. For example, in *In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, the court found that allowing expert witnesses to offer what amounted to personal opinions of corporate conduct would be confusing and unfairly prejudicial because the jury might base its decisions on those ethical opinions, rather than the pertinent legal standards.[71] Likewise, in *Concord Boat Corp. v. Brunswick Corp.*, No. LR-C-95-781, 1998 WL 35254137 (E.D. Ark. Mar. 2, 1998), the court excluded the testimony of a business ethics professor that the defendant had anticompetitive intent, made misleading statements, breached confidentiality, and lacked fair play as irrelevant and ''potentially very confusing for the jury'' because these ''ethical obligations'' did not rise to legal standards, and ethical breaches would not give rise to legal liability.[72]

---

[59] *Id.* at 1351.

[60] *Id.* at 1347; *see also, e.g.*, *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Human Servs.*, No. 98-817V, 2007 WL 2706157, at *12 (Fed. Cl. Aug. 29, 2007) (Expert's testimony ''was more evocative of the term 'hired gun' than that of 'expert witness.' ''). Note, however, that other courts have ruled that litigation or bias issues are not grounds for exclusion, but only for cross-examination. *See, e.g.*, *In re Heparin Prod. Liab. Litig.*, MDL No. 1953, 2011 WL 1059660, at *8 (N.D. Ohio Mar. 21, 2011) (''To the extent Defendants perceive a bias on her part against pharmaceutical manufacturers, Defendants can, and I assume will cross-examine her on that subject, which is not a basis for excluding her testimony.'').

[61] *See, e.g.*, *Commonwealth v. Daniels*, 390 A.2d 172, 178 (Pa. 1978) (''Undoubtedly there is a kind of statement by the witness which amounts to no more than an expression of his general belief as to how the case should be decided. . . . There is no necessity for this kind of evidence; . . . it is wholly without value to the trier of fact in reaching a decision.'' (quoting *McCormick on Evidence*, Tit. 2, Ch. 3, § 12 (2d ed. 1972)).

[62] *See, e.g.*, *Commonwealth v. Blasioli*, 685 A.2d 151, 167 (Pa. Super. Ct. 1996) (expert testimony that is not only of little help to the jury, but could mislead and confuse the jury is also inadmissible), *aff'd*, 713 A.2d 1117 (Pa. 1998); *Childers ex rel. Childers v. Power Line Equip. Rentals, Inc.*, 681 A.2d 201, 210 (Pa. Super. Ct. 1996) (testimony on ultimate issue is barred where it will ''confuse, mislead, or prejudice the jury'' (citation omitted)).

[63] *See Deutsch*, 2011 WL 790702, at *27 (expert may not comment on whether defendant was acting in good faith or otherwise testify as to defendant's intent, motivations, or state of mind); *see also In re Rezulin*, 309 F. Supp. at 547 (expert testimony that pharmaceutical company's actions ''potentially constituted 'negligence' or 'something more serious' is excluded for the additional reason that it impermissibly embraces a legal conclusion'').

[64] Fed. R. Evid. 704.

[65] *Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983).

[66] *United States v. Lumpkin*, 192 F.3d 280, 289 (2d Cir. 1999) (internal quotations and citations omitted).

[67] *Hygh v. Jacobs*, 961 F.2d 359, 364 (2d Cir. 1992).

[68] *Hogan*, 2011 WL 1533467 at *5; see also id. at *8 (excluding expert testimony which constituted ''plaintiff's attempt to elevate and advocate the value of individual evidence by having it recounted by an expert'').

[69] *See United States v. Barile*, 286 F.3d 749, 760-61 (4th Cir. 2002) (in deciding whether opinion testimony states a legal conclusion, the court determines ''whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular'' (citation omitted)); *Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (''The Court finds that the use of legal terms of art or legal conclusions by Plaintiffs' expert, could lead the jury to be prejudicial against the Defendant.'').

[70] Rule 403 of the Federal Rules of Evidence states, ''Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.''

[71] *Id.* at 545; *see also In re Cessna 208 Series Aircraft Prod. Liab. Lit.*, MDL No. 1721, No. 05-md-1721-KHV, 2009 WL 1357234 at *3-*4 (D. Kan. May 12, 2009) (excluding business ethics expert's opinions where they were not directly relevant to products liability claim and may tend to confuse or mislead the jury).

[72] *Id.* at *1; *see also In re Welding Fume*, 2005 WL 1868046, at *20-*21 (excluding expert's opinions re ethical requirements because a jury could conclude that those requirements constituted applicable legal standards). Courts have also excluded conduct expert testimony that relies on foreign regulatory actions under Rule 403. *See, e.g., In re Seroquel Prods. Liab.*

II. Challenging Specific Types Of Corporate Misconduct Testimony

Courts have applied the general standards discussed above to address specific types of corporate conduct testimony, including narrative testimony, corporate or government agency state-of-mind opinions, testimony as to regulatory compliance, and opinions on how a physician would have reacted to a different set of warnings.

A. Courts Often Exclude Corporate Conduct Narrative Opinions

Some plaintiffs' corporate conduct experts typically submit 100-250 page boiler plate expert reports that purport to set forth a narrative of relevant facts, with the expert's commentary. Courts often reject this testimony primarily because expert opinion must offer specialized knowledge (beyond mere recitation of facts), these narratives do not assist the trier of fact, and such testimony supplants the role of counsel in making arguments, and the role of the jury in weighing the evidence.[73] In *Lopez v. I-Flow, Inc.*, the court recently excluded one frequent plaintiffs' expert for providing just such a report, which the court described as ''a labyrinth that the Court cannot navigate.''[74] That court observed that the ''report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation.''[75] In other words, the expert's logical leaps ran afoul of the prohibition on expert testimony that contains ''too great an analytical gap between the data and opinion proffered.''[76]

Apart from the methodological flaws of narrative testimony being delivered by a corporate conduct expert, courts will not permit an expert to introduce evidence in the place of fact witnesses, and offer his own conclusory statement of opinion.[77] Some courts, however, have permitted experts to summarize facts that have already been put in evidence through proper fact witnesses, and explain how those facts fit within the regulatory context.[78]

Litig., 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009) (excluding plaintiffs' use of evidence relating to foreign regulatory actions to prove defendant acted improperly as such evidence posed a ''significant risk of jury confusion and waste of time'' and would ''substantially prejudice [the defendant] . . . if evidence of regulatory actions were admitted at trial'').

[73] *See, e.g.*, *In re Trasylol*, 709 F. Supp. 2d at 1336-37 (expert's opinions ''fall outside the proper scope of expert testimony because they consist of a narrative of selected regulatory events and a summary of Bayer's internal documents'' without making ''references to FDA regulations'' or tying the facts ''to the opinions that they are intended to support''), *Id.* at 1346 (''Dr. Parisian does not analyze the facts; she, in the words of the *Prempro* court, regurgitates them and reaches conclusory opinions that are purportedly based on those facts'' without analysis.); *In re Prempro*, 554 F. Supp. 2d at 887 (''[h]aving an expert witness simply summarize 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''); *In re Rezulin*, 309 F. Supp. 2d at 553 (excluding testimony on the ''history of Rezulin'' and actions taken by the manufacturer and foreign regulators with respect to Rezulin, as a ''lay matter''); *In re Diet Drugs*, 2001 WL 454586, at *10 (proposed expert's testimony on pharmaceutical company's codes of conduct ''unnecessary'' when expert ''himself testified that anyone who reads and understands the English language can interpret and apply them''); *Eiser v. Brown & Williamson Tobacco Corp.*, No. 191 EDA 2004, 2006 WL 933394, at *11 (Pa. Super. Ct. Jan. 19, 2006) (affirming exclusion of expert's ''history'' on tobacco industry's alleged misinformation campaign because it was ''not a proper subject for expert opinion''), *remanded on other grounds*, 938 A.2d 417 (Pa. 2007).

[74] *Lopez v. I-Flow, Inc.*, No. 2:08-cv-01063-SRB, slip op. at 18 (D. Ariz. Jan. 26, 2011) (referencing a 209-page report submitted by plaintiffs' corporate conduct expert).

[75] *Id.* at 18-19.

[76] *Joiner*, 522 U.S. at 146.

[77] *See, e.g.*, *In re Prempro*, 554 F. Supp. 2d at 886 (''I did not anticipate that documents would be admitted via Dr. Parisian so that she could simply engage in recitation of those exhibits; jurors are capable of reading documents.''); *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 4259332, at *9 (S.D. Fla. Oct. 21, 2010) (An expert's ''narrative history of Trasylol's initial regulatory approval is inadmissible, such evidence should be presented to the jury directly. . . . Furthermore, to the extent that [the expert] testifies as to the factual basis for the FDA's initial approval of Trasylol, his testimony will be limited to commentary on documents and exhibits in evidence, and to explaining the regulatory context, defining any complex or specialized terminology, and drawing inferences that would not be apparent without the benefit of regulatory expertise. [The expert] will not be permitted to merely read or recite the evidence.''); *In re Trasylol*, 709 F. Supp. 2d at 1346 (''Dr. Parisian assumes the role of Plaintiffs' advocate in her presentation of the facts and invades the province of the jury.''); *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 967 (D. Minn. 2009) (FDA expert's purported factual history excluded because it ''simply summarize[d] and state[d] witness' advocacy-based interpretation of documents,'' did not ''benefit from her regulatory expertise,'' and was no ''more or less persuasive than that of a layperson'' (internal quotations and citations omitted)); *Highland Capital Management v. Schneider*, 379 F. Supp. 2d 461, 468-70 (S.D.N.Y. 2005) (attorney's narrative testimony re securities fraud issues was ''simply rehashing otherwise admissible evidence about which he has no personal knowledge'' and speculative inferences about state of mind and therefore inadmissible); *see also Fisher v. Ciba Specialty Chems. Corp.*, 238 F.R.D. 273, 281 (S.D. Ala. 2006) (excluding administrative attorney's expert report concerning defendant company's environmental regulatory history on grounds that it ''simply summarizes and states her advocacy-based interpretation of documents in the record'' and ''reads like the fact section of a brief, not the report of an expert witness'').

[78] *See. e.g.*, *In re Prempro Prod. Liab. Litig.*, No. 4:03CV1507-WRW, 2006 WL 2414062, at *6 (E.D. Ark. Aug. 21, 2006) (allowing FDA regulatory expert to ''relate a brief history (assuming it is based on adequate data). Distilling voluminous documents is proper. While it is true that jurors can read the documents, the trial would last months if they were required to read every admissible document.''); *In re Welding Fume*, 2005 WL 1868046, at *17-*18 (allowing doctor to present historical review and comparison of publicly available information and defendants' internal documents, finding that through application of his expertise, witness ''may allow the trier of fact to better understand what the documents do (and don't) mean, and, thus, what the defendants did (or didn't) know''; but prohibiting witness from stating his personal beliefs—so that he ''may testify that certain opinions are reflected in the historical medical literature on this issue, he may not pass judgment on the validity of those opinions or adopt them as his own''); *see also In re Fosamax*, 645 F. Supp. 2d at 192 (''Dr. Parisian's commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized

  TXLR ISSN 0887-7394

B. Courts Usually Exclude Expert Opinions Regarding Corporate or Agency State-of-Mind

Based on their reviews of selected company documents, many plaintiffs' experts will purport to testify about what the defendant company knew, what were its intentions, and other matters that reflect ''corporate state-of-mind.'' Courts have held that such testimony is improper because it ''describes lay matters which a jury is capable of understanding and deciding without the expert's help.''[79] Therefore, courts have excluded testimony about a company's knowledge, motives, or state of mind as speculative, beyond the scope of proper expert testimony, and inadmissible under Federal Rules of Evidence 403 and 702.[80] Thus, testimony about a defendant's motives or intentions to put profits ahead of safety, or conceal important safety information, is not admissible.[81]

The same experts may also opine as to ''regulatory state of mind,'' *e.g.*, why an agency approved the company's actions or what the agency might have done if the company had provided it with different information. Courts have concluded that expert testimony regarding regulatory agency motive and intent is no more admissible than such testimony regarding corporations.[82]

C. Courts May Admit Well-Founded And Relevant Regulatory Expert Opinions

If a plaintiffs' expert is qualified to discuss regulatory matters, typically by past experience working for the relevant agency, some courts have permitted expert testimony regarding issues such as general FDA regulatory requirements and procedures.[83] Several courts have gone further and allowed the regulatory expert to testify about the defendant company's conduct. In *In re Fosamax Products Liability Litigation*, 645 F. Supp. 2d 164, the court found the regulatory expert's explanation of the regulatory framework that informs the standard of care in pharmaceutical cases, and her assessment of the reasonableness of defendant's conduct in light of her experience and understanding, would be helpful to the jury.[84] Likewise, the MDL court in *In re Diet Drugs Products Liability Litigation*, 2001 WL 454586, allowed a former FDA employee to testify regarding ''how information should be communicated to the FDA and what information should be reflected in labels, as mandated by applicable regulations.''[85] Moreover, the GBCA MDL court concluded that a properly qualified regulatory expert can testify as to a defendant's *compliance* with FDA regulations, and warning adequacy and accuracy, based only on admissible evidence.[86]

But such regulatory expert testimony must be based on objective standards. In *In re Fosamax Products Liability Litigation*, 645 F. Supp. 2d 164, the court also held that the expert's opinion that a pharmaceutical company failed to disclose that it hired ghostwriters to prepare favorable articles should be excluded because she could not identify any standard that prohibited the practice.[87] She also testified that defendant attacked the credibility of physicians not favorable to it, but the court found that this opinion was based on a single e-mail exchange and that such opinions ''are not expert opinions but mere 'bad company' testimony with marginal relevance to the issues in controversy.''[88]

Further, the testimony must reflect specialized knowledge and expert analysis. For example, the *Trasylol* court held that a regulatory expert's opinions ''fall outside the proper scope of expert testimony because they consist of a narrative of selected regulatory events and a summary of Bayer's internal documents'' without making ''references to FDA regulations'' or tying the facts ''to the opinions that they are intended to support.''[89] In short, ''You can't just say here are a lot of

---

knowledge. She will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence.'').

[79] *See In re Rezulin*, 309 F. Supp. 2d at 546 (''Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.'' (internal quotation omitted)); *In re Trasylol*, 709 F. Supp. 2d at 1338 (''courts have held that the question of (corporate) intent or motive is a classic jury question and not one for experts'').

[80] *Lopez*, slip op. at 19; *see, e.g.*, *DePaepe*, 141 F.3d at 720 (excluding as speculative expert testimony that the defendant automotive company reduced the padding in its sun visors ''to save money''); *In re Fosamax*, 645 F. Supp. 2d at 192 (Expert testimony as to corporate motives and state of mind is ''conjecture . . . [and] not a proper subject for expert or even lay testimony.''); *In re Baycol*, 532 F. Supp. 2d at 1053-54 (excluding expert testimony that ''speculates as to Bayer's motive, intent or state of mind, or speculates as to motives of the FDA or what other drug companies would do'' because ''[p]ersonal views on corporate ethics and morality are not expert opinions''); *In re Guidant*, 2007 WL 1964337, at *8 (excluding expert testimony about the defendant's knowledge); *In re Diet Drugs*, 2000 WL 876900, at *9 (''If the witnesses' bases for the opinions concerning improper intent come from other evidence such as letters, admissions of AHP officers or employees, or other admissible evidence, *that* is what the jury should hear and the question of AHP's intent would flow from such evidence to be determined by the jury.'').

[81] *See, e.g.*, *In re Diet Drugs*, 2000 WL 876900, at *2 (testimony that the defendant was ''driven by its desire to increase profits'' is inadmissible).

[82] *See, e.g.*, *In re Methyl Tertiary Butyl Ether (''MTBE'') Prods. Liab. Litig.*, 643 F. Supp. 2d 482, 502-03 (S.D.N.Y. 2009) (expert testimony on the government's motives or intent is speculative and irrelevant).

[83] *See, e.g.*, *In re Zyprexa*, 489 F. Supp. 2d at 288 (FDA expert permitted to testify as to general knowledge of FDA operations, but could not testify as to how FDA processed regulatory issues regarding drug at issue because he lacked specific knowledge of that matter).

[84] *Id.* at 191.

[85] *Id.* at *18. The court, however did not allow the witness to offer ''personal opinions'' as to pharmaceutical company standards that were not set forth in FDA regulations. *Id.*; *see also In re Heparin*, 2011 WL 1059660, at *8 (regulatory expert allowed to offer opinions regarding FDA regulations and ''what must a manufacturer do to satisfy the standard of care established under the regulatory framework,'' but ''she may not offer opinion testimony as to the reasonableness of the Defendant's conduct'' because this is a legal conclusion for the jury).

[86] *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *25, *27 (N.D. Ohio May 4, 2010).

[87] *Id.* at 191; *see also id.* at 190-91 (''An expert is permitted to draw a conclusion from a set of observations based on extensive and specialized experience. Here, [the expert] has drawn conclusions about Merck's conduct based on her review of pertinent portions of the regulatory filings for Fosamax and Merck's internal company documents. This is the methodology she applied as a Medical Officer, and Merck's regulatory experts have followed the same methodology to prepare their reports.'' (citation omitted)).

[88] *Id.* at 192.

[89] *In re Trasylol*, 709 F. Supp. 2d at 1336-37.

facts and I conclude Bayer violated the standard of care.''[90]

Expert testimony that a company acted illegally by violating a federal statute or regulation may be excluded as an improper legal conclusion. Defendants may contend that regulatory violation opinions go beyond the scope of proper expert testimony by usurping the role of the court in instructing the jury on the law, and the role of the jury in applying the law to the facts of the case.[91] This argument has been well received and courts have rejected testimony where the expert purported to opine that the defendant's actions, for example, violated federal regulations.[92]

An additional ground for excluding expert testimony concerning a company's regulatory compliance is that federal law may preempt claims that a defendant concealed information from, or failed to give complete information to, a government agency. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that state law claims based on the theory that a plaintiff's injuries were caused by a defendant's failure to provide different, or better, data to FDA during the regulatory process are preempted by federal law.[93] Accordingly, courts have stricken purported expert testimony alleging that a defendant failed to provide information to a government agency.[94] Of course, where compliance with specific regulatory provisions is a core element of a claim, expert testimony on regulatory compliance may be relevant.[95]

D. Some Courts Exclude Opinions On the Effects of 'Proper' Warnings

Plaintiffs in pharmaceutical product liability cases seek to have their experts offer testimony as to how a physician would have reacted to a ''proper'' warning. That is, the expert will testify that, if the pharmaceutical company had warned the plaintiff's prescribing doctor that the drug could cause a certain adverse effect, the doctor never would have prescribed the drug to the plaintiff. Some courts have permitted such testimony, provided that it comes from a doctor in the particular discipline of interest.[96]

In contrast, in *In re Diet Drugs Products Liability Litigation*, 2001 WL 454586, the court held that an FDA regulatory expert was ''not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information. Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge.''[97]

Moreover, other courts have refused to allow testimony as to what doctors would have done in response to additional warnings, holding that only evidence of what the actual prescribing physician would have done

---

[90] *Id.* at 1345.

[91] *In re Rezulin*, 309 F. Supp. 2d at 547; *see also Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1246 (10th Cir. 2000). (While an expert may be ''called upon to aid the jury in understanding the facts in evidence even though reference to those facts is couched in legal terms,'' expert testimony which ''attempt[s] to define the legal parameters within which the jury *must* exercise its fact-finding function'' is impermissible. (citation omitted)); *United States v. Scholl*, 166 F.3d 964, 973 (9th Cir.1999) (''[I]t is well settled that the judge instructs the jury in the law. Experts interpret and analyze factual evidence. They do not testify about the law because the judge's special legal knowledge is presumed to be sufficient, and it is the judge's duty to inform the jury about the law that is relevant to their deliberations.'' (internal quotations and citation omitted)); *Waters v. State Emps.' Ret. Bd.*, 955 A.2d 466, 471 n.7 (Pa. Commw. Ct. 2008) (''It is well-settled that an expert is not permitted to give an opinion on a question of law.'').

[92] *See, e.g., Moses v. Danek Med., Inc.*, No. CV-S-95-512PMPRLH, 1998 WL 34024164, at *3 (D. Nev. Nov. 30, 1998) (excluding improper expert testimony on ''whether or not Defendants acted 'illegally'; what is 'promotion' under the FDCA; and the interpretation of statutes and regulations''); *see also United States v. Grace*, 455 F. Supp. 2d 1156 (D. Mont. 2006) (proffered expert testimony that mine owner did not violate TSCA regulations requiring reporting of information about hazardous chemicals when it failed to inform EPA of a series of studies relating to the dangers of asbestos, was inadmissible in prosecution for conspiracy to defraud the United States because it stated a legal conclusion, purporting to explain the meaning of the law and apply the facts to the law).

[93] *Id.* at 350-51.

[94] *See, e.g., In re Trasylol*, 2010 WL 4259332, at *9-10 (''evidence or testimony that Bayer failed to adequately or timely provide information to the FDA pursuant to FDA reporting obligations that run to the FDA, such as [21 C.F.R.] § 314.80, is generally irrelevant to Plaintiffs' state-law claims and thus inadmissible. Such evidence or testimony would instead only be relevant to a fraud-on-the-FDA claim that is preempted by *Buckman* . . . .''); *In re Baycol*, 532 F. Supp. 2d at 1053 (excluding expert testimony ''offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA''); *Zwiercan v. Gen. Motors Corp.*, No. 3235 June Term 1999, 2002 WL 31053838, at *6 (Pa. C.P. Sept. 11, 2002) (citing *Buckman* and stating that the plaintiff was preempted from asserting a claim under the Unfair Trade Practices and Consumer Protection Law for the defendant's alleged fraud on a federal agency).

[95] *See, e.g., United States v. Canal Barge Co.*, No. 4:07CR-12-JHM, 2008 WL 533878, at *7 (W.D. Ky. Feb. 22, 2008) (in prosecution of a company for failing to report information under federal law, court permitted testimony of defendant's regulatory expert finding testimony on whether certain hazardous conditions were reportable under applicable law as helpful to jury in ''determining whether the Defendants' failure to report the benzene leak was a willful and knowing violation.''); *Am. Home Assurance Co. v. Merck & Co.*, 462 F. Supp. 2d 435, 453 (S.D.N.Y. 2006) (''The issue for the fact finder to decide is whether Merck's interpretation of the FDA's 'complex regulatory scheme' was reasonable under the circumstances. . . . [The testimony of Merck's expert] will assist the fact finder in understanding this regulatory scheme, including testimony regarding any 'acts' or 'guidance' that are relevant to this scheme and may bear on the extent of Merck's reasonable reliance.'').

[96] *See, e.g., In re Gadolinium Based Contrast Agents*, 2010 WL 1796334, at *19 (nephrologist could not testify about FDA regulations and defendant's compliance therewith, but could offer opinions on whether defendant's product label contained adequate information or inaccuracies or omissions that could deprive or mislead physicians like himself). In *In re Diet Drugs*, 2000 WL 876900, at *11, the court found that doctors were not qualified ''to opine as experts about what all doctors generally consider in making prescription decisions,'' but were qualified to compare medical knowledge regarding drug risks and benefits with information contained in the label, and the extent to which the label could deprive or mislead a reader regarding product risks. The MDL court did not rule on the admissibility of such opinions.

[97] *Id.* at *18; *see also In re Rezulin*, 309 F. Supp. at 557 (excluding clinical trial expert's opinion as to whether he would have prescribed drug if there had been different warnings as ''speculative'').

  TXLR ISSN 0887-7394

with different information is relevant. For example, in *Adams v. Wyeth*, 74 Pa. D. & C. 4th 500 (Pa. C.P. 2005), a pharmaceutical product liability action, plaintiff attempted to support a failure to warn claim by offering expert testimony that, if different warnings had been given, a ''reasonable doctor'' would not have prescribed the medication at issue to the plaintiff.[98] The court, in affirming summary judgment for the defendant, stated that the expert's testimony ''as to what a 'reasonable doctor' would have done with appropriate knowledge is not admissible, is irrelevant and is contrary to the legal standard long established under Pennsylvania law.''[99] The court stated that, to satisfy the plaintiff's burden, only testimony as to what the plaintiff's actual prescribing physician would have actually done with a different warning is permissible.[100]

III. Conclusion

Plaintiffs in product liability cases will seek to present expert as well as factual ''bad company'' testimony. Defendants may seek to exclude such testimony under *Daubert*, Fed. R. Evid. 702, and similar standards to ensure that a jury hears only reliable and relevant expert testimony offered by qualified witnesses.

Frank Leone is a partner at Hollingsworth LLP in Washington, D.C. He has expertise in environmental law, and the defense of toxic tort, consumer product, asbestos, and pharmaceutical product liability claims. Leone can be reached at fleone@hollingsworthllp.com.

Mark A. Miller is an associate at Hollingsworth LLP in Washington, D.C., where he practices in the firm's Complex Litigation, Pharmaceutical Products, and Toxic Tort & Product Liability groups. Miller can be reached at mmiller@hollingsworthllp.com.

[98] *Id.* at 509-10.

[99] *Id.* at 510; *see also Gronniger v. Am. Home Prods. Corp.*, No. 3584, 2005 WL 3766685, at *5 (Pa. C.P. Oct. 21, 2005) (testimony ''as to what a 'reasonable doctor' would have done with appropriate knowledge is not admissible, is irrelevant and is contrary to the legal standard long established under Pennsylvania law'').

[100] *Adams*, 74 Pa. D. & C. 4th at 510 (''the evidence required to establish a reasonable likelihood is evidence that the learned intermediary, namely, Dr. Gillett, and *only Dr. Gillett*, would provide to the effect that *he*, *Dr. Gillett*, would have altered *his* behavior'').