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Henderson, Nevada

Sunday, March 5, 2006

to

Sunday, March 12, 2006

Punitive Damages Bait and Switch: Juries or Judges; Individual Suits or Class Actions[†]

Thomas F. Segalla

I. INTRODUCTION

“How 12 angry, unsure, manipulative, thoughtful citizens reach a verdict.”¹

The American legal system has been faulted by some critics as the reason for unpredictable, erratic, and arbitrary punitive damage awards.² In fact, an ongoing debate has developed as to whether the American jury system in particular is responsible for unpredictable, erratic, random, and capricious punitive damage awards,³ or whether there is any real difference between awards made by juries and those made by judges.⁴

Succinctly stated, the question is: Who is better adept to render a punitive damage award that, in the traditional sense, is meant to punish the defendant for engaging in reprehensible conduct and to deter the defendant and others from engaging in similar conduct? Also, what affect do the forum and litigation structure have on the overall purposes of punitive damage awards? This article explores the current status of the law and provides the practitioner and claims professional with an assessment of how to better defend against claims for punitive damages.

[†] Submitted by the author on behalf of the FDCC Appellate Law Section.

¹ D. Graham Burnett, *We, the Jury*, NEW YORK TIMES MAGAZINE, § 6, p. 32, cover page, Aug. 6, 2001.

² Dana A. Schkade, *Erratic By Design: A Task Analysis of Punitive Damages Assessment*, 39 HARV. J. ON LEGIS. 121 (2002).

³ *Id.* at 121. See also Jennifer K. Robbennolt, *Determining Punitive Damages: Empirical Insights and Implications for Reform*, 50 BUFF. L. REV. 103 (2002).

⁴ Robbennolt, *supra* note 3, at 110-14. See also Richard W. Murphy, *Punitive Damages, Explanatory Verdicts and the Hard Look*, 76 WASH. L. REV. 995 (2001).



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II. THE JURY OR THE JUDGE?

Although various empirical studies now call into question some traditional beliefs about punitive damages, the practitioner must have a clear understanding of historical concepts and the procedural mechanisms available to challenge punitive damages. Absent such an understanding, the practitioner runs the risk of having his or her client fall victim to one of the huge punitive damage awards that are repeatedly reported by the media. For example, juries in the following cases have awarded some of the largest punitive damage verdicts in history:

- *Engle v. R.J. Reynolds Tobacco Co.*⁵ — \$145 billion
- *In re Exxon Valdez*⁶ — \$5 billion
- *BMW of North America, Inc. v. Gore*⁷ — \$4 million
- *Liebeck v. McDonald's Restaurants, P.T.S., Inc.*⁸ — \$2.7 million

⁵ No. 94-108273 CA-22, 2000 WL 33534572 (Fla. Cir. Ct. Nov. 6, 2000).

⁶ No. A89-0095-CV, 1995 WL 527988 (D. Alaska Jan. 27, 1995), *aff'd in part and vacated in part*, 270 F.3d 1215 (9th Cir. 2001).

⁷ 517 U.S. 559 (1996).

⁸ No. CV-93-02419, 1995 WL 360309, at *1 (D.N.M. Aug. 18, 1994).

These huge verdicts have resulted in calls to reform the judicial system and have been used to identify various weaknesses within the present system for awarding punitive damages. One commentator has noted:

The most serious weakness is that one of the tasks jurors are required to perform — assessing a specific dollar amount of punitive damages — is one that they cannot possibly be expected to perform well. It is the jurors' valiant but doomed attempts to perform this poorly designed task that produces erratic awards that fail to treat similarly situated parties similarly.⁹

Another commentator has noted that while jurors perform some aspects of their role “quite well,” other aspects are difficult:

[R]esearch demonstrates that jurors have difficulty with specific aspects of their task. Jurors are influenced by media reports about civil litigation, they do not intuitively give effect to optimal deterrence, they have trouble translating their outrage into a monetary equivalent, and they have difficulty understanding legal instructions.¹⁰

In addition, in his concurring opinion in *BMW v. Gore*, Justice Breyer stated that jurors cannot be expected “to interpret law like judges, who work within a discipline and hierarchical organization that normally promotes roughly uniform interpretation and application of the law.”¹¹ Recently, when deciding the case of *Torres v. Travelers Insurance Co.*,¹² one district court noted in the punitive damages context that “[g]enerally, the amount of damages awarded is a factual question for the jury. ‘Blinders should not be placed on a jury which it is called upon to assess punishment, i.e. punitive damages.’”¹³

As a result of these perceptions, some critics of the American jury system favor allowing judges to decide punitive damage issues rather than juries. Those critics believe that judges can better perform the functions of deciding when punitive damage awards should

⁹ Schkade, *supra* note 2, at 121.

¹⁰ Robbennolt, *supra* note 3, at 118.

¹¹ *BMW*, 517 U.S. at 596.

¹² CIV. No. 01-5056 (D.S.D., Sept. 30, 2004).

¹³ *Id.* at 26 (citations omitted).

be made and at what levels.¹⁴ While this article does not fully explore this issue, however, at least two empirical studies suggest that there is no basis for concluding that judges perform better.¹⁵

After reviewing these empirical studies concerning punitive damage awards made by juries and trial court judges, one author has concluded:

[S]ubstantial change in punitive award patterns would not result from shifting greater responsibility to judges. Juries and judges award punitive damages at about the same rate, and their punitive awards bear about the same relation to their compensatory awards. Jury punitive awards have a bit more spread than judge awards, but the effect is not robust and leads to few jury punitive awards outside the range of what judges are expected to award.¹⁶

The question posed is whether the same conclusions would be drawn if the studies compared those decisions rendered by juries and trial judges with decisions rendered by appellate courts. It may be that appellate court judges are less susceptible to bias or prejudice and, based on their qualifications and position, are more apt to strive for a uniform interpretation and application of the law.

Several recent decisions of the United States Supreme Court, while they have not specifically responded to the jury versus judge debate, will have significant impact on the way punitive damages are ultimately handled by the American judicial system. These should serve to warn lawyers that they must properly assess the pertinent case law and become familiar with the procedural and substantive impact of these decisions.

¹⁴ For a discussion of the comparative performances of jurors and judges, see Theodore Eisenberg et al., *Juries, Judges, and Punitive Damages: An Empirical Study*, 87 CORNELL L. REV. 743 (2002); David Schkade et al., *Deliberating About Dollars: The Severity Shift*, 100 COLUM. L. REV. 1139, 1167-73 (2000); Cass R. Sunstein et al., *Assessing Punitive Damages (With Notes on Cognition and Valuation in Law)*, 107 YALE L. J. 2071, 2142-45 (1998).

¹⁵ Eisenberg, *supra* note 14, at 743 (“Data covering one year of judge and jury trial outcomes from forty-five of the nation’s largest counties yield no substantial evidence that judges and juries differ in the rate at which they award punitive damages or in the central relation between the size of punitive awards and compensatory awards.”). See also Robbenolt, *supra* note 3, at 200 (“Despite these difficulties, however, it is not clear that decisions by juries differ dramatically from those of judges.”).

¹⁶ *Id.* at 779.

III.

COOPER INDUSTRIES v. LEATHERMAN TOOL GROUP, INC. — AN UPDATE

As guided by the United States Supreme Court, the Ninth Circuit Court of Appeals conducted a *de novo* review of the constitutionality of the punitive damage award in *Cooper Industries*,¹⁷ on remand of the case. It is important to review the Ninth Circuit's treatment of punitive damages on remand before discussing the overall impact of *Cooper Industries v. Leatherman* on punitive damages. In its *Leatherman* decision, the Supreme Court had "cautioned that it did not intend to 'prejudge' the issue, but only to point out how an independent review might call for a result other than our prior affirmance of the punitive damage award at issue here."¹⁸

Based on this ruling, which required *de novo* review in contrast to an abuse of discretion review, the Ninth Circuit evaluated the consistency of the punitive damage award with the due process doctrine.¹⁹ In doing so, the Ninth Circuit considered the following three criteria, previously articulated by the Supreme Court in *BMW of North America, Inc. v. Gore*:²⁰

1. The degree of reprehensibility of the defendant's conduct;
2. The disparity between the harm (or potential harm) suffered by the plaintiff and the punitive damage award; and
3. The difference between the punitive damages awarded by the jury and the judicial penalties authorized or imposed in comparable cases.

The Ninth Circuit addressed each of the *BMW* guideposts and concluded that the \$4.5 million punitive damage award was not supported by the record before it. With respect to the third guidepost, which dealt with the issue of whether a defendant's conduct would be subject to civil penalties, the court noted that the actions of Cooper Industries in this case constituted a single violation — not a statutory violation that would have sanctioned imposition of a multi-million dollar fine. Next, the Ninth Circuit assessed the ninety-to-one ratio between the compensatory damages awarded by the jury (\$50,000) and the punitive damages awarded (\$4.5 million). Although holding that "there is insufficient evidence in the

¹⁷ *Leatherman Tool Group, Inc. v. Cooper Industries, Inc.*, 285 F.3d 1146 (9th Cir. 2002) (hereinafter referred to as "Leatherman").

¹⁸ *Id.* at 1148.

¹⁹ For a discussion of the differences between a *de novo* standard and an abuse of discretion standard, see *infra* Section IV(C).

²⁰ 517 U.S. 559 (1996).

record with respect to the harm or potential harm caused by Cooper's conduct to support the punitive damage award under the second *Gore* criterion," the court declined to set a maximum ratio of punitive to actual damages.²¹

Finally, the Ninth Circuit addressed the first *Gore* criterion, which presented the most difficult determination for an appellate court. Specifically, the court was asked to independently assess the reprehensibility of Cooper Industries' conduct. When determining its role in assessing the significance of this conduct, the court framed the question as follows: "[T]he question before us is not whether the jury's award was inflamed by prejudice or passion, but whether the amount of punitive damages ultimately awarded was constitutional under the circumstances."²² While the court expressed strong disapproval of the conduct of Cooper Industries, it held that the punitive damage award "exceeded constitutional limits."²³ Cooper Industries had urged the court to view its conduct as arguably inadvertent and negligent rather than as fraudulent and deceitful. The court agreed to some extent, noting that Cooper's conduct was more "foolish than reprehensible."²⁴

Having concluded that the \$4.5 million punitive damage award was unconstitutional, the court next had to consider "whether we simply should determine the maximum constitutional award ourselves or remand to the district court with instructions to issue a remittitur in accordance with the views expressed in our opinion."²⁵ Based on the holding of the Eleventh Circuit in *Johansen v. Combustion Engineering, Inc.*,²⁶ the Ninth Circuit determined that it need not remand a case every time it held that a punitive damage award "exceed[ed] the constitutional maximum."²⁷ Therefore it could determine the constitutional maximum based on the appellate record. However, this same court, in the case of *In re Exxon Valdez*,²⁸ likewise had found that the punitive damage award exceeded the constitutional maximum but had remanded the case to the district court to determine the appropriate amount. Since the *Exxon Valdez* case pre-dated *Gore* and *Leatherman*, the Ninth Circuit remanded the case for a discussion of constitutionality in the first instance.

²¹ *Id.* at 1150 (indicating that the Supreme Court in *Gore* has similarly declined to set a maximum ratio). See *BMW of N. Am., Inc. v. Gore*, 517 U.S. at 583; cf. *Johnson v. Combustion Engineering, Inc.*, 170 F.3d 1320, 1337, 1339 (11th Cir. 1999) (upholding a 100-to-1 ratio).

²² *Leatherman*, 285 F.3d at 1150.

²³ *Id.*

²⁴ *Id.* at 1151.

²⁵ *Id.*

²⁶ 170 F.3d 1320 (11th Cir. 1999).

²⁷ *Leatherman*, 285 F.3d at 1151.

²⁸ 270 F.3d 1215 (9th Cir. 2001).

Citing judicial economies and the interests of justice, the district court in turn concluded that it would decide the excessiveness issue based on the existing record. In doing so, it relied on the rationale of the Third Circuit Court of Appeals in *Inter Medical Supplies, Ltd. v. EBI Medical Systems, Inc.*:²⁹

It is not an enviable task. We have searched vainly in the case law for a formula that would regularize this role, but have not found one. . . . In the last analysis, an appellate panel, convinced that it must reduce an award of punitive damages, must rely on its combined experience and judgment. When different members reach different figures, they must seek an accommodation among their views, a process that recurs throughout appellate decision making.³⁰

In *Leatherman*, the Ninth Circuit recognized the difficulties an appellate court faces in reviewing a punitive damage award and noted that it was not compelled in all cases to arrive at an appropriate sum. But in this case, “the maximum award of punitive damages consistent with due process on the facts of this case is \$500,000.”³¹ The court in effect held that a ratio of ten-to-one (i.e., \$500,000 to \$50,000) was permissible. The court recognized that there might be cases where prior remittitur or some other circumstance would make further trial court findings necessary. In these types of cases, the court might remand the case to the district court for a further proceeding. Absent such situations, the court itself would decide the issue. Given this perspective, the \$500,000 sanction was “not trivial,” nor was it “disproportionate to the harm caused or threatened.”³²

From a defense perspective, the fact that an appellate court will decide the issue *de novo* is important because it allows the defense counsel to articulate for the court all the evidence favorable to its position on appeal. Counsel for the plaintiff, of course, would be permitted to do the same. A *de novo* review will allow the defense to argue that the plaintiff has failed to meet its clear and convincing burden of proof. The appellate court, after *Leatherman*, would then be responsible to weigh the evidence. In effect, this allows the defense to argue its position yet another time. It should be noted, however, that defense counsel will not be given free reign.

In assigning a degree of reprehensibility to Cooper Industries’ conduct, the Supreme Court provided the following warnings:

²⁹ 181 F.3d 444 (3d Cir. 1999).

³⁰ *Id.* at 468.

³¹ *Leatherman*, 285 F.3d at 1152.

³² *Id.*

1. District courts have a decided advantage over appellate courts.
2. Even though an appellate court must review the district court's application of the *Gore* test *de novo*, it must still "defer to the district court's findings of fact unless they are clearly erroneous."³³
3. While assigning a "degree of reprehensibility ultimately involves a legal conclusion, we must accept the underlying facts as found by the jury and the district court."³⁴

A jurisdictional review of the Ninth Circuit's *Leatherman* analysis has proved critical to determining which federal or state appellate court will provide an independent constitutional analysis to punitive jury awards. This approach breaks with the tradition of letting juries alone decide these issues.³⁵

IV.

CAMPBELL V. STATE FARM MUTUAL AUTOMOBILE INSURANCE CO.³⁶

The jury in *Campbell* had previously awarded \$2.6 million in compensatory damages and \$145 million in punitive damages. The trial court reduced the awards to \$1 million and \$25 million respectively. However, the Utah Supreme Court later reinstated the \$145 million punitive damage award.

On remand from the United States Supreme Court (which had held that the imposition of a \$145 million punitive damage award was excessive and violated the due process clause), the Utah Supreme Court recalculated the punitive damage award according to the guideposts earlier articulated by the Supreme Court. The Utah Supreme Court defined its role on remand as follows: "The Supreme Court declined, . . . to fix a substitute award, choosing instead to entrust to our judgment the calculation of a punitive award which both achieves the legitimate objectives of punitive damages and meets the demands of due process."³⁷ In doing so, the United States Supreme Court "signaled its intention to vest in us *some* discretion to exercise our independent judgment to reach a reasonable and proportionate award."³⁸

³³ *Id.* at 1150 (quoting *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 441 n.14 (2001)).

³⁴ *Id.* at 1150.

³⁵ *Id.* See also *Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 272 F.3d 1335, 1348 (Fed. Cir. 2001) (noting that "to the extent that the judgment call on reprehensibility can be traced to a jury's assessment of witnesses, independent appellate review is essentially meaningless"). For a discussion of how other courts have treated *Cooper Industries*, see *infra* Section IV.

³⁶ 98 P.3d 409 (Utah 2004), *cert. denied*, 125 S. Ct. 114 (2004).

³⁷ *Id.* at 411-12.

³⁸ *Id.* at 412.

When exercising its discretion, the Utah court properly identified and applied the principles articulated by the Supreme Court in *Campbell*, which had “restated and refined the analytical tools first announced in *BMW of North America, Inc. v. Gore*”³⁹ Specifically, the role of the lower courts was circumscribed as follows:

While authorizing us to determine the amount of the punitive damages award, the Supreme Court leashed us more tightly to the established analytical guideposts of *Gore* in two ways: by narrowing the scope of relevant evidence which we may consider in evaluating the reprehensibility of State Farm’s conduct, and by providing more detailed guidance for determining the relationship between compensatory and punitive damages.⁴⁰

The Utah Supreme Court noted that even though punitive damages in Utah were analyzed under a seven-factor test (commonly known as the *Crookston* standards), it would follow the Supreme Court’s lead and restrict its review of punitive damage awards to the *Gore* guideposts. In addition, the Utah Supreme Court noted that it could only assess State Farm’s conduct within the State of Utah, making any extra-territorial evidence irrelevant. After reviewing the guideposts, the Utah Supreme Court was careful to note that the United States Supreme Court had neither drawn a bright line test nor created categorical classifications for fixing punitive damage awards. Thus, the Utah court concluded that a punitive damage award of \$9,018,780.75 in relation to a compensatory award of \$1.0 million complied with the *Gore* guideposts.

While the Supreme Court in *Campbell* did not establish a precise ratio, it did offer the following prescriptions:

“We decline again to impose a bright-line ratio which a punitive damages award cannot exceed.”⁴¹

“[F]ew awards exceeding a single-digit ratio . . . to a significant degree, will satisfy due process.”⁴²

“[A]n award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety.”⁴³

³⁹ *Id.*

⁴⁰ *Id.* at 413 (citation omitted).

⁴¹ *Id.*

⁴² *Id.*

⁴³ *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003).

The ratio established by the Utah Supreme Court on remand was nine-to-one. Of interest, however, was the *Torres* court's treatment of the ratio issue. In holding that a ratio of 174-to-1 (\$12.0 million punitive versus \$60,000 compensatory damages) violated due process and reducing the award to a ratio of 33-to-1 (\$2.0 million punitive versus \$60,000 compensatory), the court reviewed verdicts from other jurisdictions that exceeded a single digit ratio. The court expressed no inclination to limit the ratio; instead, the court determined that a large damage award was necessary to carry an impact because the defendant possessed a sizeable net worth and had acted with a high degree of reprehensibility.⁴⁴

While the impact of both *Campbell* decisions issuing from the United States Supreme Court and the Utah Supreme Court remains unclear, one commentator has noted:

In cases already briefed counsel should consider supplemental briefing to show how State Farm influences the proceedings. In cases about to be tried, where punitive damages may be an issue, counsel needs to consider how State Farm impacts all ingredients of trial practice. Safeguards may have to be raised, starting perhaps with pretrial or in limine motions, to objections against inflammatory opening statements, to testimony, cross-examination questions, exhibits and other evidence, to summations and jury instructions, to post-trial motions and even to appeals.⁴⁵

It should also be noted that the Utah Supreme Court, citing to the *Cooper* case, has indicated that punitive damages properly lie within the province of the states, and that any determinative factors used by the jury in assessing a punitive sanction are questions of state law.⁴⁶ Therefore, to the extent that the determination of a punitive damage award is left to the jury, the practitioner must take a proactive approach at each stage of the litigation process to ensure that the appropriate factors are presented and considered by the jury.

The Supreme Court in *Campbell* recognized the importance of a proper administration of punitive damages, noting:

We have admonished that “[p]unitive damages pose an acute danger of arbitrary deprivation of property. Jury instructions typically leave the jury with wide discretion in choosing amounts, and the presentation of evidence of a defendant's net

⁴⁴ For an interesting discussion of the impact of *Campbell* and the ratio issue, see Douglas W. Dunham & Ellen P. Quackenbos, *Punitive Damages after Campbell: A Mixed Bag Awaiting Definitive Resolution*, 71 DEF. COUNS. J. 228 (2004). See also Patrick J. Hagan & Anne Marie Bridges, *Punitive Damages: California Model Applying Gore and State Farm*, 54 FED’N DEF. & CORP. COUNS. Q. 343 (2004).

⁴⁵ Michael Hoenig, *Supreme Court Limits Punitive Awards*, N.Y.L.J., Apr. 14, 2003, at 3.

⁴⁶ See *Cooper*, 532 U.S. at 433; *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 278 (1989).

worth creates the potential that jurors will use their verdicts to express biases against big businesses, particularly those without strong local presences.⁴⁷

Therefore, it is incumbent upon the practitioner to fully understand the procedural mechanisms available to test punitive damages claims before they reach the jury and to marshal proof in support of those claims, if necessary. To this end, an exploration of the underpinnings of relevant decisions and their ramifications at the state level may be especially relevant.⁴⁸

V. OPEN ISSUES

Several critical issues, left undetermined by the case law, remain open for consideration. These will affect the practitioner's ability to extend the *de novo* approach to state court actions. Evaluations of and recommendations on these issues follow on a jurisdiction-by-jurisdiction basis.

A. *Are the Three BMW Guideposts Exclusive?*

One lingering question concerns whether there are any factors beyond the guideposts that can be considered in deciding whether a punitive damage award is excessive and, therefore, unconstitutional. A close reading of the *Cooper* decision indicates that it was the Court's intent to treat the three *BMW* guideposts as exclusive. While making no definitive pronouncement to this effect, the Supreme Court in *Cooper* issued the following statement:

[I]n deciding whether [the constitutional] line has been crossed, this Court has focused on the same three criteria: (1) the degree of the defendant's reprehensibility or culpability; (2) the relationship between the penalty and the harm to the victim caused by the defendant's actions; and (3) the sanctions imposed in other cases for comparable misconduct.⁴⁹

⁴⁷ *Id.* at 417 (quoting *Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 432 (1994)).

⁴⁸ For an excellent discussion of the Supreme Court's holding in *Leatherman*, see Michael Brady, *A National Breakthrough in Punitive Damages*, 44 FOR THE DEFENSE, April, 2002, at 12; George Clemon Freeman, Jr., *Constitutional Constraints on Punitive Damages and Other Monetary Punishments*, 57 BUS. LAW. 587 (February 2002). For an excellent discussion of the Supreme Court's holding in *Campbell*, see John J. Pappas & William R. Lewis, *The Campbell Cap*, 17-2 MEALEY'S LITIG. REP. INS. BAD FAITH 14, May 21, 2003, at 27; Robert T. Horst & Mark H. Rosenburg, *State Farm v. Campbell: The United State Supreme Court Reinforces Constitutional Limits on Punitive Damage Awards*, 17-1 MEALEY'S LITIG. REP. INS. BAD FAITH 11, May 1, 2003, at 17; Arnold Levinson, *The Supreme Court's Shameful Descent into Disrepute*, 16-24 MEALEY'S LITIG. REP. INS. BAD FAITH 12, Apr. 16, 2003, at 19, 21.

⁴⁹ *Cooper Industries*, 532 U.S. at 425.

In addition, the Supreme Court instructed appellate courts to consider the same three criteria when evaluating a punitive damage award consistent with due process. In this regard, it is clear that “each of the three *Gore* factors reveals a series of questionable conclusions by the District Court that may not survive *de novo* review.”⁵⁰

It is less clear whether the Utah Supreme Court considers the three guideposts to be exclusive. Based on the following language in its decision, the opposite conclusion is arguable:

Since *Campbell II*, we have continued to apply our state standards, recognizing that they substantially reflect the Supreme Court’s directives and modifying them as necessary to fully meet the federal requirements. *See, e.g., Smith v. Fairfax Realty*, 2003 UT 41, ¶ 31, 82 P.3d 1064. However, in this case we follow the lead of the Supreme Court and restrict our review to the guideposts set forth in *Gore*.⁵¹

As noted above, the Utah courts use a seven-factor test and arguably have retained that test as augmented by *Gore*.

The debate about extraneous criteria is likely to continue in assessing whether a punitive award is excessive. As noted below, such a debate already has evolved concerning the relevance of a defendant’s wealth to the award of punitive damages.

B. *Is the Defendant’s Wealth a Viable Criterion in Assessing an Excessive Award?*

Neither the Ninth Circuit in *Leatherman* nor the Utah Supreme Court in *Campbell* referred to the defendant’s wealth in determining whether the punitive damage award was excessive. In fact, even though the wealth of Cooper Industries was significant to the district court’s determination that the \$4.5 million punitive damage award was not constitutionally excessive and was critical to the Ninth Circuit in its initial review of the award, the United States Supreme Court did not specifically list financial wealth as a criterion. Therefore, a similar review of the relevant decisions is necessary to resolve this dilemma.

The Utah Supreme Court in *Campbell* did not consider wealth at all in reaching its determination. However, it should be noted that one of the seven factors considered by Utah courts when conducting a review under state standards is the “relative wealth of the defendant.”⁵² On review of *Campbell*, the Supreme Court cited *BMW v. Gore* with an oblique reference to the relevance of wealth: “The fact that BMW is a large corporation rather than an impecunious individual does not diminish its entitlement to fair notice of the demands that the several States impose on the conduct of its business.”⁵³ The Supreme Court also issued this telling statement:

⁵⁰ *Id.* at 441.

⁵¹ *Campbell*, 98 P.3d at 414.

⁵² *Id.*

⁵³ *Campbell*, 538 U.S. at 427 (quoting *BMW*, 517 U.S. at 585).

[T]he argument that State Farm will be punished only in the rare case, coupled with reference to its assets (which, of course, are what other insured parties in Utah and other States must rely upon for payment of claims) had little to do with the actual harm sustained by the Campbells.⁵⁴

By contrast, the relevancy of wealth surfaced in the *Torres* case when the court noted that “South Dakota also considers a defendant’s net worth or net income. ‘The wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award.’ Wealth is relevant.”⁵⁵

Obviously, there are two schools of thought developing on this issue. One commentator has noted: “[s]ome observers from the defense side have also claimed that *Cooper* provides limits on whether a defendant’s wealth and profits can properly be considered in determining punitive damages. This is wishful thinking.”⁵⁶ Other commentators have concluded that, “[n]otwithstanding the central role played by *Cooper*’s net worth in the lower courts, the Supreme Court gave no indication that a defendant’s substantial financial condition is a valid consideration in evaluating a punitive award for excessiveness under the Due Process Clause.”⁵⁷ Until the Supreme Court either rejects or specifically includes the defendant’s wealth as an additional criterion or as a relevant aspect of the three *BMW* criteria, the practitioner will have to rely upon a historical analysis of this issue.

Various studies have treated the issue of wealth and found that there are “positive relationships between the wealth of the defendant and the punitive damages awarded.”⁵⁸ Even in light of these experimental studies, some commentators have argued from history that the defendant’s wealth (i.e., financial condition) should not be a criterion that is utilized in determining whether the punitive award is excessive. Other commentators, however, contend that the defendant’s wealth is an appropriate consideration to underscore the deterrent or punitive purpose of any such award.⁵⁹

⁵⁴ *Campbell*, 538 U.S. at 427.

⁵⁵ *Torres v. Travelers Ins. Co.*, CIV. No. 01-5056 at 39-40 (D.S.D., Sept. 30, 2004).

⁵⁶ Robert S. Peck, *Winning Increased Awards after Cooper*, 37 *Trial* 51, 54 (Oct. 2001). See also Theodore J. Boutros, Jr. et al, *Supreme Court Speaks Out on Punitive Damages: Cooper v. Leatherman*, unpublished paper available at www.anet.org/cle/programs/nosearch/tcsmo.html (last visited Sept. 23, 2002).

⁵⁷ Evan M. Tager, *Reading Between the Lines of Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 121 S. Ct. 1678 (2001), 6-17 MEALEY’S EMERGING DRUGS & DEVICES 9, Sept. 6, 2001.

⁵⁸ Robbennolt, *supra* note 3, at 123 n.87 (referencing Mark Peterson et al., *RAND Inst. for Civil Justice, Punitive Damages: Empirical Findings*, 49-53 (1987); VALERIE HANS, *BUSINESS ON TRIAL: THE CIVIL JURY AND CORPORATE RESPONSIBILITY*, 112-37 (2000)). See also Daniel Kahneman et al., *Shared Outrage and Erratic Awards: The Psychology of Punitive Damages*, 16 *J. RISK & UNCERTAINTY* 49, 64 (1998); Edith Greene et al., *The Effects of Limiting Punitive Damage Awards*, 25 *LAW & HUM. BEHAV.* 187, 197 (2000).

⁵⁹ See Robbennolt, *supra* note 3, at 126 n.91 (which references a detailed comparison of the approach taken by various legal scholars).

Recognizing that scholars have joined both sides of this issue, it is important to review how the Supreme Court has treated this issue historically. In at least two cases that pre-date *Cooper*, the Supreme Court has referenced the defendant's financial position as a factor when reviewing a jury award.⁶⁰ However, Justice O'Connor's dissent in *TXO Products Corporation* has not gone unnoticed.⁶¹ In her dissent, Justice O'Connor refers to "strong economic arguments that permitting juries to consider wealth is unwise if not irrational."⁶² Based on this comment, two scholars have concluded that wealth is irrelevant to deterrence and that "punishment based on the characteristics of the actor, rather than on specific misconduct, threatens fundamental notions of freedom from government constraint."⁶³

The reaction of various courts and legislative bodies to use of a defendant's wealth in the assessment of punitive damages is another factor that bears consideration. Beyond the promulgation of Section 7(4) of the Uniform Model Punitive Damages Act, the following states have enacted legislation that allows for consideration of a defendant's wealth: Alaska, California, Kansas, Maryland, Minnesota, Montana, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, and Texas. In contrast, the states of Colorado and North Dakota have enacted specific prohibitions on the use of information pertaining to the defendant's wealth.⁶⁴

How does the fact that a particular state has enacted specific legislation on the issue of wealth impact the Supreme Court's protocol for assessing the constitutionality of a punitive damage award? In *Cooper*, the Court reaffirmed the *Gore* premise that: "States necessarily have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case."⁶⁵ The Court further observed that "legislatures enjoy broad discretion in authorizing . . . punitive damages awards."⁶⁶ One commentator has utilized these statements to conclude that: "where a state punitive damage statute authorizes consideration of the defendant's wealth, the evidence will be admitted."⁶⁷

⁶⁰ See *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 464 n.29 (1993); *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 22 (1991).

⁶¹ See Kenneth S. Abraham & John C. Jeffries, Jr., *Punitive Damages and the Rule of Law: The Role of Defendant's Wealth*, 18 J. LEGAL STUDIES 415 (1989).

⁶² *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 491 (1993) (O'Connor, J., dissenting).

⁶³ Abraham & Jeffries, *supra* note 61, at 423 (citing *Robinson v. California*, 370 U.S. 660 (1962)).

⁶⁴ See Robbennolt, *supra* note 3, at 125 n.93 (citing the various state statutes).

⁶⁵ *Cooper*, 532 U.S. at 433 (quoting *Gore*, 517 U.S. at 568).

⁶⁶ *Cooper*, 532 U.S. at 433.

⁶⁷ Peck, *supra* note 56, at 54 (citing N.C. GEN. STAT. § ID-35 and *Pendelton v. Davis*, 46 N.C. 98 (N.C. 1853) ("[A] thousand dollars may be less punishment to one man than a hundred dollars to another.")).

Recently, the California Court of Appeal also considered the wealth issue in the case of *Romo v. Ford Motor Co.*⁶⁸ Affirming a punitive damage award of \$290 million after conducting a *Cooper* analysis, the California court observed:

We note that neither the United States Supreme Court nor any California court has held that a jury's consideration of the size and resources of a defendant invalidates a punitive damages award. Rather, the courts recognize that a defendant's wealth cannot be the sole criterion for the size of a punitive damages award: ability to pay an award cannot justify an *otherwise excessive* punitive damages award. Here the punitive damages verdict was not "otherwise excessive"; instead, consideration of the size and net worth of a corporate defendant was necessary if the jury was to appropriately vindicate the state's interest in protecting the lives of its citizens.⁶⁹

It should be noted that the defendant, Ford Motor Company, has filed a petition asking the California Supreme Court to determine whether the Court of Appeal was correct in reinstating the \$290 million punitive damage award. Ford Motor contends that the lower court's decision contradicts *BMW* and *Cooper* on the issue of whether evidence of net worth or evidence of profitability derived from a defendant's misconduct constitutes a proper excessiveness criterion.⁷⁰

C. *Must State Courts Follow the De Novo Standard?*

One of the issues derived from a *Cooper/Campbell* analysis concerns whether decisions that arise within the context of the federal court system are applicable to state appellate courts. If the federal decisions are applicable, state appellate courts will be compelled to utilize a *de novo* standard of review. On the other hand, if their review standard is inapplicable, state appellate courts will require an abuse of discretion standard, provided that the state court imposes such a standard.

A *de novo* standard requires an appellate court to conduct an independent, detailed, factual analysis of the record instead of deferring to a trial court. Under an abuse of discretion standard, the appellate court must affirm the lower court's determination if there is some basis to support the conclusion reached by the trial court, even if the appellate court disagrees with the conclusion reached.

⁶⁸ 122 Cal. Rptr. 2d 139 (Ct. App. 2002).

⁶⁹ *Id.* at 167 (internal citation omitted).

⁷⁰ *See also* *Adams v. Mura Kami*, 813 P.2d 1348 (Cal. 1991).

Although an analysis of the *Erie* doctrine⁷¹ (which provides that the federal Courts of Appeals must apply the forum state's substantive law and federal procedural rules) is beyond the scope of this article, the practitioner must recognize that the *Cooper* decision intrudes as well on *Erie* principles. One author characterizes the potential *Erie* problem as follows:

A clash appears inevitable. And although one might argue that the principle upon which *Cooper* rests—that punitive damages are not a “fact” to be found by the jury, and therefore not entitled to abuse of discretion review in the first instance—it remains the case that the vast majority of jurisdictions which permit punitive damage awards have historically viewed punitive awards as being within the province of the jury. Indeed, until *Cooper*, such was the view of the Supreme Court.⁷²

Since the decision in *Cooper*, various courts have considered whether they are compelled to follow the *de novo* standard or may follow the standard prescribed by the state instead.⁷³ Their determinations vary.

1. Jurisdictions That Declined to Follow or Otherwise Distinguished *Cooper*

The following states have either refused to follow *Cooper* or distinguished its applicability:

- California: (*Simon v. San Paolo U.S. Holding Co.*⁷⁴). The court purported to follow *Cooper*, deciding however that it should defer to the jury's holding unless it is “clearly erroneous.”
- Georgia: (*Time Warner Entertainment Co. v. Six Flags Over Georgia, LLC*⁷⁵). The Georgia court found that *Cooper* did not apply because the defendant failed to assert that the punitive damage award violated the U.S. Constitution. The Supreme Court had remanded the case in light of *Leatherman*. This appellate decision also overturned *Kent v. A.O. White*,⁷⁶ which had held that the *de novo* standard applied.

⁷¹ *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

⁷² Lisa Litwiller, *Re-examining Gasperini: Damages Assessments and Standards of Review*, 28 OHIO N.U. L. REV. 381, 384 (2002).

⁷³ *See id.* at 411-420 (contains a complete discussion of the cases cited in text indicating how they have treated the *Cooper* rationale).

⁷⁴ No. B121917, 2001 WL 1380836 (Cal. Ct. App. Nov. 7, 2001) (an unpublished opinion that cannot be relied upon per Cal. R. Ct. 977(a)).

⁷⁵ 563 S.E.2d 178 (Ga. Ct. App. 2002).

⁷⁶ 559 S.E.2d 731 (Ga. Ct. App. 2002).

- New Jersey: (*Lockley v. Turner*⁷⁷). The court only found *Cooper* to be instructive, noting that a jury verdict should be affirmed if there is “reasonable support on the record.” Furthermore, the decision of the trial judge on a motion should not be reversed “unless it clearly appears that there was a miscarriage of justice under the law.”
- New Mexico: (*Seitzinger v. Trans-Lux Corp.*⁷⁸). The court stated that *Cooper* did not impose a *de novo* review standard as a matter of federal constitutional imperative, but merely constituted a procedural federal option. Consequently, the court was free to apply its own standard.
- Oregon: (*Bocci v. Key Pharmaceuticals, Inc.*⁷⁹). The court applied its “rational juror” test in reversing awards of punitive damages and held that nothing in *Cooper* questioned that standard.

2. Jurisdictions That Followed *Cooper*

The following cases have specifically reviewed the *Cooper* decision and recognized applicability of the *de novo* standard:

- Alabama: (*Horton Homes, Inc. v. Brooks*⁸⁰). The court applied the *de novo* standard required by *Cooper* and remitted the case to the trial court to determine the punitive award. The court had previously voided a state statute providing that no presumption of correctness exists in a jury’s punitive damage award.⁸¹
- Louisiana: (*In re New Orleans Train Car Leakage Fire Litigation*⁸²). The court reviewed the due process argument by conducting a *de novo* review as required by *Cooper*. In addition, the court reviewed whether the amount was reasonable under Louisiana law (applying an abuse of discretion standard).
- Utah: (*Campbell v. State Farm Mutual Automobile Insurance Co.*⁸³). The court noted that because the Fourteenth Amendment of the United States Constitution applied to state courts, it would adopt the *Cooper de novo* standard.

⁷⁷ 779 A.2d 1092 (N.J. Super. Ct. App. Div. 2001).

⁷⁸ 40 P.3d 1012 (N.M. Ct. App. 2001), *cert. granted*, 40 P.3d 1008 (N.M. 2002).

⁷⁹ 35 P.3d 1106 (Or. Ct. App. 2001).

⁸⁰ 832 So. 2d 44 (Ala. 2001).

⁸¹ *See also* Acceptance Ins. Co. v. Brown, 832 So. 2d 1 (Ala. 2001).

⁸² 795 So. 2d 364 (La. Ct. App. 2001).

⁸³ 65 P.3d 1134 (Utah 2001).

- Arkansas: (*McNair v. McNair*⁸⁴). The court followed a *de novo* standard prior to *Cooper*.
- Iowa: (*Spaur v. Owens-Corning Fiberglas Corp.*⁸⁵). The court followed a *de novo* standard prior to *Cooper*.
- West Virginia: (*Gannes v. Fleming Landfill, Inc.*⁸⁶). The court followed a *de novo* standard prior to *Cooper*.

3. Jurisdictions That Have Not Considered *Cooper* Applicability

In those jurisdictions that have not yet addressed *Cooper* applicability, the practitioner must undertake a search to determine the rationale and history of the standard applied by the court. The courts generally will apply an abuse of discretion standard or a standard which is based on a finding that the award is clearly erroneous. Various jurisdictions can be divided into broad categories with different means of conducting a deferential review of the jury's award.⁸⁷

- The States of Michigan, Mississippi, Pennsylvania, Rhode Island, and South Carolina have applied an abuse of discretion standard and will reverse when there is a finding that the punitive damage award shocks the conscience of the court.
- The States of Arizona, Delaware, Oklahoma, and Vermont apply the abuse of discretion standard and will reverse when the award is the product of the jury's "passion and prejudice."
- The States of Colorado, Tennessee, and Texas apply the abuse of discretion standard and will reverse if there is a finding that the award was based on passion or prejudice.
- The States of Connecticut, Idaho, Montana, New Hampshire, and Virginia apply an abuse of discretion standard and will reverse if the award is not supported by "substantial evidence."
- The State of Nevada applies the abuse of discretion standard and will not reverse if the award is supported by "substantial clear and convincing evidence."

⁸⁴ 870 S.W.2d 756 (Ark. 1994).

⁸⁵ 510 N.W.2d 854 (Iowa 1994).

⁸⁶ 413 S.E.2d 897 (W. Va. 1991).

⁸⁷ See Litwiller, *supra* note 72, at 417-19 (for a complete discussion of the cases in each of the jurisdictions cited).

- The State of New York utilizes an abuse of discretion standard and applies a statutory test that requires reversal when there is a “material deviation.”
- The State of Minnesota applies a “clearly erroneous” test and will reverse if the award is unreasonable.
- The States of Hawaii, Illinois, and Maine apply the abuse of discretion standard but do not articulate a threshold for reversal.
- The States of Kentucky, North Dakota, South Dakota, Wisconsin, and Wyoming established a threshold but are deferential to the jury’s award.
- The State of Ohio, in the case of *American States Insurance Co. v. Sovereign Chemical Co.*,⁸⁸ recently held that the jury had a “reasonable basis” for determining the amount of a punitive damage award, which did not result from passion or prejudice.
- The State of Washington utilized several standards in assessing whether the verdict should be reversed. These included verdicts “outside the range of substantial evidence;” verdicts that “shock the conscience of the court;” or verdicts resulting from jury “passion or prejudice.”
- The States of Maryland and North Carolina do not have a standard of review and do not recognize an appeal which challenges the punitive damage award as excessive.

Until a particular jurisdiction has considered how it will treat the *de novo* standard recommended in *Cooper* and confirmed by *Campbell*, the practitioner should challenge a jury award based on the *Cooper* rationale, utilizing the applicable state standard of review and threshold as well. That being said, counsel should not concede that *Cooper* is inapplicable to state court actions and need not be followed by state appellate courts. Nor should the state standard be ignored.⁸⁹

The case of *Textron Financial Corp. v. National Union Fire Insurance Co.*⁹⁰ is instructive about how to preserve the *Cooper* challenge and how to ensure that the state standard is considered by the appellate court. In determining whether the punitive damage award was constitutionally excessive, the California appellate court initially reviewed the jury’s award of \$10 million and the trial court’s reduction to \$1.7 million under the factors enumerated in *Cooper*. The case had been remanded to the appellate court by the California

⁸⁸ No. 20794, 2002 WL 1376057 (Ohio Ct. App. June 26, 2002).

⁸⁹ See, Tager, *supra* note 57, at 9.

⁹⁰ 2002 WL 1399105 (Cal. Ct. App. June 28, 2002).

Supreme Court with instructions to review the constitutional validity of the punitive damage award under the *Cooper* standard of independent review. Following its *de novo* review, the Court of Appeal concluded that the punitive award did not violate the defendant insurance company's constitutional right of due process. The court's analysis, however, went on to consider the punitive damage award under California law. Specifically, the court stated:

As for the excessiveness of the punitive damages award under state law, “[t]he California Supreme Court has established three criteria for making that determination: (1) the reprehensibility of the defendant’s misdeeds; (2) the amount of compensatory damages, though there is no fixed ratio for determining whether punitive damages are reasonable in relation to actual damages; and (3) the defendant’s financial condition [Citations].”⁹¹

With respect to the first two criteria (reprehensibility and ratio), the court concluded that its analysis would warrant the same conclusions as those reached by a *de novo* review conducted pursuant to the *Cooper* instructions. As noted above, *Cooper* does not consider the wealth of the defendant in determining the excessiveness of any award. By contrast, California currently does consider the defendant's wealth, and will likely continue to do so. Without addressing whether the defendant's wealth retains validity under *Cooper* or whether the court considers the criteria set forth in *BMW* to be exclusive, the court noted:

“[t]he wealthier the wrongdoer, the larger the punitive damage award must be to meet the goals of punishment and deterrence [Citations].” Consequently, to enforce the purpose of punishing the wrongdoer and determining similar future wrongful conduct, the award necessarily had to be large enough to affect a corporate entity such as National Union.⁹²

Until the highest court of a particular state concludes that the criteria provided by *BMW* are exclusive, or the United States Supreme Court decides whether state appellate courts must apply the *BMW* criteria on constitutional grounds, or a state legislature otherwise addresses the issues, the practitioner should follow the mechanism used by the *Textron* court. This protocol will require the practitioner to litigate and preserve the record based on both the *Cooper/Campbell* standard and the state standard. The failure to approach a punitive damage award in this fashion could result in the loss of an appeal.

⁹¹ *Id.* at *16 (quoting *Stevens v. Owens-Corning Fiberglas Corp.*, 57 Cal. Rptr. 2d 525, 533 (Ct. App. 1997)).

⁹² *Textron Fin. Corp.*, 2002 WL 1399105, at *16 (internal citations omitted).

VI. PROCEDURAL ALTERNATIVES

A. *Pleadings*

When faced with a complaint which includes a claim for punitive damages, the practitioner immediately should investigate the basis for the underlying factual predicate and determine the status of applicable law within the pertinent jurisdictions. Once the initial investigation and research is completed, the practitioner should prepare an answer that contains specifically drafted affirmative defenses which are tailored to the particular case. Based on the impact of *Cooper* and *Campbell*, these defenses should include all relevant affirmative defenses allowed by state and federal law, including various constitutional challenges.⁹³

B. *Pretrial Motions*

Once paper discovery is completed, the practitioner should assess the allegations contained in the complaint and those in the discovery response to determine whether the allegations are sufficient to withstand a motion to dismiss and/or a motion for summary judgment. For example, a plaintiff in California has the burden of proof that he or she is entitled to a punitive damage award based on clear and convincing evidence.⁹⁴ Therefore, where it appears from the pleadings that a plaintiff cannot meet this burden of proof, a motion for summary judgment is warranted.⁹⁵ One study has indicated that a jury may have difficulty differentiating the traditional burden of proof (i.e., a preponderance of the evidence) from the clear and convincing standard. It has even been suggested that this difficulty may work in the plaintiff's favor or have little to no effect.⁹⁶

⁹³ See Appendix A, which includes sample affirmative defenses premised upon various constitutional challenges; see generally Christina J. Imre, *Punitive Damages and Bad Faith: Improving the Odds*, American Conference Institute Seminar on Bad Faith and Punitive Damages, San Francisco, Cal., Apr. 18-19, 2002; Philip L. Johnson, *Defending Against Punitive Damages*, DRI Seminar Insurance Claims Supervision, May 20-21, 1999 at 131.

⁹⁴ See *Basich v. Allstate Ins. Co.*, 105 Cal. Rptr.2d 153 (Ct. App. 2001); *Adams v. Allstate Ins. Co.*, 187 F. Supp. 2d 1207 (C.D. Cal. 2002).

⁹⁵ See Robbenolt, *supra* note 3, at 176-77 (for a discussion of the higher standard of proof (i.e., clear and convincing)).

⁹⁶ See *id.* (discussing the research conducted to date and the reports of David Crump, *Evidence, Economics, and Ethics: What Information Should Jurors Be Given to Determine the Amount of a Punitive Damage Award*, 57 MD. L. REV. 174 (1998); Jan Woodward Fox & Kate McConnico, *Punitive Damages in Texas 1995: Chapter 41 of the Texas Civil Practice & Remedies Code*, 21 T. MARSHALL L. REV. 21, 27 (1996)).

Consequently, where it is apparent from the pleadings that the plaintiff may be unable to meet its burden, it may be more prudent for the practitioner representing the defendant to enter a motion for summary judgment. A judge may be better situated to understand the higher burden and strike the punitive damages claim. In some instances where the facts are not clear, it may be necessary to depose the parties before challenging the punitive damage claim. Making the motion for summary judgment at an early stage holds strategic advantage; if the defendant is successful, he or she may get the upper hand in settlement. Even if the defendant's motion is denied, the plaintiff would have had to expose its proof in the opposing papers, providing counsel with a further road map on how to defend the case.⁹⁷

C. *Trial Stage*

1. Motions

a. *Bifurcation*

Consistent with the procedural rules of the particular jurisdiction and prior to trial, the defense practitioner should consider a motion to bifurcate, requesting that the issue of punitive damages be segregated from the rest of the trial. The following states have enacted legislation which, in one way or another, allows a separate proceeding: Alaska, California, Georgia, Kansas, Minnesota, Missouri, Montana, Nevada, New Jersey, North Dakota, Ohio, Oklahoma, Texas and Utah. In addition, Section 11 of the Uniform Model Punitive Damages Act and Rule 42(b) of the Federal Rules of Civil Procedure also allow separate proceedings.⁹⁸ The concept of bifurcation follows the rationale that the issues surrounding a claim for punitive damages may prejudice the jury in deliberating liability and the amount of any compensatory damage award.⁹⁹

b. *Experts*

Depending on the nature of the underlying claim (i.e., products liability, medical malpractice, bad faith, or toxic tort), the practitioner should be prepared to file a motion *in limine* or a lone pine motion that challenges the qualifications of the opposing party's experts.¹⁰⁰

⁹⁷ See Imre, *supra* note 93, at 6.

⁹⁸ See Robbennolt, *supra* note 3, at 178 n.339.

⁹⁹ See *id.* (discussing the empirical findings in the report of Stephen Landsman et al., *Be Careful What You Wish For: The Paradoxical Effects of Bifurcating Claims for Punitive Damages*, 1999 WIS. L. REV. 297, 330, 331).

¹⁰⁰ For a discussion of the procedural aspects of these types of motions, see Thomas F. Segalla, *Bad Faith as a Continuum: From Claim to Trial*, 52 FED'N DEF. & CORP. COUNS. Q. 103, 143 (2001).

2. Jury Instructions

The New York Pattern Jury Instructions list varying criteria by which to determine the amount of punitive damages (i.e., reprehensibility, actual and potential harm, and defendant's financial condition) but indicate as well that there is no exact formula. In addition, the instructions provide that such damages are meant to punish the defendant for "wanton and reckless, malicious acts."¹⁰¹ While each jurisdiction may have its own procedural rules governing the propriety of relevant instructions, the instructions should be crafted well in advance of the charging conference. In fact, a clear understanding of the burden of proof can help defense counsel draft discovery demands at the pleading stage. It is axiomatic that a vague jury instruction can be more harmful than no instruction at all. However, it is critically important that where punitive damages must be decided by the jury, the court should not invade the province of that jury.

Relevant instructions governing the issue of punitive damages in the various states have been scrutinized by the United States Supreme Court on several occasions.¹⁰² It should be noted, however, that providing more detailed instructions to the jury may not compensate for a jury's "low comprehension and ability to use punitive damages instructions."¹⁰³ Such reservations offer greater reason to opt for the judge, who may be better equipped to avoid arbitrariness, passion, or bias.

3. Trial Evidence.

The *Cooper* and *Campbell* cases, which authorize *de novo* review of the trial record, make it extremely important to have a complete trial record. Therefore, counsel should take every step to preserve the record. This requires making proper objections to the trial court's rulings as well as an offer of proof where testimony is excluded. In addition, counsel should request that the court rule on the precise testimony. The same is true with regard to documentary evidence. When a document is excluded, it should be offered and marked as an excluded exhibit. The excluded testimony and exhibits should be made part of any record on appeal.¹⁰⁴

¹⁰¹ N.Y. P.J.I.3d 2:277 (2004).

¹⁰² See *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 22, 42-43 (1991); *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 464, 475 (1993). See also Robbennolt, *supra* note 3, at 188-90, for a discussion of the more detailed instructions provided by California and the Uniform Model Punitive Damages Act §7 (1996).

¹⁰³ Robbennolt, *supra* note 3, at 189-90.

¹⁰⁴ See *Imre*, *supra* note 93, at 11; *Johnson*, *supra* note 93, at 139.

4. Trial and Post-Trial Motions.

As with the trial of any lawsuit, the practitioner should develop specifically crafted motions that test the plaintiff's burden of proof during the course of the trial and at the end of the case. A discussion of these motions is beyond the scope of this article; however, the practitioner should consider entering a motion for directed verdict, a motion notwithstanding the verdict, or a motion for new trial. Motions at these stages of the litigation will call upon the judge to interject his or her judgment in the determination process. As noted above, the judge may be the more favorable trier of fact in a punitive damages situation.

D. *Actions after Judgment*

Before a money judgment is entered, counsel for the defendant should seek a stipulation from opposing counsel that stays the enforcement of any such judgment. Absent the ability to secure a stipulation, counsel should seek judicial intervention and request a stay from the court pending a decision on appeal.

If counsel intends to appeal, a security bond will be required in most jurisdictions. The requirement of a security bond attempts to balance the injured plaintiff's interest in full compensation with the defendant's interest in avoiding a legally flawed judgment (i.e., a constitutionally excessive punitive damage award).¹⁰⁵ While various states have established different requirements concerning the amount of the security bonds, the monetary requirements in some jurisdictions are so large that they may interfere with the defendant's ability to perfect and prosecute an appeal.¹⁰⁶ An affordable appellate bond may be justified in some instances, but in other instances, "[a] better response to the threat of aberrant verdicts would be to reconsider altogether the requirement of supersedeas bonds to stay enforcement of punitive damages judgments."¹⁰⁷ As an alternative, the practitioner should explore Section 13 of the Uniform Model Punitive Damages Act and Rule 62(d) of the Federal Rules of Civil Procedure, as appropriate. Either may provide greater flexibility with a remedy other than payment of a full security bond.

¹⁰⁵ See Michael Finch, *Giving Full Faith and Credit to Punitive Damages Awards: Will Florida Rule the Nation?*, 86 MINN. L. REV. 497, 524 (2002).

¹⁰⁶ *Id.* at 524-25.

¹⁰⁷ *Id.* at 525.

VII. CLASS ACTION IMPLICATIONS

A. *In General*

Given the jury verdicts in *Engle v. R.J. Reynolds Tobacco Co.*,¹⁰⁸ and *Bullock v. Philip Morris*,¹⁰⁹ it is clear that tobacco industry litigation is venturing into untested waters. While the *Bullock* case concerned an individual claim against the tobacco industry, the *Engle* litigation arose in the context of a class action.

The dilemma facing defendants in the tobacco litigation and any other mass tort litigation has been contextualized as follows: “Punitive damages are not an entitlement of the victims, but of society: a punitive damages award is a civil punishment visited upon defendants to vindicate the public interest in deterrence, and to penalize conduct that violates the social contract and injures society.”¹¹⁰ Critics of these verdicts have noted that a mechanism is needed to redress “any imbalance created when successive punitive damages awards for the same violative conduct threaten overdeterrence. . . .”¹¹¹ Any relevant mechanism should be able “to reach and distribute equitably a sufficient and proportional punitive damages award among all victims.”¹¹² The mechanism must be crafted to avoid a windfall to the select few who win the race to the courthouse.

As a consequence of applying traditional class action concepts, many individuals with equally viable claims have not shared in punitive awards because of their financial impact on defendants. Similarly, in one-on-one non-class litigation, there exists no procedural mechanism to rectify inconsistent, cumulative, or excessive awards. Consequently, the task of crafting a procedural mechanism that will satisfy the purposes of punitive damages without otherwise destroying an industry or prejudicing victims with subsequent claims is relegated to defense practitioners and the courts. For example, in the *Engle* case, the court instituted a three-phase jury trial which asked one jury to render three special verdicts: liability of the defendant to the class; assessment of massive punitive damages against each defendant,

¹⁰⁸ No. 94-082073 (Fla. Cir. Ct., Dade Co. 2000) (returning a verdict of \$145 billion in punitive damages on July 14, 2000).

¹⁰⁹ No. BC249171, 2002 WL 31833905 (Cal. App. Dep’t Super. Ct. Dec. 18, 2002) (awarding \$28 billion in punitive damages).

¹¹⁰ Elizabeth J. Cabraser, *Unfinished Business: Reaching the Due Process Limits of Punitive Damages in Tobacco Litigation Through Unitary Classwide Adjudication*, 36 WAKE FOREST L. REV. 979, 981 n.3 (2001) (citing *Fuzzy Hairstylists, Inc. v. Eagle Star Ins. Co.*, 392 N.Y.S.2d 554, 556 (N.Y. Civ. Ct. 1977)).

¹¹¹ *Id.* at 981-82.

¹¹² *Id.* at 982.

and compensatory damage verdicts for each class representative. The mechanism established in *Engle* clearly has its critics; however, any criticism is purely speculative at this point. Ultimately, the issues will resolve only when this case finds its way to the Supreme Court.

From a pragmatic standpoint, however, the judgment in *Engle* only confers a benefit on smokers in the State of Florida. Residual questions concern whether the victims/smokers in other states will be able to collect, and what will happen if repeated and cumulative judgments exceed the industry's ability to pay. It is beyond dispute that there is an economic need to apply some procedural mechanism to protect, reconcile, and harmonize the interests of the victims (and society itself) in the defendant's punishment and deterrence, counterbalanced by the defendant's due process rights to avoid extinction in the name of atonement. Of all the available procedural mechanisms, Federal Rule 23(b)(1)(B) is the most elegant, comprehensive, and fair.

In the case of *In re Simon II Litigation*,¹¹³ Federal District Judge Jack B. Weinstein applied Rule 23(b)(1)(B) of the Federal Rules of Civil Procedure to certify a punitive damage class that covers millions of smokers in the United States who are living or deceased, and who have been diagnosed with a tobacco-related disease since April 9, 1993. In certifying the class, Judge Weinstein stated that he was granting certification as "an attempt to provide a procedural solution to the problem of repetitive and unrelated judgments for punitive damages (limited by constitutionally required overall [damage] caps) in this massive and complex litigation."¹¹⁴ The court there likewise established a three-stage trial:

- Stage 1 — Jury will make a class-wide determination on liability and the estimated total value of compensatory damages. If liability and compensatory damages are found, the jury will proceed to the next stage.
- Stage 2 — Jury will make a determination about whether the defendant's conduct warrants punitive damages. If the jury decides that the threshold has been met, the case will proceed to the next stage.
- Stage 3 — The punitive damages amount will be determined and allocated on a disease-by-disease basis according to an established plan.

It should be noted, of course, that class certification is not only applicable to mass tort litigation. In the case of *Rose v. United Equitable Insurance Co.*,¹¹⁵ the North Dakota Supreme Court determined that a class action could proceed. The claim there alleged that

¹¹³ 211 F.R.D. 86 (E.D.N.Y. 2002).

¹¹⁴ *Id.* at 96.

¹¹⁵ 651 N.W.2d 683 (N.D. 2002).

nursing home insurance policies written by United Equitable were improperly written and defectively underpriced. As a result, the insurer knew that premium increases would be exorbitant when implemented on renewal.

The application of Rule 23(b)(1)(B), which creates a mandatory punitive damages class, is generally appropriate where there are multiple claimants to a “limited fund” which faces likely depletion when those who are first to sue recover damages, leaving no means of recovery for late-comers.¹¹⁶ Rule 23(b)(1)(B) is also appropriate when multiple punitive damage claims are instituted in different jurisdictions at different times by multiple victims, with the potential to exhaust the substantive legal limits established by the court as permissible punishment. This is referred to as the “limited punishment theory.”¹¹⁷

B. *Affect of Cooper and Its Progeny*

It has been noted that the addition of the *Cooper* decision “create[s] a Supreme Court punitive quartet, and the controlling jurisprudence with the procedural mechanism of Rules 23(b)(1), 23(c)(4)(A), and 42(b) creates a mechanism tailored to balance the scales through unitary adjudication of the total punitive damages liability, yield[ing] a resulting award that is ‘just right.’”¹¹⁸ The three other cases comprising the quartet are *Haslip*, *TXO*, and *BMW*. The latest addition is *Campbell*. The rationale of these cases, including the *de novo* review standard prescribed by the Supreme Court in *Cooper*, has been tested in the case of *In re New Orleans Train Car Leakage Fire Litigation*.¹¹⁹ The jury in that case followed a trial structure similar to that used in *Simon* and awarded \$2.5 billion in punitive damages against the defendant railroad. The case involved injuries sustained during and after the explosion of railroad tank cars filled with butadiene, which was flammable and toxic. The trial court later reduced the aggregate punitive damage award to \$850 million, but the ratio of punitive to compensatory damages was approximately 850-to-1.

The Louisiana Court of Appeals affirmed the \$850 million punitive damage award after reviewing the ratio of punitive to compensatory damages awarded in *TXO* (526-to-1) and in *BMW* (500-to-1).¹²⁰ The court rejected any need to find mathematical precision or bright line boundaries. However, the court noted that “in order to assess the extent of the punishment and deterrence that will be inflicted by a particular amount of punitive damages, it is necessary to consider the financial situation of the defendant.”¹²¹

¹¹⁶ See Cabraser, *supra* note 110, at 1027-28.

¹¹⁷ *Id.* at 1030-33.

¹¹⁸ *Id.* at 1037.

¹¹⁹ 795 So. 2d 364 (La. Ct. App. 2001). For a complete analysis of the *New Orleans Train Car* case, see Cabraser, *supra* note 110, at 1037-41.

¹²⁰ 795 So. 2d 382-88.

¹²¹ *Id.* at 388.

Analyzing whether the \$850 million punitive damage award was more than necessary to achieve its punitive and deterrent purposes, the court first determined that the award was eighteen percent of the defendant's net worth but then concluded that such an award was not an abuse of discretion. In so doing, it appears that the court conducted a *de novo* review and also utilized the state's abuse of discretion standard to determine whether the trial court's reduction should be reversed or affirmed.

Within the context of class action litigation, the concomitant need for an appropriate punitive award mechanism is best articulated as follows:

[A] carefully structured, and fairly conducted, general compensatory liability, punitive damages liability, and punitive damages quantum trial can pass constitutional muster, and is far superior, from the standpoints of efficiency, economy, and equity, to the present regime of scattered, piecemeal, repetitious, inconsistent, and endlessly challenged individual . . . punitive damages awards.¹²²

Until the United States Supreme Court tests the trial structure devised by the judges in *Simon and New Orleans Train*, the creative and collective wisdom of these trial courts and counsel who represent litigants will surface the best structures to fulfill punitive sanctions and afford protection to all parties.

¹²² Cabraser, *supra* note 110, at 1041. See also Laura J. Hines, *Obstacles to Determining Punitive Damages in Class Actions*, 36 WAKE FOREST L. REV. 889 (2001); Joan Steinman, *Managing Punitive Damages: A Role For Mandatory "Limited Generosity" Class and Anti-Suit Injunctions?*, 36 WAKE FOREST L. REV. 1043 (2001); Richard A. Nagareda, *Punitive Damage Class Actions and the Baseline of Tort*, 36 WAKE FOREST L. REV. 943 (2001).

VIII. CONCLUSION

It is beyond dispute that the Supreme Court decisions in *Cooper* and *Campbell*, combined with the *de novo* analysis conducted by the Ninth Circuit on remand, have changed the perspective of trial lawyers and trial court judges. If consistency, uniformity, and predictability in the manner and methods used to impose and assess punitive damage awards are not achieved, the tort restrictionists will continue their call for punitive damage reform. Though the viability and need for any proposed reforms are left for another day, the practitioner, in the interim, must tread a conservative step in handling punitive damage claims. This approach should include a jurisdictional analysis of the prevailing standard of review (abuse of discretion or *de novo*); the burden of proof (clear and convincing or preponderance of the evidence); and the threshold for imposing such damages (shocking to the conscience or passion and prejudice). Furthermore, when confronting a class action and potential class certification, the defense practitioner must assess whether available award mechanisms will afford uniformity and consistency while limiting exposure in a multiple claims situation.

The last chapter on these issues has yet to be written, since empirical data does not yet define any benefits derived in switching from juries to judges or individual lawsuits to class actions. And the final parameters have yet to be judicially or legislatively set. Given the comments made by the Utah Supreme Court in *Campbell* that it will continue to apply “state standards,”¹²³ and given that South Dakota continues to incorporate a five-factor test within the three *Gore* guideposts,¹²⁴ a further Supreme Court pronouncement is surely in order.

¹²³ *Campbell*, 98 P.3d at 414.

¹²⁴ *Torres v. Traveler’s Ins. Co.*, CIV. No. 01-5056 (D.S.D., Sept. 30, 2004).

APPENDIX A
AFFIRMATIVE DEFENSES*

As and for a First, Separate and
Distinct Affirmative Defense on Behalf of Defendant

1. The imposition of punitive damages on the facts alleged in the complaint would violate the due process clauses of the Constitutions of the United States and the State of New York.

As and for a Second, Separate and
Distinct Affirmative Defense on Behalf of Defendant

2. The imposition of punitive damages on the facts alleged in the complaint would violate the excessive fines clause of the Constitution of the State of New York.

As and for a Third, Separate and
Distinct Affirmative Defense on Behalf of Defendant

3. The imposition of punitive damages on the facts alleged in the complaint is barred by the double jeopardy clause of the Fifth Amendment to the United States Constitution, and Article I, Section 6 of the New York State Constitution.

As and for a Fourth, Separate and
Distinct Affirmative Defense on Behalf of Defendant

4. The imposition of punitive damages on the facts alleged in the complaint is barred by the *ex post facto* clause of the United States Constitution.

*These defenses should be assessed for each particular case.

As and for a Fifth, Separate and
Distinct Affirmative Defense on Behalf of Defendant

5. The imposition of punitive damages on the facts alleged in the complaint is barred by the United States Constitution and by the Constitution of the State of New York.

Expert Witnesses on Insurance Issues: Locating Them, Retaining Them, and Presenting Their Testimony[†]

Douglas G. Houser
Dennis J. Wall

I. INTRODUCTION

At first blush, insurance may seem like a fairly narrow area on which to focus discussion about opinion testimony by expert witnesses. But since the insurance field itself is actually very broad, the presence or retention of expert witnesses figures prominently in the resolution of many insurance cases. Thus, the comments, suggestions, and observations made in this article will apply, whether the policyholder or the insurance company is seeking the services of an expert witness, or whether it is the policyholder counsel or the carrier counsel who is called upon to locate, retain, and employ the opinion testimony of expert witnesses on insurance-related matters.

Initially, this article addresses the threshold question of when an expert should be used in related insurance litigation. Assuming the decision to employ an expert, the article proceeds to discuss some of the sources available to locate experts, the qualifications necessary to support expert testimony on insurance issues, and the actual presentation of expert testimony in the insurance case.

[†] It should be noted that both authors have been retained as experts on many insurance matters. This article represents their collective research and judgment on the various insurance issues as they affect expert opinion testimony.



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In considering when an expert should be used and when an expert might be avoided, this article narrows its focus to the particular area of expertise within the field of insurance, citing cases and offering practical examples of when opinion testimony is necessary and when precedent has allowed for its introduction. After focusing on the particular field of expertise involved, the article proceeds to address the qualifications of expert witnesses. This concentration offers practical ideas for locating appropriate expert witnesses and posing questions for discussion with the potential expert in a given case, including fees. Finally, this article will address the case law requirements concerning what might be called "record fundamentals," covering additional issues upon which expert witnesses might or might not successfully offer opinion testimony.

II. WHEN TO USE AN EXPERT

Not every case lends itself to the use of an expert witness. If the insurance issue is one of "coverage" and the policy is unambiguous, the trial judge is the appropriate person to



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interpret the policy language rather than an outside “expert.”¹ Furthermore, depending upon the degree of sophistication commonly held by the parties to the dispute, it may be that “custom or practice” or “special industry meaning” is appropriate.² This need might occur in the case of an inter-company coverage issue between two different insurers.

The insurance company is less likely to favor using an expert than is the policyholder. The insurance company frequently would prefer to argue that the policy language is free from ambiguity and that expert testimony is not appropriate. If that is not the case, an imaginative party in an insurance dispute might be able to greatly affect the resolution of

¹ See, e.g., *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016-17 (9th Cir. 2004) (California law); *Employers Reinsurance Corp. v. Mid-Continent Cas. Co.*, 358 F.3d 757, 764 (10th Cir. 2004) (Oklahoma law); *Montoya Lopez v. Allstate Ins. Co.*, 282 F. Supp. 2d 1095, 1104-05 (D. Ariz. 2003) (rejecting preferred opinion of an expert in part because the opinion consisted “primarily of legal conclusions as to the reasonableness of Allstate’s actions, which are not proper matters for an expert opinion”); *Employers Reinsurance Corp. v. Mid-Continent Cas. Co.*, 202 F. Supp. 2d 1212, 1218 (D. Kan. 2002) (involving good faith and fair dealing insurance issues: “The Court will determine whether a [good faith] duty exists and so instruct the jury. Expert testimony on the subject is improper (citations omitted).” *But cf.* *Royal Maccabees Life Ins. Co. v. James*, 146 S.W.3d 340, 354 (Tex. Ct. App. 2004) (holding that “the insurance policy is ambiguous as a matter of law,” for which reason the trial court did not abuse its discretion in allowing an expert witness “to testify as to his interpretation of the policy. [The expert] testified that the conduct of Royal Maccabees constituted bad faith, unfair dealing and fraud and also that it violated various provisions of the insurance code and the deceptive trade practices act.”)).

² For example, in *Employers Reinsurance*, although an expert was not allowed to provide opinion testimony on the existence of legal duties or on the legal meaning of various terms such as “waiver” and “estoppel,” the same expert *was* allowed to offer other opinions that related instead to the meaning of an insurance agreement “in light of insurance industry custom and practice.” 202 F. Supp. 2d at 1217.

the dispute by creatively finding opportunities to utilize expert testimony.³ For example, in an insurance property loss where the policyholder claims she was the victim of burglary or vandalism, the insurance company might call a police officer or other specially trained law enforcement officer to express an opinion about whether “forcible entry” occurred. In other cases, a former FBI or other specially trained law enforcement officer may be utilized to describe the “personality profile” of the suggested vandal, which might arguably match the personality profile of the policyholder.

There is, of course, one overriding caveat: a rose by any other name might smell as sweet, but an expert is never an expert on everything. It has been suggested that counsel should narrowly select the area of insurance where expertise is needed in the form of opinion testimony. That should ordinarily, if not always, be the most important area at issue in each particular insurance case.

The field of insurance is broadly defined. Though that fact might prove amazing to persons not familiar with the field, it will come as no surprise to insurance practitioners, whether they be lawyers, risk and business managers, third-party claim administrators, or others who are familiar with insurance policies, concepts, administration and claims handling. In fact, courts have been found to admit the opinion testimony of expert witnesses concerning the following insurance issues:

1. The “proper internal procedures for handling a claim” in a bad faith wrongful refusal to defend case.⁴
2. “[T]he standard of care owed by an insurance company to its insured in overseeing the defense of a third-party claim.”⁵
3. The meaning of certain insurance contracts “in light of industry custom and practice.”⁶

³ See, e.g., *Thomas v. Farm Bureau Ins. Co.*, 698 S.W.2d 508, 509 (Ark. 1985) (it was error to exclude the proffered opinion testimony of an investigator with the state insurance department indicating that the first-party insurer had failed to comply with the Arson Reporting-Immunity Act).

⁴ *Westfield Cos. v. O.K.L. Can Line*, 804 N.E.2d 45, 58 (Ohio Ct. App. 2003), *appeal denied*, 809 N.E.2d 33 (Ohio 2004).

⁵ *Herbert A. Sullivan, Inc. v. Utica Mut. Ins. Co.*, 788 N.E.2d 522, 536-37 (Mass. 2003). The Supreme Judicial Court of Massachusetts went further in this case than courts in other jurisdictions have been willing to go. In *Sullivan*, the Massachusetts high court held that expert testimony on that issue is *required*.

⁶ *Employers Reinsurance*, 202 F. Supp. 2d at 1217.

4. That lost policies of excess liability insurance had likely followed the same form as certain primary insurance policies, i.e., followed the terms of those certain primary insurance policies where all but one of the primary insurance policies in question were in the record in a lawsuit filed by the policyholder for payment under the lost excess liability policies.⁷
5. That, in the opinion of the judge who tried the underlying liability case, it would have been reasonable for the defendant liability insurance company to make a settlement offer for an amount *less* than the amount of the offer the insurance company actually made.⁸
6. Industry standards⁹ and customary claims practices and procedures in the insurance industry.¹⁰
7. “The scope of the appropriate investigation” by the insurance company in the particular case.¹¹
8. “[E]xplaining both the applicable statutes governing defendant’s claim processing and the issues relative to claims management practice.”¹²
9. Violation of Idaho Insurance Department regulations (in the opinion of a “former Nevada insurance official”) concerning the insurance company’s advertising of a cancer insurance policy.¹³

⁷ *PSI Energy, Inc. v. Home Ins. Co.*, 801 N.E.2d 705, 720-22 (Ind. Ct. App. 2004). The Indiana appellate court further held that the policyholder-plaintiff in this case, “must prove, by a preponderance of the evidence, the substance of the relevant policy provisions” at trial. *Id.* at 722.

⁸ *Centennial Ins. Co. v. Liberty Mut. Ins. Co.*, 404 N.E.2d 759, 763 (Ohio 1980). This case involved a claim of bad faith during settlement negotiations in the underlying or original liability case.

⁹ *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004).

¹⁰ *E.g.*, *Red Carpet Corp. v. Calvert Fire Ins. Co.*, 393 So. 2d 1160, 1160-61 (Fla. Dist. Ct. App. 1981), *review denied*, 402 So. 2d 608 (Fla. 1981); *Aetna Ins. Co. v. Loxahatchee Marina, Inc.*, 236 So. 2d 12, 14 (Fla. Dist. Ct. App. 1970).

¹¹ *See State Farm Fire & Cas. Co. v. Simmons*, 963 S.W.2d 42, 44-45 (Tex. 1998).

¹² *Novell v. Am. Guar. & Liab. Ins. Co.*, 15 P.3d 775, 779 (Colo. Ct. App. 1999).

¹³ *Walston v. Monumental Life Ins. Co.*, 923 P.2d 456, 459 (Idaho 1996). Contrast the *Walston* decision with the case of *City of Hobbs v. Hartford Fire Ins. Co.*, 162 F.3d 576, 586-87 (10th Cir. 1998), in which the Tenth Circuit Court of Appeals held that the federal trial court had not abused its discretion by refusing to admit the opinion testimony of an expert witness who, in pertinent part, did not demonstrate knowledge of New Mexico procedures concerning liability claims handling.

10. That the conduct of a defendant first-party insurance company “constituted bad faith, unfair dealing and fraud and also that it violated various provisions of the insurance code and the deceptive trade practices act.”¹⁴

Attorneys, in particular, are increasingly allowed to provide their opinions as expert witnesses by testifying in insurance cases. The authors, however, strongly and respectfully caution that, like themselves, these attorneys absolutely must be qualified as expert witnesses in these cases in order to provide reliable opinion testimony on the particular issue at hand. The following cases subscribe to the same proposition:

1. The contrary opinion testimony of “an experienced personal-injury litigator who had been made familiar with the facts available to [the liability insurer] and its lawyers”¹⁵ was “relevant evidence” where the plaintiff in a bad-faith case attacked as unreasonable the company’s rejection of his offer to settle.
2. Two attorneys’ opinion testimony on behalf of a liability insurance company in a recent bad-faith case concerning “the quality of [the liability insurance company’s] communication with [its policyholder] concerning the status of settlement negotiations and the potential for a verdict in excess of policy limits,” where the plaintiff had “expressly challenged” the sufficiency of those communications.¹⁶
3. Testimony by two attorneys on behalf of a policyholder in a bad-faith case that the liability insurer had “breached its duty . . . in failing to settle the [underlying] case.”¹⁷
4. Whether an uninsured motorist (“UM”) insurance carrier acted “reasonably” in response to the UM claim.¹⁸

¹⁴ Royal Maccabees Life Ins. Co. v. James, 146 S.W.3d 340, 354 (Tex. Ct. App. 2004). “These opinions on mixed questions of law and fact were proper.” *Id.*

¹⁵ Johnson v. Am. Family Mut. Ins. Co., 674 N.W.2d 88, 91 (Iowa 2004) (the plaintiff was the assignee of the policyholder’s bad faith claims for failure to settle against the liability insurance company).

¹⁶ *Id.* “Consequently, this was a matter as to which [the defendant liability insurance company] was entitled to present evidence contradicting plaintiff’s claims.” *Id.* The two attorneys permitted to offer expert opinion testimony on this issue were different from the attorney allowed to offer opinion testimony on a different issue, as discussed in footnote 15, *supra*, and accompanying text.

¹⁷ Warren v. Am. Family Mut. Ins. Co., 361 N.W.2d 724, 728 (Wis. Ct. App. 1984).

¹⁸ Furr v. State Farm Mut. Auto. Ins. Co., 716 N.E.2d 250, 258-59 (Ohio Ct. App. 1998).

5. That policy limits should have been offered in settlement negotiations in the underlying liability case after the liability insurer received the results of a certain independent medical examination undergone by the injured claimant.¹⁹
6. That the injured claimants' previous lawsuit against the company that insured the owner of another vehicle involved in an automobile accident had conferred a benefit upon their own defendant insurance company in a case in which the trial court awarded the injured claimants their previous collection expenses under the common fund doctrine.²⁰

III.

SEEKING A QUALIFIED INSURANCE EXPERT

Once the narrow insurance issues have been determined, the relevant qualifications of any expert on those issues should fall into place. Searching for expert witnesses by word of mouth and questioning people who have retained or worked with expert witnesses on similar insurance issues will allow for intelligent inquiry of other persons who may be familiar with expert witnesses. Those same persons may be familiar with *sources* of expert witnesses, including the sources they themselves used in prior situations.

Ultimately it will be necessary to determine what special *credentials* are critically needed to match the issues of the specific dispute. Will it be necessary to secure a former Insurance Commissioner, or perhaps even subpoena a current Commissioner or Deputy? Would the case be better served by an academic, obtained perhaps from the local law school, who teaches insurance law and is well-known in the community? Or do the facts and issues raised by the case suggest the desirability of using an experienced person from "the trenches," such as a current or retired claims executive or adjuster? How about a lawyer or banker? The internet may be another source, accessed by conducting a search consisting of the key words and phrases connected with the insurance issue in the particular case. The same is

¹⁹ See *Majorowicz v. Allied Mut. Ins. Co.*, 569 N.W.2d 472, 478 (Wis. Ct. App. 1997), *review denied*, 576 N.W.2d 281 (Wis. 1997).

²⁰ *Boll v. State Farm Mut. Auto. Ins. Co.*, 92 P.3d 1081, 1090 (Idaho 2004). The trial court's award against the recalcitrant insurance company sued in the later case was affirmed on appeal.

true of similar searches available on Westlaw and LexisNexis. The latter services ordinarily are available at a cost to the subscriber; however, each will put the questioner in touch with reported cases in which the opinion testimony of expert witnesses on potentially similar issues has been either accepted or rejected by the courts. For members of various legal organizations, there are expert database resources that can be exceedingly helpful. These services may prove to be an invaluable tool for locating expert witnesses in various areas of insurance litigation.

More particularly, queries made to all these systems will help to accumulate information that will answer important questions, such as a particular expert witness's level of familiarity with the standard of good faith and fair dealing applicable in the particular jurisdiction whose law will govern the case.²¹ Such queries also will provide initial answers to questions regarding a particular expert witness's familiarity with first-party versus third-party or property versus casualty insurance. An expert in one area is not necessarily an expert in other areas. For example, in the recent fire loss case of *North Star Mutual Insurance Co. v. Zurich Insurance Co.*,²² the plaintiff North Star initially paid the policyholder's claim. North Star then sued Zurich claiming that Zurich actually had an insurance policy in effect at the time of the fire loss, under which Zurich (rather than North Star) should have paid the loss. North Star proffered expert opinion testimony to the effect that communications between an insurance agent and an insurance broker obligated Zurich to cover the fire loss.

The United States District Court in *North Star* rejected this opinion testimony for several reasons, one of which invoked the rule that although a person may be qualified as an expert witness in one area, that particular expert may not be qualified to offer expert testimony in other areas.²³ The particular expert's testimony had been based only on his professional legal opinion and not on "any treatise, any industry code of conduct, or anything outside of his self-professed opinion."²⁴

²¹ A federal trial judge in New Mexico, for example, recently excluded the testimony of an expert in an insurance case based on findings that the particular expert's testimony would not assist the trier of fact. In part, the trial judge determined that the particular expert "lacked specialized knowledge on New Mexico bad faith cases and his experience was with first party, not third party insurance disputes." *City of Hobbs v. Hartford Fire Ins. Co.*, 162 F.3d 576, 587 (10th Cir. 1998). "Therefore, the judge did not abuse its [sic] discretion in relying upon these factors to exclude the testimony." *Id.*

²² 269 F. Supp. 2d 1140 (D. Minn. 2003).

²³ *Id.* at 1147.

²⁴ *Id.* at 1148.

A contrasting approach was adopted by the Missouri Court of Appeals in *Bailey v. Cameron Mutual Insurance Co.*,²⁵ another fire loss case that also confronted the admissibility of expert opinion testimony. In *Bailey*, however, a foundation existed in the record and in the experience of the proffered experts — as well as in Missouri state law precedent — to support their expert testimony on the issue. The two experts offered opinion testimony as to the cause and origin of the fire, concluding that the fire was intentionally set. Their testimony was proffered by the fire insurer which defended against coverage due to arson.

The Missouri appellate court applied the identical rule of evidence under which the federal court in the *North Star* case had ruled the opinions inadmissible. The two experts in *Bailey* “investigated the scene of the fire and testified that the fire was intentionally set.”²⁶ The experts focused on the cause and origin of the fire, but did not address personal motivation to do or avoid any act, including arson. Instead, the experts examined and eliminated every possible accidental cause of the fire, able to do so because “[s]uch testimony was relevant and rested on a reliable foundation.”²⁷ Both experts in this particular case “were properly qualified to testify as experts on the subject of the origin of the fire because of their knowledge, skill, experience, training, and education.”²⁸ Thus, “[t]he trial court did not err in admitting the testimony of the fire investigators.”²⁹

Practices and procedures surrounding claims handling, investigating and adjusting insurance claims, underwriting or inspecting particular risks, or other areas involved in insurance, may be familiar to some potential expert witnesses but not to others.³⁰ This is another area where information can be profitably gathered from the beginning.

²⁵ 122 S.W.3d 599 (Mo. Ct. App. 2003).

²⁶ *Id.* at 603.

²⁷ *Id.* at 604.

²⁸ *Id.* at 603.

²⁹ *Id.* at 604.

³⁰ Defendant disability insurers apparently challenged the wrong expert when they argued that the federal trial court abused its discretion by admitting the opinion testimony of an expert who allegedly “lacked sufficient qualifications to testify about claims adjustment standards in the context of an insurance bad faith claim.” *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) (California law). In response, the appellate court recounted the expert’s qualifications: he had twenty-five years of experience as an employee of insurance companies and as a consultant to them; he evaluated claims, marketed insurance products, and evaluated insurance policies; he worked for both of the defendant insurance companies during the time they sold the policy at issue to the plaintiff at bar, and they themselves trained this particular expert on how to adjust claims; in addition, he had been qualified as an expert witness twelve previous times “on insurance practices and standards,” and had “never been found to be unqualified.” *Id.* at 1016. Given this particular expert’s “significant knowledge of and experience within the insurance industry, the district court did not abuse its discretion in concluding that he was qualified to testify as an expert witness.” *Id.*

If the issues involve valuation of property disputes, it is best to consult with professional companies who will have their own areas of expertise. When dealing with a loss of allegedly valuable antiques or fine arts, special experts may be needed on areas such as Persian rugs, jewelry, furniture, paintings, or the like. If real property or business valuations are at issue, an MAI certified appraiser may not be needed or wanted. Instead, it may be best to secure the most respected local realtor, whose lawn signs and advertisements will be known to every prospective juror. Thus, in the recent decision in *Brantley v. State Farm Insurance Co.*,³¹ the opinion testimony of a fire investigator was held not to be admissible on a subject for which the investigator—a district fire chief—was shown not to be qualified. Specifically, the trial court excluded expert opinion testimony offered by the district fire chief “regarding the amount of property damage caused by the fire.”³²

The district fire chief in *Brantley* had “responded to the fire at the property,” after which he prepared an official report.³³ In the report, the fire chief estimated that the loss totaled \$50,000. The insurance company “objected to his qualifications to make such an estimate.”³⁴ The trial judge apparently had voir dired the chief, who testified “that he had received ‘very little’ training in estimating the value of property losses from fires.”³⁵ The trial court thus excluded the district fire chief’s opinion based on his lack of training to make such an estimate. The Louisiana appellate court later affirmed the trial court’s determination, ruling that the trial court did not abuse its discretion in excluding the district fire chief’s opinion testimony concerning the estimated value of the fire loss.³⁶

Ultimately, the choice of an expert will be greatly shaped by perceptions about the expert’s credibility with the local judges and juries. If the particular case involves coverage issues that are dependent upon provisions within the policies themselves, ascertaining the familiarity of potential expert witnesses with such provisions likely will be aided as well by queries from reliable sources of information like those suggested above.

³¹ 865 So. 2d 265 (La. Ct. App. 2004).

³² *See id.* at 269.

³³ *See id.* at 269.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* In contrast, in a recent non-insurance case involving “the senior loan market,” the court held that a valuation expert who was “a generalist on loan markets” was sufficiently qualified to allow her to testify to opinions concerning the senior loan market, given the knowledge displayed in the expert’s report, her education, and the research displayed in her publications: “One need not have been a participant in a particular market in order to qualify as an academic expert who can provide useful testimony.” *Abrams v. Van Kampen Funds, Inc.*, No. 01-C-7538, 2005 WL 88973, at *14 (N.D. Ill. Jan. 13, 2005).

IV. FINDING THE RIGHT EXPERT

There are many possible sources for locating potential experts on particular issues, including insurance matters. Some have been suggested above.

Once the field of potential expert witnesses on a particular insurance matter has become manageable, it is time to begin contacting the potential experts. By the time this contact begins, the focus should be narrowed to the particular area for which expertise is sought. At this point, the field of potential witnesses will cover areas of insurance similar to the focus area in the particular case as derived from a study of past cases, whether reported or unreported.

It is suggested, however, that the wide field of potential expert witnesses be narrowed *before* contacting potential expert witnesses. Adopting the following protocol will serve to create a manageable list of experts before the company begins contacting a desirable few:

- Revisit the narrow dispositive issue of insurance that will determine the outcome of either the entire case, or one or more claims within the case.
- Compare the focus issue to the reported areas of insurance for which witnesses have been permitted to offer expert opinions in court. If a consulting expert is desired, compare the focus issue to the areas of insurance for which *consulting* expert witnesses have been known to provide services.
- Carefully consider reports of any cases or files in which a particular expert witness's opinion was either deemed inadmissible by a court, or appeared in some way to be inconsistent with the local insurance law or with the local jurisdictional law in general.
- There is no substitute for talking to other lawyers and receiving transcripts of earlier expert testimony to gauge the effectiveness of a potential expert's communication skills and powers of persuasion.

V.

ANTICIPATE A *DAUBERT*³⁷ RELATED CHALLENGE TO THE POTENTIAL EXPERT

In most instances, the initial contact with a potential expert witness should be direct. The initial contact should come from counsel and occur between counsel and the potential expert witness — either by having a telephone conversation or (better yet) a personal meeting. Typically, the initial contact will occur after placing a telephone call to the potential expert.

Before making any initial contact, issues affecting selection of a potential expert witness should be fully researched. Satisfy yourself that the expert knows what he or she is talking about and in fact will serve to *assist* the trier of fact. If proceeding by telephone to make initial contact with an expert witness, the following outline suggests a comprehensive plan for dealing with insurance matters. It offers the collective wisdom of the authors:

³⁷ Limitations on the admissibility of expert witness testimony in federal courts were originally announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The court later applied such restrictions to *all* expert opinion testimony in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Currently, Federal Rule of Evidence 702 “codifies” the rulings made in *Daubert* and *Kumho*, as amended effective December 1, 2000, and may even go beyond those rulings. *See* FED. R. EVID. 702 advisory committee’s note.

In areas covering opinion testimony in insurance cases, however, these seemingly specific and technical requirements often yield to a broader guideline for admissibility, i.e., reliability. For example, qualification of an expert witness under Rule 702 of the Federal Rules of Evidence was the first issue considered in the recent decision in *Century Indem. Co. v. Aero-Motive Co.*, 254 F. Supp. 2d 670 (W.D. Mich. 2003), in which the court held that “[t]his requirement is met where the witness’ qualifications provide a foundation for the witness to answer a specific question.” *Id.* at 676. That case involved the reconstruction of lost insurance policies. An expert’s qualification on that insurance issue was the first requirement. The proponent of the expert witness’s opinion testimony demonstrated to the court that the subject “expert” “has significant experience in commercial insurance underwriting practices and has an historical knowledge of forms used and coverages offered in the commercial insurance industry. More importantly, [he] has performed insurance reconstruction services for clients in cases involving lost insurance policies.” *Id.* at 677.

Thereafter, the court in *Century Indemnity* held that reliability is the key to the gate-keeper function of the federal trial judge: “Thus, in certain cases, all of the *Daubert* factors may be helpful to the court’s inquiry, while in other cases where reliability derives solely from the personal knowledge or experience of the witness, the factors may not be helpful at all.” 254 F. Supp. 2d at 678. To like effect is the decision in *Tapatio Springs Builders, Inc. v. Md. Cas. Ins. Co.*, 82 F. Supp. 2d 633, 648-49 (W.D. Tex. 1999).

Moreover, the Supreme Court’s decisions in *Daubert* and *Kumho* and the 2000 Amendment to Federal Rule of Evidence 702 did not change the elemental equation that even though a person is qualified as an expert witness in one area, that same person still may not be qualified to offer opinion testimony *outside* that area of expertise. *North Star Mut. Ins. Co. v. Zurich Ins. Co.*, 269 F. Supp. 2d 1140, 1147 (D. Minn. 2003).

1. Begin with a “conflict check.” Establish that no conflicts exist between potential expert witnesses and the principals or subjects of your particular case. If such conflicts do exist, the conversation should be reasonably terminated.
2. Establish a privilege as the conversation begins. Enter a verbal agreement with the witness from the outset that if something uncomfortable or sensitive should surface in the conversation, you or the potential expert will immediately and politely stop the conversation. Beyond that, establish an agreement with the potential expert that the communication will be privileged in every other way.
3. Follow up with any questions regarding the expert’s qualifications – including background, experience and training.
4. In capsule form, review the focus area of insurance with the potential expert in order to obtain her or his initial impression(s) of the particular case.
5. Request that the potential expert forward his or her resumé if retention seems likely or possible.
6. Inform the potential expert of any deadlines at the outset. Deadlines not only establish candor, they also allow you to gauge whether the potential expert can meet the timeframes for the particular litigation.
7. Inquire of the potential expert whether he or she has prepared other reports on similar cases or matters. This inquiry is important to avoid “inconsistencies;” it will also save time if the expert has had that experience and knows how to prepare a proper report, such as those required in federal court.³⁸
8. If the attorney or retaining agent knows of some “awkward” or “painful” fact that will be revealed to an expert *after* the expert reviews documents to prepare an opinion, telephone the expert and discuss it. The preferable time to address such issues is *before sending the documents*. Satisfy yourself in advance that it will not be a needless expenditure of your time and the client’s money to forward documents that will reveal the potentially painful fact. Facts themselves are not painful, but facts have the potential to produce pain depending on how you address the issue to which the fact relates.

³⁸ For example, see the requirements articulated in Fed. R. Civ. P. 26(a)(2)(B) governing when and how an expert report is to be prepared in federal court. In addition, see the defects attributed by the federal district judges to expert reports in the recent cases of *Crowley v. Chait*, 322 F. Supp. 2d 530, 542 (D.N.J. 2004), and *Montoya Lopez v. Allstate Ins. Co.*, 282 F. Supp. 2d 1095, 1104-05 (D. Ariz. 2003).

VI. EXPERT WITNESS FEES

In general terms, the case or matter will determine the range of expert witness fees payable to the particular pool of potential expert witnesses. Whether to retain any expert from among that pool of potential expert witnesses will depend upon the budget allotted by the client for both travel and hourly time charges.

Whether a retainer will be required or not by a particular expert witness depends largely upon the expert witness. Often, the witness's familiarity with you, your firm, your corporation, or your client, may affect whether that expert wishes to charge a retainer. It is not unusual for the expert to charge a retainer against which the expert will perform services and provide an initial opinion after reviewing the relevant documents provided to her or him. As the case or matter proceeds, it is also usual and ordinary for expert witnesses to require that the amounts of their retainers, presumably held in trust, will be replenished from time to time as agreed in advance between you and the expert.

A retention agreement may or may not be required by the expert. Ordinarily, in the experience of the authors, a retention agreement outlining obligations, deadlines, and confidentiality of the parties, is usual and preferable to avoid misunderstandings. In particular, the retention agreement will address the subject of fees chargeable by the expert witness for his or her time, deposition, and trial testimony. The retention agreement should be written with the likelihood that it may be read to a jury. Most jurisdictions allow expert witness fees in connection with their depositions as taxable costs of the case.³⁹

Typically, the expert's hourly fee range depends on her or his location. For example, expert insurance witnesses located in New York City are perhaps more likely to charge a higher rate or range of fees for their services than experts located in the Midwest. However, in general terms, \$250 to \$450 an hour appears to be the prevailing range for insurance bad faith and complex insurance coverage cases currently in litigation.

VII. RECORD FUNDAMENTALS

It is clear that in the majority of jurisdictions at present, the opinion testimony of expert witnesses no longer needs to be supported by facts in the record to be admissible.⁴⁰ However, the decided cases are such that courts *frequently* uphold verdicts for or against one

³⁹ See, e.g., FED. R. CIV. P. 26(b)(4)(C).

⁴⁰ See, e.g., FED. R. EVID. 703 & 705.

party or another because the verdict is supported by the opinion testimony of an expert or experts, which is based in turn upon *facts in the record* that properly support the jury's verdict. Thus, in opposing a disability insurer's summary judgment motion, the Ninth Circuit Court of Appeals recently held that a policyholder's expert opinion testimony had to both (1) display the grounds upon which the opinion was based, and (2) be consistent with and based on some evidence that was in the record.⁴¹

In another very recent insurance case involving reconstruction of lost insurance policies, an expert witness was allowed to testify that the provisions of lost excess liability insurance policies had likely followed the terms of certain primary insurance policies. It was significant to the court that all but one of the primary insurance policies were themselves available *and were in the record*.⁴² Moreover, it has been held that expert witness testimony is not a conduit for the admission of testimony which is otherwise improperly admitted into evidence.⁴³

The authors strongly suggest that all documents potentially related to the insurance area at issue be sent to the expert for review. This is not the time or place to save relatively small photocopy expenses and risk the fallout from an unprepared expert who could not review a document that was critical to the outcome of the issue.

The authors prefer (and greatly appreciate) documents received in "ready to file" form. Sometimes these are sent in labeled folders that match the files contained in the sending attorney's office. Otherwise, if the documents are received in scattered form, the expert will have to assemble, organize, and file the documents, for which an appropriate charge will be made. This charge is likely to exceed any photocopying expenses that would have been incurred. No expert wants to admit on the stand that he or she has never seen a relevant document. In addition, these authors, as expert witnesses, *never* want to say that they *asked* for something and did not get it.

Finally, many experts will ask the lawyer on the "other side" during the expert's deposition whether there exist any other documents that the expert should review. This takes some of the "sting" out of cross examination or a *Daubert* challenge during trial.

⁴¹ See *Prieto v. Paul Revere Life Ins. Co.*, 354 F.3d 1005, 1011 (9th Cir. 2004) (Arizona law).

⁴² *PSI Energy, Inc. v. Home Ins. Co.*, 801 N.E.2d 705, 720-22 (Ind. Ct. App. 2004), *transfer denied*, 812 N.E.2d 805 (Ind. 2004).

⁴³ For example: "To be sure, an expert may not be used simply as a vehicle for the admission into evidence of otherwise inadmissible hearsay testimony. . . . Likewise, neither Johnson nor any other witness will be permitted to simply summarize the facts and the depositions of others." *Crowley v. Chait*, 322 F. Supp. 2d 530, 533 (D.N.J. 2004).

VIII. CONCLUSION

Currently, courts in most insurance-related cases will allow expert opinion testimony into evidence. These expert witnesses typically address issues that range from insurance coverage, to the “archaeology” or reconstruction of provisions in lost insurance policies, to insurer good faith and fair dealing regarding compliance with fair claims practices statutes and deceptive trade practices acts. That being said, all courts recognize at least one exception to this practice. That exception is universally recognized and concerns the attempted admission into evidence of opinion testimony covering what a given court perceives as “a legal conclusion,” strictly reserved for determination by the court.

Another reservation regarding the introduction of expert testimony, also recognized by most such courts, applies when the particular expert witness testifies about how to apply standards of conduct to the facts of the particular case rather than providing an opinion about which legal standards ought to govern the particular case. When the facts underlying such testimony are a matter of record, even though disputed by other facts of record, most appellate courts will not disturb the outcome. In that sense, testimony of the expert witness holds sway in significant measure. It should be noted in closing that this approach will apply whether it is the policyholder, the insurance company, the policyholder counsel, or the carrier counsel who seeks to locate, retain, and employ the opinion testimony of an expert witness.

Litigating on the New Frontier: Inroads on the Duties of Sponsors and Investigators in Clinical Trials[†]

Roxanne M. Wilson

I. INTRODUCTION

Clinical trials are scientific investigations designed to test the safety or efficacy of a pharmaceutical, medical device, or other medical treatment.¹ Clinical trials are performed under the jurisdiction and authority of the Food and Drug Administration (“FDA”).² The FDA has adopted the *Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance* [“GCP”], an international ethical and scientific quality standard for designing, recording, and reporting clinical trials that involve the participation of human subjects.³ In addition, the Executive Committee of the Pharmaceutical Research and Manufacturers (“PhRMA”), an industry group committed to the development of medicines, recently adopted Principles for the Conduct of Clinical Trials and Communication of Clinical Trial Results, which, although voluntary, set forth existing industry practice. In addition, four major international pharmaceutical associations have recently agreed on voluntary principles for disclosing information about clinical trials called the “Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases.”

[†] Submitted by the author on behalf of the FDCC Drug, Device and Biotechnology Section. The author gratefully acknowledges the assistance of Junga P. Kim, an associate at Reed Smith LLP, Jobina Jones, Chris Rivas and Michelle Lyu, summer associates at Reed Smith LLP.

¹ See *Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance*, § 1.12 (ICH, April 1996).

² 21 U.S.C. § 355 (2005).

³ 21 C.F.R. § 312.145 (2005).



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Clinical trials conducted by research institutions are governed by assurance agreements with the U. S. Department of Health and Human Services ("HHS"), which is the department that oversees and regulates institutions that conduct activities affecting human health. In addition, most sponsors and investigators enter into indemnity agreements dictating their responsibilities in the event of an adverse outcome.

Despite the heavily regulated nature of clinical trials, they have increasingly become targets of litigation when the subjects who participate in them are injured.

II.

REGULATIONS AND OTHER RESTRICTIONS ON CLINICAL TRIALS

A. *FDA Regulations on Clinical Trials*

The integral parties involved in administering a clinical trial include (1) a sponsor, (2) an investigator, and (3) an Institutional Review Board ("IRB"). The FDA details the duties and responsibilities of each party in the Code of Federal Regulations.

1. Duties of a Sponsor

A sponsor takes responsibility for and initiates a clinical investigation, but does not conduct the study.⁴ Indeed, the regulations provide that sponsors must use physician investigators to conduct the study, to ensure compliance with FDA protocols.⁵ A sponsor may be an individual or pharmaceutical company, governmental agency, governmental institution,

⁴ *Id.* § 312.3.

⁵ *Id.* § 312.50.

private organization, or other organization.⁶ In many instances, the sponsor will delegate its responsibilities to a contract research organization (“CRO”). Typical tasks assumed by a CRO include the design of a research protocol, monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the FDA.⁷ A CRO must comply with the obligations of a sponsor.⁸

If a sponsor wants to conduct a clinical trial on human subjects, the sponsor must first submit a new investigational drug application (“IND”) for FDA approval. The FDA’s primary objectives in reviewing an IND are to assure the safety and rights of subjects and assure that the quality of scientific evaluation of the drug is adequate to permit an evaluation of the drug’s effectiveness and safety.⁹

In an IND, a sponsor has to detail the logistics of the study. Information provided includes where the clinical investigation will be conducted; a commitment that an IRB will be responsible for the initial and continuing review of the study; a commitment that the clinical investigator will report any proposed changes to the IRB; and a commitment to conduct the investigation in accordance with all applicable federal regulations.¹⁰ This requirement has been misinterpreted to mean that it is the sponsor’s obligation to determine IRB compliance with the regulations.¹¹ This is not the case. Sponsors should rely on the investigator’s assurance that the study will be reviewed by an IRB.¹² Because clinical investigators work directly with IRBs, it is appropriate that they assure the sponsor that the IRB is functioning in compliance with regulations.¹³

The sponsor must also develop the research protocol. The research protocol includes the clinical trial’s objectives; the name and qualifications of the investigator and sub-investigators; the criteria for patient selection and exclusion; the design of the study (including methods to be used to minimize bias on the part of subjects, investigators, and analysts, and the method for determining the doses to be administered by the investigator); and a description of the observations and measurements to be made to fulfill the objectives of the study.¹⁴

⁶ *Id.* § 312.3.

⁷ *Id.*

⁸ *Id.* § 312.53(b).

⁹ *Id.* § 312.22(a).

¹⁰ *Id.* § 312.23.

¹¹ Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators 1998 Update, U.S.F.D.A., available at <http://www.fda.gov/oc/ohrt/irbs/toc4.html>.

¹² *Id.*

¹³ *Id.*

¹⁴ 21 C.F.R. § 312.23.

The sponsor must also include information about the chemistry of the drug to be tested, a brief summary of any other animal or human experience with the drug including other investigations – in or outside of the United States, and any withdrawal of the drug from an investigation or world market.¹⁵

The sponsor must also provide each investigator with an investigator brochure, which contains the same information that is included in the protocol and IND application submitted to the FDA. The investigator brochure must be used by the physician investigator to conduct the trial.¹⁶

The sponsor must monitor the progress of all clinical trials being conducted under an IND.¹⁷ The purpose of the monitoring is to ensure that the trials generate consistent, reliable data that can be used to support an application for FDA approval of a drug.¹⁸ To that end, the sponsor's responsibilities during the course of a clinical trial include (1) evaluating the safety and effectiveness of the drug as data is obtained from the physician investigator, and (2) reporting to the FDA, physician investigators, and IRB any known adverse affects of the drugs.¹⁹ Contrary to the position often taken in litigation, the sponsor's duty to warn of known adverse affects of the drugs does not extend to clinical trial subjects. Indeed, the sponsor does not have any contact with clinical trial subjects.

2. Duties of Physician Investigators

To preserve the integrity of the results of a clinical trial and the safety of human subjects, FDA regulations dictate that an investigating physician alone conducts clinical trials.²⁰ The sponsor selects a qualified physician to conduct the clinical trial.²¹ The physician investigator assesses the health and medical history of potential study participants, determines whether the study inclusion criteria are met, determines whether exclusion criteria are present, and actually administers or dispenses the study drug to those enrolled in the study.²²

¹⁵ *Id.*

¹⁶ *Id.* § 312.56.

¹⁷ *Id.*

¹⁸ *Nexell Therapeutics v. Amcell Corp.*, 143 F. Supp. 2d 407, 412 (D. Del. 2001) (discussing the federal regulatory framework of clinical trials).

¹⁹ *Id.*

²⁰ 21 C.F.R. § 312.3(b).

²¹ *Id.* § 312.53 (a); GCP § 5.6.1; see also World Medical Association Declaration of Helsinki, Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects, (1964) at 2 *available at* <http://www.wma.net/e/policy/pdf/17c.pdf> (last modified 2002) (stating biomedical research "should be conducted . . . only under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person . . .").

²² 21 C.F.R. §§ 312.3 (b), 312.60.

Throughout the course of a clinical trial, the physician investigator works with an IRB to ensure that adequate informed consent is obtained from each clinical trial subject.²³ Once informed consent is secured from a clinical trial subject, the physician investigator has an ongoing duty to provide a statement to the subject of any significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation.²⁴

The physician investigator, with his medical background and training, is responsible for dealing with the patients and safeguarding their well-being.²⁵ Industry guidelines state that a physician investigator "should be responsible for all trial-related medical (or dental) decisions."²⁶ To that end, the physician investigator also has the power to deviate from the protocol when necessary to protect the safety, rights, or welfare of clinical trial subjects.²⁷

3. Duties of Sponsor/Investigator

In some instances, an individual can be both a sponsor and investigator of a clinical trial. A sponsor-investigator is an individual who both initiates and actually conducts, alone or with others, a clinical investigation.²⁸ A sponsor-investigator can only be an individual, and his responsibilities under the FDA include both those of a sponsor and an investigator.²⁹

B. *Duties Imposed by GUIDANCE FOR INDUSTRY: E6 Good Clinical Practices*

When a sponsor applies for an IND, in addition to obtaining FDA approval, the IND must be approved by the IRB that has agreed to review the clinical trial.³⁰ An IRB is any board, committee, or other group formally designated by the investigator and the institution conducting the clinical trial to review, approve the initiation of, and conduct periodic review of clinical trials.³¹ An IRB is required for any FDA-regulated clinical trial.³² The paramount purpose of an IRB is to safeguard the rights, safety, and well-being of all trial subjects.³³

²³ *Id.* § 50.25.

²⁴ *Id.*

²⁵ *See, e.g., id.* § 312.60 (investigator has responsibility for protecting the rights, safety, and welfare of human subjects under the investigator's care).

²⁶ GCP § 4.3.1.

²⁷ 21 C.F.R. § 312.53.

²⁸ *Id.* § 312.3.

²⁹ *Id.*

³⁰ *Id.* § 56.109.

³¹ *Id.* § 56.102(g).

³² *Id.* § 56.103.

³³ *Id.* §56.101.

An IRB is comprised of at least five individuals with varying backgrounds to promote adequate review of research activities commonly conducted by an institution.³⁴ In addition to possessing the professional competence necessary to review the specific research activities, members must be able to determine the acceptability of a proposed clinical trial under applicable laws and standards of professional conduct and practice.³⁵

The FDA requires that an IRB (1) determine that risks to subjects have been minimized and are reasonable in relation to anticipated benefits, if any, to subjects, and (2) assess the importance of the knowledge that may reasonably be expected to result.³⁶ The regulations do not specify any particular method the IRB must use to carry out the risk assessment.³⁷

In addition, the IRB is responsible for ensuring the adequacy of the physician investigator's plans for obtaining informed consent, as well as the proposed methods for selecting subjects, monitoring the data, and addressing issues related to privacy and confidentiality.³⁸ If the IRB does not approve of elements of the protocol, it can change them, or disapprove the entire clinical trial.³⁹ The IRB also has the power to terminate a clinical trial if the trial "has been associated with unexpected serious harm to subjects."⁴⁰

C. *Duties Imposed on Publicly Funded Research Institutions - Assurance Agreements*

Assurance agreements are contracts between research institutions and the Department of Health and Human Services ("HHS"), which bind the institutions to follow the guidelines within the agreement. HHS is the department that oversees and regulates institutions that conduct activities affecting human health. The office that is directly responsible for approving and enforcing assurance agreements for research on human subjects is called the Office for Human Research Protections ("OHRP"), which inherited all human research protection activities from the National Institutes of Health ("NIH") and the Office for Protection from Research Risks ("OPRR").⁴¹ Notwithstanding the name change, the regulations that govern assurance agreements and human research still refer exclusively to the OPRR.⁴² The OHRP has assurance agreements with more than 10,000 federally funded universities, hospitals and other medical and behavioral research institutions.⁴³

³⁴ *Id.* § 56.107.

³⁵ *Id.*

³⁶ *Id.* § 56.111.

³⁷ Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1, 13 (2004).

³⁸ 21 C.F.R. §§ 56.107, 56.111.

³⁹ *Id.* § 56.113.

⁴⁰ *Id.*

⁴¹ 65 Fed. Reg. § 37136 (2005).

⁴² *See* 45 C.F.R. § 46.103.

⁴³ Information about the Office for Human Research Protections, *available at* <http://www.hhs.gov/ohrp/about>.

The OHRP enforces assurance agreements with the help of IRBs.⁴⁴ The IRB is responsible for reviewing all research proposals by institutions with assurance agreements and is given the power to approve or reject an institution's research proposals.⁴⁵

Several types of assurance agreements have been used by the OHRP at various times: (1) Multiple Project Assurances (MPA), which cover multiple unrelated research activities at a single location; (2) Single Project Assurances (SPA), which apply to a single research activity at a single location; (3) Cooperative Project Assurances (CPA), which cover multiple research activities at multiple locations; and (4) Federal Wide Assurances (FWA), which were created to streamline the OHRP registration process and eventually replace all other assurances.⁴⁶

The FWA will also allow a research institution with an FWA on file with the OHRP to "receive funds from any department or agency that subscribes to the Common Rule without filing any additional assurances."⁴⁷

1. The Common Rule

The regulations that govern assurance agreements are usually called the "Common Rule," and the contents of assurance agreements are often referred to as the "Belmont Report" or the Common Rule.⁴⁸ Assurance agreements serve two main purposes. First, they mirror the language in the Common Rule so that privately-funded institutions and pharmaceutical company sponsors who sign them are then bound by the federal regulations. Second, they are highly theoretical and broadly stated agreements to make difficult research decisions ethically and to provide for the safety of human research subjects.

At a minimum, an assurance agreement must include (1) a statement of principles that governs the research institution's responsibilities for protecting human research subjects; (2) the designation of at least one IRB, with provisions to provide sufficient space and staff to support the IRB's review duties; (3) a list of IRB members, their information and their credentials that is sufficient to describe the member's contributions to the IRB; (4) procedures for the IRB to pursue research review, determine which projects require extra review, and receive information about proposed research activity changes; and, (5) procedures for ensuring prompt reporting to the IRB and "appropriate" government officials of any unanticipated research problems and any termination of IRB approval.⁴⁹

⁴⁴ Dale L. Moore, *An IRB Member's Perspective on Access to Innovative Therapy*, 57 ALB. L. REV. 559, 560 (1994).

⁴⁵ 45 C.F.R. § 46.109.

⁴⁶ Lori A. Alvino, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 899-900 (2003).

⁴⁷ *Id.* at 900.

⁴⁸ 45 C.F.R. § 46 Subpart A.

⁴⁹ 45 C.F.R. § 46.103(b).

An institution can satisfy the Common Rule requirement that it submit research principles in two ways. It can either elect to be guided by the Belmont Report, or it can submit its own statement of principles. The Belmont Report is broken into two conceptual parts. First, it is a list of rules that allow institutions to be regulated adequately. Second, it is a “highly abstract” and “philosophical” document that aims to prevent harm to human research subjects and was originally created as a response to the research horrors uncovered at Nazi concentration camps.⁵⁰ The Belmont Report’s function was to provide an “analytical framework” for institutions to resolve “ethical problems arising from research involving human subjects.”⁵¹

The institution filing the FWA, if conducting federally supported human subject research, must agree to comply with a document called the Terms of Assurance for Protection of Human Subjects for Institutions Within the United States (“Terms”).⁵² The Terms bind the institution to follow the ethical guidelines in the Belmont Report, the Common Rule, and any other appropriate ethical guidelines.⁵³ Additionally, an institution bound by the Terms is responsible for ensuring that its IRB follows the requirements in the Terms and is notified that investigators employed by the institution are bound by the Terms.

Privately funded institutions, which are not bound by the Terms, may voluntarily bind themselves to the requirements of the Common Rule (that generally covers humans) and to all of the other subparts of federal regulations that offer additional guidelines for research on women, fetuses, children, and prisoners.⁵⁴ Under the Common Rule, an institution “engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance.”⁵⁵ An institution is “federally supported” if it is provided with any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) or the conduct of the research involves United States Government employees.⁵⁶ Additionally, because IRBs are required to follow the guidelines in the Terms, they are bound by assurance agreements as well.

Institutions such as pharmaceutical companies, which often sponsor research involving human subjects, are private companies and the research they sponsor is usually privately funded. Since they are not federally funded, sponsors are not required to file assurances with the OHRP unless they do so voluntarily. Although privately funded research

⁵⁰ *Ancheff v. Hartford Hospital*, 799 A.2d. 1067, 1074 (Conn. 2002).

⁵¹ *Id.* at 1073.

⁵² The Terms can be found at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>.

⁵³ *Id.*

⁵⁴ 45 C.F.R. § 46.

⁵⁵ *Id.* § 46.103(a).

⁵⁶ Terms of Assurance, *available at* <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>, n.1.

institutions are not required to file assurance agreements with the OHRP, they are required to work under IRBs if their research involves drugs, medical products, or devices that are subject to FDA approval. Therefore, they are not completely outside of the federal government's reach.⁵⁷

2. Enforcement of Assurance Agreements

Both IRBs and the OHRP have the power to suspend research and force institutions to work within the boundaries of their assurance agreements. For example, in 1999 the OHRP suspended assurances for all human-subject research at Duke University because of IRB deficiencies.⁵⁸ The IRB, as the oversight entity directly over a research institution, is the most likely to detect and repair deficiencies in research or ethical violations by institutions. The OHRP, on the other hand, primarily addresses non-compliance problems and deficiencies in the IRBs, although it must then remediate any deficiencies in the institution that the IRB overlooked.⁵⁹

3. Legal Issues Regarding Assurance Agreements

Assurance agreements for human research have rarely been the subject of litigation, but there are two areas where issues pertaining to them have been addressed by the courts.

a. *Third-Party Beneficiary Theory*

In order to be considered a third-party beneficiary to a government contract, proof must exist that there was specific intent to include that party as a third-party beneficiary with the right to enforce the contract.⁶⁰ The primary obstacle for research subjects seeking relief under this theory is that the Common Rule does “not expressly establish a private right of action for injured research subjects.”⁶¹

In *Wright*, the court held that even though the plaintiffs benefited from the research institution's assurance agreement with the HHS, they were merely incidental beneficiaries of the agreement because there was no language in the assurance agreement that evidenced a clear intent to the contrary.⁶² *Wright* is the only case that has directly addressed the issue of whether research subjects may sue as third-party beneficiaries of an assurance agreement between an institution and the OHRP.

⁵⁷ Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 236 (2003).

⁵⁸ E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts On a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 3 n.14 (2003).

⁵⁹ Common Findings and Guidance, available at <http://www.hhs.gov/ohrp/compliance/findings.pdf>.

⁶⁰ *Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1290 (W.D. Wash. 2002).

⁶¹ Alvino, *supra* note 46, at 909.

⁶² *Wright*, 269 F. Supp. 2d at 1290.

b. *Duty of Care*

One court has held that the Common Rule standards provided a duty of care that the research institution violated.⁶³ The research institution, which received federal grants, tested lead levels in healthy young children by encouraging landlords to rent apartments with lead paint to families with young children. The court held that the assurance agreement created duties that “translate[d] into a duty of care arising out of the unique relationship that is researcher-subject, as opposed to doctor-patient.”⁶⁴ The court further held that, regardless of consent by the parents, it violated the contractual ethical duty of the research institution to do harmful tests on healthy children.

A Connecticut court reached a different conclusion, upholding the trial court’s decision that the Belmont Report did not provide a standard of care for the defendants, a hospital and physician that conducted clinical trials on the patient-plaintiff.⁶⁵ The court held that admitting into evidence the Belmont Report, which was part of the assurance agreement filed by the hospital, would have been more prejudicial than probative. The trial judge was concerned that the Belmont Report had very limited evidentiary value because it merely provided guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects, rather than a clear duty of care to which the defendants had subscribed.

4. Private Sponsors Should Not File an Assurance Agreement

It is axiomatic that, in most circumstances, it is not in a private sponsor’s best interest to file an assurance agreement if it is not otherwise required to do so. There is no benefit to the gained by placing itself under additional regulations and laws.

D. *Indemnity Agreements*

Virtually all contractual agreements between the sponsor and investigator contain indemnity provisions. These are often battlegrounds in litigation. On the one hand, the investigator expects a defense and indemnity under the agreement. On the other, the sponsor may be hesitant to agree to provide even a defense until it determines through investigation and discovery whether the investigator has conducted the clinical trial in accordance with the protocol or whether the investigator has been negligent in conducting the clinical trial. That may have occurred, for example, by failure to obtain proper informed consent. The unfortunate result may be that the sponsor and investigator become adverse parties in litigation rather than presenting a unified defense. This only benefits the plaintiff.

⁶³ Grimes v. Kennedy Kreiger Inst. Inc., 782 A.2d 807 (Md. 2001).

⁶⁴ *Id.* at 849.

⁶⁵ Ancheff v. Hartford Hospital, 799 A.2d. 1067 (Conn. 2002).

E. *PhRMA Principles for the Conduct of Clinical Trials*

The Executive Committee of PhRMA, an industry group committed to the development of medicines, recently adopted Principles for the Conduct of Clinical Trials and Communication of Clinical Trial Results.⁶⁶ Although compliance with these Principles is voluntary and in many cases is a restatement of existing industry practice, the Principles emphasize, *inter alia*, (1) the independence of clinical investigators so they can exercise their own decision-making authority to protect research participants; (2) the IRB review process; (3) timely communication of study results without the veto or suppression of publications by sponsors; and (4) the investigator's ability to review relevant statistical tables, figures and reports of the entire study.

Recently, four major international pharmaceutical associations have agreed on voluntary principles for disclosing information about clinical trials, called the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases."⁶⁷ The four associations are (1) The European Federation of Pharmaceutical Industries and Associations (EFPIA), (2) the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), (3) the Japanese Pharmaceutical Manufacturers Association (JPMA), and (4) the Pharmaceutical Research and Manufacturers of America (PhRMA).⁶⁸ The voluntary principles (1) describe the types of information that association members should make available through clinical trial registries, (2) provide that member companies should include information on ongoing and new trials in a registry by September 13, 2005, (3) express member companies' commitment to post clinical trial results in an accessible database on all marketed products, (4) instruct member companies to establish compliance and verification procedures for their participation in both clinical trial registries and clinical trial databases, and (5) support worldwide standardization of clinical-trial disclosure policies.⁶⁹ From a patient perspective, this database would enable patients and their doctors to locate ongoing clinical trials. From a litigation perspective, the availability of clinical trial results would apply only to marketed drugs, not to trial drugs that were never marketed.

⁶⁶ <http://www.phrma.org/mediaroom/press/releases/30.06.2004.427.cfm>.

⁶⁷ <http://www.pharmalive.com/news/index.cfm?articleID=202488&categoryid=9&newsletter=1>.

⁶⁸ *Id.*

⁶⁹ *Id.*

III. THEORIES OF LIABILITY

A. *Products Liability against the Sponsor*

1. Approved Drugs

In some instances clinical trials involve drugs already approved by the FDA and marketed by the sponsor. Such trials may involve efficacy or ease of use of two approved drugs or one approved and one non-approved drug. If the drug is approved and marketed, then standard products liability law applying to pharmaceuticals will apply.

2. New Uses for Approved Drugs

Once the FDA has approved a prescription drug for a particular use or uses, the drug's manufacturer cannot market or promote the drug for an off-label use until it resubmits the drug for another series of clinical trials similar to those required for initial approval of a new drug application.⁷⁰ As such, in litigation involving clinical trials regarding new uses for approved drugs, the trial drug should be treated like a non-approved drug because the FDA has not approved the new use for the general public.

3. Non-Approved Drugs

By contrast, the law is clear that when a plaintiff is injured by a defective "product" that has not been placed on the market, a cause of action for strict product liability is unavailable.⁷¹ Products are placed on the market or in the "stream of commerce" when the manufacturer or seller has placed them "with the expectation that they will be purchased by consumers in the forum State."⁷²

⁷⁰ Richardson v. Miller, 44 S.W.3d 1, 12 (Tenn. Ct. App. 2000) (citing 21 C.F.R. §§ 314.54, 314.70 -.71 (1999)); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 55 (D.D.C. 1998); Steven R. Salbu, *Off-Label Use, Prescription and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 187-88 (1999).

⁷¹ Thibos v. Pac. Gas & Elec. Co., 232 Cal. Rptr. 11 (Ct. App. 1986) (utility-owned and -maintained streetlight was not in commerce and therefore not a proper basis of strict liability action); Greenman v. Yuba Power Products, 377 P.2d 898, 900 (Cal. 1963) (stating that "[a] manufacturer is strictly liable in tort when an article he placed on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being"); World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297-98 (1980) (defining "stream of commerce" for purposes of determining whether courts may exercise personal jurisdiction against nonresidents in product liability actions).

⁷² Woodson, 444 U.S. at 298 (defining "stream of commerce" for purposes of determining whether courts may exercise personal jurisdiction against nonresidents in product liability actions).

In the case of clinical trials involving non-approved drugs, the FDA has not approved the investigational drug for use by the general public and, in fact, the purpose of the clinical trial is to determine whether the drug is safe and efficacious for consumers. While in the clinical testing phase, drug manufacturers distribute investigational drugs without charge only to the investigator of the clinical research study. The investigator is not permitted to sell the trial drug. Since the investigational drug has not been placed on the market or in the stream of commerce, the manufacturer cannot be strictly liable.

Moreover, manufacturers of drugs, especially investigational drugs, that are dangerous by their very nature, i.e., “unavoidably unsafe,” are exempt from strict liability.⁷³ The Restatement takes the view that the use of the product should not result in strict liability in tort to the manufacturer because of the grave dangers that could result if the product is not used at all. Comment k has been interpreted as requiring adequate warning in order for the product not to be defective or unreasonably dangerous.⁷⁴ In other words, as long as proper warnings were given with respect to the investigational drug, the manufacturer cannot be strictly liable.

In the case of new investigational drugs, it is imperative that the sponsor inform the trial subject of all known risks associated with the investigational drug in the consent form.

A. *Negligence – An Area of Expanded Litigation*

1. Sponsors Owe No Duty to Clinical Trial Subjects and No Liability for Physician Investigators Negligent Conduct

There is sparse case law discussing the duty of a sponsor in pharmaceutical clinical studies. In the available cases, courts look to the duties imposed by federal regulations to decide the issue of duty owed a clinical trial subject.⁷⁵ While it is tragic when death or injury results from a subject’s participation in a clinical trial, progress in the battle against deadly diseases often will be made only when medical experimentation is permitted.⁷⁶

FDA regulations are aimed at ensuring the safety and scientific soundness of a trial, while fostering the necessary freedom for scientific innovation. Violations of FDA regulations are punishable by significant fines, civil penalties, and imprisonment.⁷⁷ Because of

⁷³ RESTATEMENT (SECOND) OF TORTS, § 402 A, cmt. k (1965).

⁷⁴ See, e.g., *Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988) (adopting the approach of comment k with regard to drugs classified as “unavoidably unsafe products”).

⁷⁵ See *Kernke v. Menninger Clinic*, 173 F. Supp. 2d 1117, 1118 (D. Kan. 2001) (holding FDA regulations did not create a sponsor’s duty of care to clinical trial subject to ensure adequate informed consent was obtained, determine subject’s eligibility for the study and supervise the subject while he participated in the study).

⁷⁶ *Goodman v. United States*, 298 F.3d 1048, 1058 (9th Cir. 2002).

⁷⁷ See, e.g., 21 U.S.C. § 331.

the strict FDA regulations, courts are unwilling to allow plaintiffs alleging injury as a result of their participation in a clinical trial to pursue state law claims that impose different or stricter duties on clinical trial sponsors not found in FDA regulations.

For example, in an Arizona case, the plaintiff filed suit against a sponsor, alleging breach of warranty and strict tort liability.⁷⁸ The plaintiff was injected with sponsor's experimental drug for the treatment of a herniated disk. The procedure resulted in multiple complications, including an E-coli infection in the plaintiff's spine. The court held that there was no basis for the plaintiff's claims against the sponsor. It reasoned that even if the physician-investigator violated the sponsor's protocol in choosing the plaintiff as a suitable candidate for injection, or in the performance of the operation, the sponsor was not a proximate cause of the plaintiff's injuries. Since the sponsor did not cause the patient's injuries, recovery against the sponsor was barred.

The court also held that so long as the FDA determined that pre-clinical research justified clinical trials on human subjects, no liability should be imposed on the manufacturer of an experimental drug in the absence of fraud, deceit, misrepresentation, or negligence. The sponsor reasonably initiated the trial since potential risks of the drug did not outweigh the expected benefits from the drug. Further, the sponsor provided adequate warnings about the known risks associated with the drug. The sponsor's duty to warn is satisfied if a proper warning is given to the prescribing physician-investigator, since it is that person who is responsible for the subject's welfare. Further, the sponsor distributed the drug with a protocol, which gave detailed instructions on the use of the drug, and the sponsor kept in close touch with its investigators to monitor possible adverse reactions of their patients. Because the sponsor reasonably performed all of its duties, no liability was imposed for the plaintiff's injuries.

More recently, a Kansas district court held that a sponsor owes no duty of care to a clinical trial subject.⁷⁹ The plaintiffs filed suit against a pharmaceutical manufacturer/sponsor alleging wrongful death of a participant in a clinical trial designed to test the safety and effectiveness of a drug used to treat schizophrenia. In their negligence cause of action, the plaintiffs alleged that the sponsor owed the study subject three duties: (1) to determine whether the risks in allowing the subject to participate in the study outweighed the benefits; (2) to secure informed consent from the subject; and (3) to supervise the subject while he participated in the clinical trial. Relying on FDA regulations, the sponsor contended that all of the alleged duties advanced by the plaintiffs rested with the physician-investigator, not the sponsor.

⁷⁸ *Gaston v. Hunter*, 588 P.2d 326 (Ariz. Ct. App. 1978).

⁷⁹ *Kernke v. Menninger Clinic, Inc.*, 173 F. Supp. 2d 1117 (D. Kan. 2001).

The court agreed with the sponsor and held that sponsor owed no duty of care to the clinical trial subject. To reach its holding, the court relied on FDA regulations and cases interpreting the duties imposed by the regulations. It relied on the fact that physician-investigator is defined as an individual who actually conducts a clinical trial and under whose immediate direction the drug is administered to the subject. FDA regulations state that investigators are responsible for “protecting the rights, safety, and welfare of subjects under the investigator’s care.”⁸⁰ It is also the physician-investigator’s duty to obtain informed consent from each clinical trial subject.⁸¹ The court further reasoned that it is a physician investigator’s duty to determine whether a drug should be administered to a patient in light of the patient’s susceptibilities and propensities.⁸² Because the theories of duty the plaintiff relied upon were within the realm of duties of a physician-investigator, and not a sponsor, the sponsor did not owe a duty of care to the clinical trial subject.

The holdings in these cases support two conclusions. First, a sponsor does not owe a duty of care to a clinical trial subject. Second, as long as the sponsor adequately initiates a clinical trial and reveals all known risks of the experimental drug to the physician investigator, the sponsor cannot be held liable for the physician-investigator’s failure to adequately conduct an investigational clinical trial.

2. Physician-Investigator Owes Duty to Clinical Trial Subjects

Courts have held that FDA regulations establish a physician-investigator’s duty of care to clinical trial subjects.⁸³ Because an investigator is charged with protecting the welfare of the subject, if a clinical trial subject is negligently enrolled in a trial, not properly removed under protocol guidelines, negligently administered the drug, or not given adequate information to make an informed consent, the investigator’s duty to the clinical trial subject is breached.⁸⁴

For example, in the same Kansas district court case previously referred to, the plaintiff alleged medical malpractice against the principal investigators resulting in the death of the decedent, a participant. A sub-investigator believed that the decedent qualified for partici-

⁸⁰ *Id.* at 1124 (citing 21 C.F.R. §§ 312.3 (b), 312.60).

⁸¹ 21 C.F.R. § 50.20.

⁸² *Kernke*, 173 F. Supp. 2d at 1124 (citing *Gile v. Optical Radiation Corp.* 22 F.3d 540, 543 (3rd Cir. 1994)) (holding that informed consent is the duty of the physician and not the manufacturer); *Anderson v. George H. Lanier Mem. Hosp.*, 982 F.2d 1513, 1516-17 (11th Cir. 1993).

⁸³ *See, e.g., Vodopost v. MacGregor*, 913 P.2d. 779, 789 (Wash. 1996) (stating that a clinical trial subject is dependant on the clinical investigator, and therefore the investigator should be held to at least a normal duty of care. “The public’s interest in the safety of human subjects and the public’s interest in the integrity of legitimate and necessary research militate against allowing researchers to negligently conduct research . . .”).

⁸⁴ *Kernke*, 173 F. Supp. 2d at 1117.

pation and would benefit from the study. The principal investigator reviewed the decedent's signed informed consent and enrolled the decedent in the study. The informed consent form warned the decedent of the potential risks and hazards involved in participating in the study, including worsening of schizophrenic symptoms, depression, suicidal thoughts and the fact that a previous participant had committed suicide. Following a two-week "wash out" period the decedent began to receive the experimental drug. During this period, his condition declined. He repeatedly asked to go home. After the decedent escaped from the facility where the study was being conducted, the investigators did not search for him. He was found dead approximately three months later.

The plaintiffs filed a malpractice claim alleging that physician-investigators had breached their duty of care to decedent by (1) negligently supervising him; (2) allowing him to participate in the clinical trial when he did not meet the protocol criteria for inclusion in the study; (3) failing to secure adequate informed consent from the decedent; (4) misrepresenting to him the potential benefits of participation in the trial; (5) failing to diagnose properly and treat several his medical conditions; and (6) failing to establish or follow security measures that would have prevented the decedent from leaving the clinic.

The court held that the physician-investigators owed the decedent a duty of care and allowed the medical malpractice claim to proceed to trial. It reasoned that it was immaterial that the physician-investigators did not directly handle the decedent's care. As the principal physician-investigators, they owed him a duty of care throughout his participation in the clinical trial.

This holding makes it clear that an investigator has a duty of care to clinical trial subjects, not to the sponsor. The holding comports with FDA regulations since under the regulations, the physician investigator is charged with protecting the safety and welfare of a research subject. Holding otherwise would allow physician-investigators to negligently conduct research with impunity.⁸⁵ The public policy in favor of protecting a subject's safety counsels against such an outcome.⁸⁶

3. Case Law Further Illustrates Duty of Care of Physician, Not Sponsor

Despite the dual responsibilities, the duty that a sponsor-investigator owes to the clinical trial subject is established by relying on an investigator's responsibilities, rather than a sponsor's responsibilities. For example, in an Illinois case the decedent joined a cancer treatment clinical trial at the suggestion of his doctor.⁸⁷ He died during treatment, and his estate sued the sponsor-investigator of the clinical trial, alleging negligence primarily based on the allegedly defective consent form given the decedent.

⁸⁵ *Vodopost v. MacGregor*, 913 P.2d. 779, 789 (Wash. 1996).

⁸⁶ *Id.*

⁸⁷ *Lenahan v. Univ. of Chicago*, 808 N.E.2d 1078 (Ill. App. Ct. 2004).

The plaintiff alleged that the doctor owed a duty to decedent because he not only was the sponsor and principal investigator of the clinical trial, but also personally designed all aspects of the research protocol including eligibility criteria, pre-treatment evaluation, and the treatment plan – all sponsor-related responsibilities under FDA regulations. The plaintiff also presented the investigator responsibilities that support a duty owed by the doctor to the decedent. The doctor approved and enrolled the decedent in the clinical trial, and the decedent signed a consent form drafted by the doctor. Throughout the course of the clinical trial, the doctor directed other doctors in the treatment of the decedent, performed laboratory tests, and examined test results. The court held that the doctor’s conduct was sufficient to establish a duty toward the decedent. It reasoned that although the relationship between the doctor and the decedent was not a traditional physician-patient relationship, a “special relationship” was formed by the “myriad of services” the doctor performed for the decedent.⁸⁸ It did not matter that the doctor never met the decedent, or that the doctor performed the same services on all the clinical trial subjects. A special relationship and corresponding duty toward the decedent was established because the doctor directed other doctors in their treatment of the decedent, performed laboratory tests, and examined results. Therefore, the doctor could be liable for injuries the decedent incurred as a result of the breach in duty. The court further held that issue of negligence should proceed to trial since the plaintiff adequately plead that the doctor, as the investigator, was negligent for enrolling and later failing to remove the decedent from the clinical trial, and for failing to draft an adequate informed consent.

It is instructive that the court did not rely on the sponsor’s responsibilities to establish the doctor’s duty of care owed to the decedent. The court’s holding further illustrates that it is an investigator’s duty, not a sponsor’s, to ensure welfare of a clinical trial subject under the investigator’s care.

4. IRB May Be Held Liable for Inadequate Informed Consent Claims

There is no precedent for holding any individual IRB members liable for negligence.⁸⁹ Nonetheless, courts have held institutions liable where the IRBs are established and conduct IRB reviewing functions. Case law discussing the duty of IRBs to clinical trial subjects in pharmaceutical trials primarily deals with the adequacy of informed consent. Since FDA regulations charge an IRB with the duty to ensure that adequate informed consent is obtained for all research subjects, at a minimum, an IRB must review the signed forms to verify that each individual subject has given adequate informed consent.⁹⁰

⁸⁸ *Id.* at 1086.

⁸⁹ Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 238 (2003).

⁹⁰ *Kus v. Sherman Hosp.* 644 N.E.2d 1214, 1220 (Ill. App. Ct. 1995) (stating that the institution, through its IRB, was charged by FDA regulations with the reviewing of the informed consent process and had a duty to ensure that the IRB approved consent form was being used).

Because of an IRB's reviewing duty, an institution may be held liable if a physician-investigator obtains inadequate informed consent from a clinical trial subject.⁹¹

In one case, the plaintiff filed suit against the university and hospital responsible for the IRBs reviewing the clinical trial in which the decedent was enrolled.⁹² The physician investigator allegedly changed the IRB-approved informed consent form, omitting the fact that the trial involved an experimental drug. The plaintiff alleged institutional negligence for failing to provide and obtain from the decedent an adequate informed consent. The plaintiff claimed that (1) the defendants deviated from their policy and from the FDA regulations by negligently failing to disclose in the decedent's consent form all the risks and alternatives to treatment; (2) that the decedent's injuries and death were caused by his participation in the clinical trial; and (3) the decedent would not have participated in the clinical trial had the defendants provided him an adequate consent form.

The court held that the plaintiff adequately pleaded that the university and hospital owed the decedent the duty to provide him with a consent form complying with FDA regulations. It reasoned that the defendants adopted policies to conduct research at their institutions and in furtherance of FDA policies established an IRB to ensure that legally effective informed consent was obtained. Hence, the defendants were liable to the decedent because the IRB deviated from its policy and FDA regulations by negligently failing to disclose all the risks and alternatives to treatment in the decedent's consent form.

The court's decision comports with the paramount purpose of an IRB to assure the protection of the rights and safety of human research subjects. Since one of the primary duties of an IRB is to ensure that adequate informed consent is obtained from all research subjects, if an IRB's institution is not held liable for an IRB's failure to obtain adequate informed consent, the purpose of protecting the rights and safety of human research subjects would be undermined.

There is no case law dealing with an IRB's negligent assessment of a clinical trial's risks and benefits to research subjects. Such a claim could be asserted by clinical trial subjects, since the FDA requires that an IRB determine that risks to subjects have been minimized and that the risks are reasonable in relation to anticipated benefits. Failure to do so would constitute a breach of the IRB's duty to protect the rights and safety of human research subjects.

⁹¹ *Id.* at 1221 (holding as matter of law, an IRB has a duty to plaintiff to make sure legally sufficient informed consent is obtained); *see also* Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001) (discussing negligent oversight of a study to compare different methods of lead paint abatement in housing occupied by children); Friter v. Iolab Corp., 607 A.2d 1111, 1113 (Pa. Super. Ct. 1992) (holding that where a patient who received an investigational intraocular lens implant was never informed that the device was experimental or that his treatment was being delivered under the auspices of a research protocol, "the hospital, as a participant in a clinical investigation . . . specifically assumed a duty to ensure that an informed consent was obtained by any patient participating in the study").

⁹² Lenahan v. Univ. of Chicago, 808 N.E.2d 1078 (Ill. App. Ct. 2004).

C. *Agency Principles: Clinical Investigators Are Independent Contractors Not Agents of Sponsor*

Agency is “the fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent by the other so to act.”⁹³ Of relevance here are the basic agency principles governing the “independent contractor,” who may or may not be considered an agent of the principal, but is definitely *not* an employee.⁹⁴

1. Fact-Intensive Determination of Employee v. Independent Contractor

Distinguishing between an employee and an independent contractor remains a fact-intensive, contextually driven discussion. Courts have generally used the factors listed in the Restatement as guidance.⁹⁵

Despite being held to the guidelines provided by the sponsor, the clinical investigator does not possess obligations commensurate with the status of an employee. The federal regulations dictate that clinical investigators are selected only to conduct clinical trials for investigational new drugs.⁹⁶ Sponsors have no part in conducting the trials. They merely provide the investigators with enough information to conduct the investigation properly

⁹³ RESTATEMENT (SECOND) OF AGENCY §1 (1958)

⁹⁴ The Restatement of Agency states: “An independent contractor is a person who contracts with another to do something for him but who is not controlled by the other nor subject to the other’s right to control with respect to his physical conduct in the performance of the undertaking. *He may or may not be an agent.*” *Id.* § 2(3) (emphasis added).

⁹⁵ Section 220 of the Restatement of Agency offers a series of factors that courts have followed when distinguishing between an employee and an independent contractor:

- (a) the extent of control which, by the agreement, the master may exercise over the details of the work;
- (b) whether or not the one employed is engaged in a distinct occupation or business;
- (c) the kind of occupation, with reference to whether, in the locality, the work is usually done under the direction of the employer or by a specialist without supervision;
- (d) the skill required in the particular occupation;
- (e) whether the employer or the workman supplies the instrumentalities, tools, and the place of work for the person doing the work;
- (f) the length of time for which the person is employed;
- (g) the method of payment, whether by the time or by the job;
- (h) whether or not the work is a part of the regular business of the employer;
- (i) whether or not the parties believe they are creating the relation of master and servant; and
- (j) whether the principal is or is not in business.

Id. § 220(2)(a)-(j).

⁹⁶ 21 C.F.R. § 312.50.

and in accordance with the general investigational plan.⁹⁷ The sponsor's responsibility primarily lies in overseeing the clinical investigations, ensuring that there is proper compliance with the protocols, reviewing the data and discontinuing the investigation, if it presents an "unreasonable and significant risk to subjects."⁹⁸ Sponsors hold little power over the clinical investigator's everyday discretionary decisions and operating procedures.⁹⁹ The clinical investigators work in their own labs or clinics, use their equipment and employees, work for the sponsor on specific clinical trials, and are paid upon completion of the clinical trials rather than on a salary.¹⁰⁰ The Industry Guidelines also state that the "investigator should be able to demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period"; "the investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely."¹⁰¹ Nothing is said about the sponsor's responsibility in providing these basic necessities for the investigator. These factors all point to the logical conclusion that clinical investigators are *not* the sponsor's employees but are instead independent contractors who are contracted to perform a specific project.

2. Clinical Investigators as Independent Contractors and Also Agents

There is a difference between *independent contractor-agents* and *independent contractor non-agents*.¹⁰² The distinguishing factor is that an independent contractor-agent acts as a fiduciary to the principal.¹⁰³ The key difference between an independent contractor and an employee is that the independent contractor may not act in ways that are "equitable with the actions of the principal in all circumstances and for all purposes."¹⁰⁴ In other words, the vicarious liability principles that dominate an agency relationship in an employer-employee relationship are not present in independent contractor relationships.

⁹⁷ *Id.*

⁹⁸ 21 C.F.R. § 312.56(a), (c), (d).

⁹⁹ See also U.S. Dep't of Health and Human Services, *The Guidance for Industry, Good Clinical Practices*" (Apr. 1996) (Industry Guidelines), available at, www.fda.gov/oc/industry/guidance/iche6.htm.

¹⁰⁰ *Id.* at 13-16.

¹⁰¹ *Id.* at 19.

¹⁰² RESTATEMENT (SECOND) OF AGENCY §14N, cmts. a & b (1965).

¹⁰³ The Restatement of Agency states, in pertinent part:

In fact, most of the persons known as agents, that is, brokers, factors, attorneys, collection agencies, and selling agencies are independent contractors as the term is used in the Restatement of this Subject, since they are contractors but, although employed to perform services, are not subject to the control or right to control of the principal with respect to their physical conduct in the performance of the services. However, they fall within the category of agents. They are fiduciaries; they owe to the principal the basic obligations of agency: loyalty and obedience.

Id. at § 16N, cmt. a.

¹⁰⁴ *JMB Enters. v. Atl. Employers Ins. Co.*, 550 A.2d 764, 768 (N.J. Super. Ct. App. Div. 1988).

In the case of clinical trials, it is clear that clinical investigators are independent contractors who are also agents. According to the federal regulations, sponsors must provide clear guidelines to their clinical investigators through their protocols. These protocols must contain, among other things, an outline of the investigation that includes an estimate of the number of subjects involved, a description of the safety exclusions, a description of the monitoring plan, and other details necessary for the safety of the subjects.¹⁰⁵ Other than these guidelines specifically set to ensure statistically verifiable data and to fulfill federal regulatory requirements, sponsors hold no authority over the investigator's discretion in the actual recruitment of the subjects or the care of the subjects during the trial.

D. *Generally Negligence of Independent Contractors Not Imputed to Principal*

It is well settled among the courts that common law agency principles governing principal-employee relationships are not applicable to principal-independent contractor situations. For instance, an employee's negligent actions within the scope of his employment may be imputed to his employer.¹⁰⁶ In the case of an independent contractor, however, his negligent actions may not be imputed to his principal, except in the following circumstances: (1) the independent contractor was contracted to engage in ultra-hazardous or peculiar risk situations; (2) the principal contracted duties that were non-delegable; (3) the "apparent authority" principle or the doctrine of "agency by estoppel" prohibits principals from escaping their liability; or (4) the principal retained a right to control a portion of the work and was negligent in its endeavor.

Clinical investigators, as independent contractors, are not engaged in ultra-hazardous or peculiar risk situations, and no case has applied this exception to clinical investigational drug cases.

Generally, non-delegable duties are those statutorily imposed upon a party due to public policy reasons. These duties may not be waived or delegated to an independent contractor. Here, the federal regulations clearly state that sponsors must select, or delegate, qualified investigators to conduct the clinical trials.¹⁰⁷ Given this regulatory mandate, it is apparent that this exception does not apply in the clinical trial context.

1. Sponsors May Be Liable Under Doctrine of Apparent Authority

The Restatement defines apparent authority as "the power to affect the legal relations of another person by transactions with third persons, *professedly* as agent for the other, arising from and in accordance with the other's manifestations to such third persons."¹⁰⁸ In

¹⁰⁵ 21 C.F.R. § 312.23(a)(6).

¹⁰⁶ RESTATEMENT (SECOND) OF AGENCY, § 140 (1965).

¹⁰⁷ 21 C.F.R. § 312.50.

¹⁰⁸ RESTATEMENT (SECOND) OF AGENCY, § 8 (1965) (emphasis added).

other words, apparent authority occurs where a principal is “bound not only by the authority that it actually gives to another but also by the authority that it *appears* to give.”¹⁰⁹

The principles of apparent authority are grounded in the equitable doctrine of estoppel. Therefore, courts have found that principals will be liable for the independent contractor-agent’s misrepresentations “upon matters which the principal might reasonably expect would be the subject of representations, provided the other party has no notice that the representations are unauthorized.”¹¹⁰ Furthermore, if an agent is authorized to conduct a particular transaction and the third party is unaware of “*any limitation upon the agent’s authority*, a problem similar to that of the limits of the scope of employment by a servant arises.”¹¹¹

Although no uniform test for apparent authority exists, most courts generally adhere to a fact-driven analysis that examines whether the independent contractor-agent was authorized to act on the principal’s behalf without clear limits on the scope of its authority, *and* whether there was detrimental, justifiable reliance by the innocent third party.¹¹² Here, the relevant question is whether the sponsors have held the investigators out to hold apparent authority that extended far beyond what was required by the federal regulations, and whether a third party could reasonably rely on such (mis)representations. Because no cases exist to demonstrate the doctrine’s application for clinical trial contexts, analogous cases may be helpful.

The highest court in Illinois examined how the apparent authority doctrine applied to health maintenance organizations (HMOs) and its independently contracting doctors.¹¹³ The patient alleged that the doctors were negligent in their untimely diagnosis of her oral cancer. She also alleged that her HMO provider, “Share,” was vicariously liable under the agency principles of apparent authority and implied agency, and that summary judgment entered against her should be reversed. The court agreed.

The court first examined whether the HMO held the doctors out as its employees rather than as independent contractors. In this regard, the HMO cited to independent contractor provisions contained in its master agreements with the doctors, stating that such provisions constituted sufficient evidence of the doctors’ independent contractor status. The court disagreed, because there was no evidence that the patient knew or should have known of the doctors’ master agreements with Share. Additionally, the HMO presented as evidence the benefits contract provided for patients, which contained the subscriber certificate with language regarding the doctors’ independent contractor status. Regardless, the court held that such evidence was not sufficient to show that the patient actually received the information and knew that the doctors were independent contractors.

¹⁰⁹ *Petrovich v. Share Health Plan*, 719 N.E.2d 756, 765 (Ill. 1999) (emphasis added).

¹¹⁰ RESTATEMENT (SECOND) OF AGENCY, § 258 (1965). *See also* *Am. Tel. & Tel. Co. v. Winback & Conserve Program*, 42 F.3d 1421, 1437 (3rd Cir. 1994).

¹¹¹ *Am. Tel. & Tel. Co.*, 42 F.3d at 1438.

¹¹² RESTATEMENT (SECOND) OF AGENCY, § 8 cmt. D (1965). *See also* *Am. Tel. & Tel. Co.*, 42 F.3d at 1438.

¹¹³ *Petrovich*, 719 N.E.2d at 766.

In contrast, the plaintiff cited to the member handbooks patients received from the HMO, which stated that it offered “comprehensive high quality services” and referenced the physicians as “your Share physician” and the physician’s offices as “Your Share physician’s office.”¹¹⁴ There was no mention that the doctors were independent contractors. The court concluded that there was a triable issue of fact for the jury and reversed the lower court’s summary judgment for Share.

The court next examined whether the patient justifiably relied on the doctors’ apparent authority as Share’s employees. Specifically, it focused on whether the patient relied on Share as an HMO that provided health care services, or whether she sought a specific physician and the HMO was merely the “conduit.”¹¹⁵ This distinction was considered important because if the patient relied on Share to provide health care services, which included *its* selection of doctors, then it was more likely that the patient believed the doctors to be the HMO’s employees, rather than its independent contractors.

Given the state of the law, it may not be enough that the Study Agreement created between the sponsor and the investigator enumerates the independent contracting relationship. The sponsor must ensure that the investigator makes the relationship clear to third parties such as clinical participants, for example, in the consent form signed by the participant.

2. Sponsors Retaining Right to Control Impacts Clinical Investigator’s Status

A closer question is found in this last exception to the general agency doctrine that does not impute an independent contractor’s actions upon the principal. Often this exception is classified as the implied agency doctrine, i.e., whether the principal retains any control over its independent contractor’s duties “so as to negate that person’s status as an independent contractor, at least with respect to third parties.”¹¹⁶ Courts engage in a fact-intensive analysis to determine whether the alleged agent retained the right to control the manner of the work.

Although there are no reported cases on this issue, plaintiffs may argue that the federal regulations give sponsors significant control and power in overseeing the clinical trials and that, as a result, sponsors should be held liable for the investigator’s negligent oversight of the clinical subjects. On the one hand, the plaintiff’s argument may be successful precisely because the Study Agreement between the clinical investigator and the sponsor is tailored to create a uniform testing environment for all participating investigators. If the clinical investigator’s actions with respect to the clinical trials are guided by the sponsor’s extensive guidelines, then plaintiffs may argue that sponsors do exercise control

¹¹⁴ *Id.* at 768.

¹¹⁵ *Id.* at 769.

¹¹⁶ *Id.* at 770. *See also* *Cubby v. Compuserve Inc.*, 776 F. Supp. 135, 143 (S.D.N.Y. 1991) (holding that the principal will only be vicariously liable for the independent contractor’s tort where the “employer must have directed the act from which the injury resulted or have taken an affirmative, active part in its commission”).

over the portion of the clinical investigator's work that negligently caused injury to the clinical subject and that the sponsor has therefore negated the clinical investigator's independent contractor status.

Such an argument may be countered by the fact that the sponsor's general responsibilities do not speak specifically as to how the clinical investigator should order his everyday affairs, organize the office and personnel, or render medical and professional decisions relating to the clinical trial subjects.¹¹⁷ Significantly, the federal regulations contain no mention of how the sponsors will monitor the investigator's relationship with the clinical trial subjects.¹¹⁸ Rather, the federal regulations place the burden of "protecting the rights, safety, and welfare of subjects under the investigator's care."¹¹⁹

In addition, some courts have held that contractual provisions "intended to insure compliance with applicable governmental regulations" should not be viewed as control mechanisms.¹²⁰ One concluded that under an agreement created between the city and an ambulance service, the ambulance service was an independent contractor.¹²¹

Here, the contact between a sponsor and a clinical trial subject is limited by the federal regulations and the need for unbiased results in medical and scientific research. For example, the clinical investigators are required to ensure that they receive informed consent from potential subjects regarding the drugs and further required to develop a general plan of the investigation, including the number of participants in the trial and their descriptions.¹²² Additionally, the regulations require the sponsor to review and evaluate the evidence with regard to the "safety and effectiveness of the drug as it is obtained from the investigator," and if it determines that there is an unreasonable and significant risk to subjects, the investigation must be terminated according to FDA procedures.¹²³ The regulations make clear that any information with regard to the clinical subjects is conveyed through the investigators. Thus, these extensive guidelines for the sponsors relate to the progress and completion of the clinical trial itself. They do not address the investigator's discretion with regard to the clinical subjects who participate in the trial.

¹¹⁷ 21 C.F.R. § 312.50.

¹¹⁸ See also Industry Guidelines.

¹¹⁹ 21 C.F.R. § 312.60 (2005).

¹²⁰ *Palmer v. City of Yonkers*, 22 F. Supp. 2d 283, 288 (S.D.N.Y. 1998).

¹²¹ *Id.* at 288 ("... (1) requires Empress to establish a medical reporting system, (2) prohibits Empress from making changes in services to be provided without written approval of the City, (3) requires standard emergency medical technician training, (4) reserves to the City the right to require additional training, (5) sets out required equipment, (6) requires certain staffing requirements, and (7) provides for a \$200,000 payment by the City to Empress."); see also *Chainani v. Bd. of Educ.*, 663 N.E.2d 283 (N.Y. 1995) (holding that despite having safety sessions, the schools did not retain control over the manner in which the bus company performed its work).

¹²² 21 C.F.R. § 312.53(c)(1)(vi)(d) and § 312.53 (c)(3)(i)-(ii).

¹²³ *Id.* § 312.56(b)-(c).

Furthermore, courts have not changed the learned intermediary analysis when the doctor and patient are in a clinical trial setting.¹²⁴ The courts' analysis is primarily fact-sensitive, case-by-case and directed at determining whether that relationship is different enough to impose upon the manufacturer an additional duty of warning or supervising the patients directly. Notably, the theory of agency is not mentioned in their decisions.

For example, the doctor in one case determined the subject's suitability for the program, performed a physical examination, elicited the subject's medical history, and retained the right to remove the patient from the study if circumstances warranted such actions.¹²⁵ Although the manufacturer paid the doctor for every clinical participant in the study, the court found no indication that the doctor was employed by the manufacturer or that the doctor could not exercise independent medical judgment. Rather, the court determined that the physician acted independently of the manufacturer and was a learned intermediary. The court specifically held that the "status of the drug with the FDA does not alter the relationship between the drug manufacturer, physician and patient."¹²⁶ The court did not engage in an analysis of agency principles, yet it implicitly concluded that the physician investigator was free to act independently as the learned intermediary in the care of the patient participant.

Although the issue of agency was not discussed explicitly, the highest court in Arizona noted that, among other things, the distribution of proper warnings to the clinical investigators through the protocols and the manufacturer's "close touch with its investigators to monitor possible adverse reactions of [] patients" constituted sufficient fulfillment of the manufacturer's duties.¹²⁷ The investigator's allegedly negligent selection of the plaintiff as a patient and the administration of the drug did not impute liability upon the manufacturer under a theory of strict liability or negligence. Implicitly, because the court did not find that the manufacturer breached its duty, it acknowledged that the manufacturer's duty is fulfilled once the learned intermediary is informed of the drug's risks.

In a third case, the court held that the clinicians conducting a study for an investigational drug acted as learned intermediaries to their schizophrenic patient.¹²⁸ It noted that the clinicians "promised [the manufacturers] that they would obtain informed consent, that they had read and understood the Investigational Drug Brochure and that they would at all

¹²⁴ The learned intermediary doctrine provides that pharmaceutical manufacturers discharge their duty to warn purchasers of their product if they provide adequate warnings to the learned intermediary – the prescribing physician. *Oksenholt v. Lederle Labs.*, 625 P.2d 1357, 1362 (Or. Ct. App. 1981). The prescribing physician is in the best position to "balance the risk of possible harm against the benefits to be gained by the patient's use of that drug." *Id.* (quoting *McEwen v. Ortho Pharm.*, 528 P.2d 522, 529 (Or. 1974).

¹²⁵ *Tracy v. Merrell Dow Pharm.*, 569 N.E.2d 875 (Ohio 1991).

¹²⁶ *Id.* at 880.

¹²⁷ *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. 1978).

¹²⁸ *Kerneke v. Menninger Clinic, Inc.*, 173 F. Supp. 2d 1117 (D. Kan. 2001).

times exercise their independent medical judgment as to the compatibility of a prospective study participant with the study protocol requirements.”¹²⁹ The court also clearly stated that the manufacturer was “entitled to rely” on the clinicians to properly relay these risks to the study’s subjects.¹³⁰ In addition, it noted that the clinicians determined whether the patient met the participation requirements for the Phase I and II of the study. Taken together, the court found that the learned intermediary doctrine shielded the manufacturer from liability so long as the manufacturer fulfilled its legal duty of warning the doctor of the drug’s risks.

These cases demonstrate the courts’ general reluctance to create an exception to the learned intermediary rule, even in clinical trial settings where the sponsor/manufacturer occupies a larger role than in the traditional doctor-patient relationship.

E. *Public Policy Argument*

It is the physician-investigator who is charged with taking care of the patients’ welfare, including determining whether it is in the patient’s best medical interest to enter or stay in the study.¹³¹ Outside interference in that decision would be chaotic. A divergence of opinion between the sponsor-retained oversight physician and the physician-investigator on a whole range of issues – including what diagnosis should be ascribed to particular findings, how that should be communicated to the participant, and whether that diagnosis means a participant should be excluded or removed from the trial – would compromise data integrity, patient safety and the timely conduct of the trial.

Even more fundamentally, the creation of such a costly, unreasonable and unwarranted control or oversight duty, by agency principles or otherwise, contravenes sound public policy – the watershed for any duty analysis. One court explained that duty “is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.”¹³²

The paramount societal goals of any clinical trial are the cost-effective reduction of disease and betterment of public health. A sponsors’ willingness to invest in the research, investigation and marketing of new medicines is society’s most effective weapon for developing revolutionary health breakthroughs that enhance our lives and ease our suffering.¹³³

¹²⁹ *Id.* at 1119-20.

¹³⁰ *Id.* at 1122.

¹³¹ 21 C.F.R. § 312.60 (investigator’s responsibility to follow study protocol and to protect the safety and welfare of the patients under his care).

¹³² *Friedman v. Merck & Co.*, 131 Cal. Rptr. 2d 885 (Ct. App. 2003) (declining to impose a duty on a drug test distributor to warn vegetarian plaintiff that TB test contained animal products; although court did not doubt validity of plaintiff’s emotional distress injury, public policies did not support imposing duty to warn of potential idiosyncratic or unusual product reactions on this defendant).

¹³³ *See Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988) (public interest in availability and affordability of drugs to save lives and reduce pain and suffering).

IV. CONCLUSION

Under FDA regulations, the welfare of a clinical trial subject is the duty of the physician-investigator, not the clinical trial sponsor. As the courts and FDA regulations illustrate, a physician-investigator is responsible for all facets of a clinical trial subject's care during the duration of the trial. Sponsors should not be held liable for the negligent actions of a physician-investigator conducting the clinical trial. It is that person who has a duty of care to clinical trial subjects, not the sponsor.

In fact, the only scenario where courts are willing to extend liability for a physician-investigator's negligent actions is in the case of informed consent. Even then, courts do not extend the liability to sponsors, but to the IRB charged with reviewing the informed consent, since it is the paramount purpose of an IRB to protect the rights and safety of clinical trial subjects. Therefore, under FDA regulations and case law, the welfare of a clinical trial subject ultimately rests with the physician-investigator and the reviewing IRB, not the sponsor.

Assurance agreements, which are contracts between various institutions and the OHRP, do not provide a reliable method for research subjects to recover from institutions that have filed them. Since private sponsors are not required to file assurance agreements with the OHRP, they should not do so unless the risks outweigh the benefits. The law is still sufficiently undeveloped that a court may break new ground and use assurances to give research subjects relief.

There is a dearth of cases that explicitly address the theory of agency in a clinical sponsor-investigator context. It is unlikely that courts will impute to the clinical sponsor liability for the negligent actions of its investigator. The clinical investigator's independent contractor status clearly establishes that its actions will not be imputed to the principal. In rare circumstances, a third party beneficiary theory might be actionable, if clinical sponsors are not vigilant in policing their investigator's representations. In considering whether the sponsor held and exercised its right to control the investigator's work with regard to his medical discretion over the clinical trial subjects, courts have extended the learned intermediary doctrine to the clinical trial context and found no liability for the sponsor.

While reassuring, the fact remains that an increasing number of cases are being filed against clinical sponsors and investigators for injuries arising in the clinical trial context. When faced with such claims, where possible, sponsors and investigators should present a united defense and try to avoid "pointing the finger" at each other. Indemnity issues should not be played out in front of the plaintiff, but should be reserved. The same is true if IRBs, CRAs or other agents of the sponsor or investigator are brought in to the litigation.

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Handling “Bad” Company Documents: Preventing Admission at Trial[†]

Leslie C. O’Toole
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I. INTRODUCTION

One of the most powerful evidentiary tools available to plaintiffs is the use of a company’s own “bad” documents against it at trial. In this age of technology, “bad” documents are more likely to be accessible because of increased use of computers, e-mail, and the Internet. Requests for production of documents are no longer limited to paper documents; instead, they have been expanded to include e-mail, electronic calendars, draft documents in softcopy form, and computer files. Many of these “bad” documents have never been printed, read, or even disseminated among company employees or executives.

The creation of a “bad” company document happens quickly and easily. An employee writes a quick email to a co-worker. Without understanding the implications of the message, the employee refers to a chart of fatalities associated with a drug as a “death list.” Years later, a skilled trial lawyer representing a deceased plaintiff seizes upon this reference. By tying together a few pieces of documentary evidence, the attorney can paint a negative picture of the company – shaded by hues of improper motive, dishonesty, and a sundry list of other items. Admission of this evidence at trial can imply product defect and liability by showing that the company marketed the drug as safe at the same time it maintained a “death list.”

Once “bad” company documents are created, they can become powerful weapons in the hands of an adversary. Despite their marginal relevance to the case, these documents

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are highlighted, enlarged, and mounted for display to jurors, or copied and given to jurors for examination during their deliberations. Given the significance of this dilemma, this article will highlight strategic legal bases for excluding such “bad” corporate documents at trial in drug and medical device cases.

II.

DRUG AND MEDICAL DEVICE ADVERSE EVENT REPORTING

Under the Federal Food, Drug, and Cosmetic Act and its accompanying regulations, drug and medical device manufacturers submit product safety reports to the Federal Drug Administration (“FDA”). Voluntary reports also can be submitted by healthcare professionals, patients, and others.¹ One such report includes compilations of anecdotal data regarding alleged drug failures. Typically, these are designated as Adverse Drug Events (“ADEs”).²

¹ U.S. Food and Drug Administration, available at <http://www.fda.gov> (last visited Sept. 8, 2005).

² U.S. Food and Drug Administration, available at <http://www.fda.gov/medwatch/report/consumer/consumer.htm> (last visited Sept. 8, 2005).



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ADEs should be excluded from evidence at trial because they lack reliability, they lack relevance, and they pose a significant danger of unfair prejudice, issue confusion, and waste of time. ADEs are inherently unreliable because they are based on anecdotal data that cannot be verified. Although rooted in protecting the public health, ADEs at most provide a temporal association between a drug and an unexpected physical reaction.³ Proximity in time, however, simply does not equate with causation. Accordingly, judicial use of such reported information is shielded by statute. Under Section 379v of the United States Code, safety reports and information submitted by any entity pursuant to the Federal Food, Drug, and Cosmetic Act cannot be construed as “an admission that the product involved malfunctioned, caused, or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness.”⁴ Further, the statute specifically allows the submitting entity to deny that the safety report or other reported information constitutes an admission of product defect or causation.

³ See *DeLuca v. Merrell Dow Pharm.*, 791 F. Supp. 1042, 1050-51 (D.N.J. 1992), *aff'd*, 6 F.3d 778 (3rd Cir. 1993) (recognizing that drug experience reports contain inherent biases and distortions and cannot be used to prove causation); *Golod v. Hoffman La Roche*, 964 F. Supp. 841, 855-56 (1997) (adverse experience reports were not admissible on issue of causation, but were admissible to show whether drug manufacturer had notice of certain side effects).

⁴ 21 U.S.C. § 379v (1997).

At least one court has recognized that the “most significant analytical defect [of ADEs] is that they don’t isolate the investigative effects of alternative causation agents.”⁵ Accordingly, expert opinion testimony on causation, when based on such anecdotal data, has been excluded as insufficiently reliable to satisfy the requirements of *Daubert* and its progeny.⁶

Lack of reliability also supports the exclusion of ADEs as inadmissible hearsay evidence. When proffered by an adversary at trial, ADEs constitute nothing more than out-of-court statements offered to prove the truth of the matter, e.g., a product defect or liability. Under the Federal Rules of Evidence, such hearsay is not admissible unless it falls within a recognized exception to the hearsay rule.⁷

ADEs, however, are unlikely to satisfy the requirements of an exception to the hearsay rule. For example, ADEs do not satisfy the business records exception because they are not made in the regular course of business and are not prepared at or near the time of the event.⁸ ADEs instead are based on subjective reports of lay persons. There may be a delay of weeks, months, or even years between the time of the unexpected “event” and the report of the event as provided by the patient to a physician. As a result, important details may be innocently omitted or misconstrued without challenge since no independent investigation into the underlying truth of the information is undertaken by any individual or entity. Similarly, ADEs do not satisfy the public records exception because they are not “activities of the office or agency” or “matters observed pursuant to a duty imposed by law.”⁹ ADEs are prepared by private individuals or entities. They are anecdotal reports that are submitted to a public body. Even if certain elements of the business record or public records exceptions could be established, the inherent unreliability of ADEs favors their exclusion due to lack

⁵ *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999).

⁶ *See Caraker v. Sandoz Pharm. Corp.*, 188 F. Supp. 2d 1026, 1034-35 (S.D. Ill. 2001) (rejecting expert causation opinion testimony to the extent it relied on anecdotal case reports); *Glastetter v. Novartis Pharm. Corp.*, 107 F. Supp. 2d 1015, 1044 (E.D. Mo. 2000), *aff’d*, 252 F.3d 986 (8th Cir. 2001) (rejecting experts’ opinions to the extent that they relied on selective use of statistically insignificant data from case studies); *Hollander v. Sandoz Pharm. Corp.*, 95 F. Supp. 2d 1230, 1236-39 (W.D. Okla. 2000), *aff’d*, 289 F.3d 1193 (10th Cir. 2002) (excluding experts because they did not meet the reliability requirements of Federal Rule 702 and *Daubert* when based in part on anecdotal case reports); *Brumbaugh*, 77 F. Supp. 2d at 1155-57 (holding that expert causation testimony should be excluded under Federal Rule of Evidence 702 and 703 because their opinions, based in part on ADEs, did not have sufficient evidentiary reliability to be admissible); *cf. Globetti v. Sandoz Pharm. Corp.*, 111 F. Supp. 2d 1174, 1177-80 (N.D. Ala. 2000) (finding expert opinions on causation based in part on ADEs and case reports sufficiently reliable under *Daubert*).

⁷ Fed. R. Evid. 802; *Rowland v. Am. Gen. Fin., Inc.*, 340 F.3d 187, 194-95 (4th Cir. 2003) (recognizing that letter was inadmissible hearsay unless it met an exception to the hearsay rule).

⁸ *See* FED. R. EVID. 803(6).

⁹ FED. R. EVID. 803(8).

of trustworthiness. Thus, such reports should be excluded as inadmissible hearsay and as inherently unreliable.¹⁰

An alternative basis for the exclusion of ADE evidence at trial focuses on its irrelevance and the danger of unfair prejudice, issue confusion, and waste of time.¹¹ The reported adverse events are not relevant when they are not substantially similar to the plaintiff’s claimed injury. As a general rule, evidence of previous accidents is not admissible in product liability cases unless it is shown that the previous accident occurred under similar circumstances.¹² Even if such reports were deemed relevant, alternative grounds for exclusion exist under Federal Rule 403 because any probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and waste of time.¹³

In the medical device context, manufacturers submit Medical Device Reports (“MDRs”) regarding incidents of product failure.¹⁴ Voluntary reports can be submitted by healthcare professionals and others. Like ADEs, MDRs provide only a temporal association between an individual who receives or uses a medical device and an adverse physical reaction that is reported to a physician. Neither ADEs nor MDRs undergo scientific analysis to isolate and investigate alternative causes of unexpected or adverse physical reactions.

The discovery and admissibility of certain MDRs is prohibited by statute. First, the United States Code expressly states that when a hospital, outpatient facility (that is not also a physician’s office), ambulatory surgical facility, or nursing home becomes aware of information that reasonably suggests that a medical device may have caused a death or serious injury, the report “shall [not] be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.”¹⁵ In addi-

¹⁰ See, e.g., *Figuroa v. Boston Scientific Corp.*, No. 00-CV-7922, 2003 WL 21488012, at *3, *5 (S.D.N.Y. June 27, 2003) (granting motion in limine to exclude study reporting out-of-court statements obtained by physicians during interviews as unreliable hearsay and double hearsay); cf. *Becker v. Nat’l Health Prod., Inc.*, 896 F. Supp. 100, 104 (N.D.N.Y. 1995) (holding, without analysis, that FDA complaint reports were admissible hearsay under business record and public records exceptions and that probative value was not substantially outweighed by danger of unfair prejudice).

¹¹ See FED. R. EVID. 402, 403.

¹² See *Barker v. Deere & Co.*, 60 F.3d 158, 162-63 (3rd Cir. 1995); *Rye v. Black & Decker Mfg. Co.*, 889 F.2d 100, 108 (6th Cir. 1989).

¹³ See FED. R. EVID. 403.

¹⁴ U.S. Food and Drug Administration, available at <http://www.fda.gov/medwatch/report/hcp.htm> (last visited Sept. 8, 2005).

¹⁵ 21 U.S.C. § 360i (1997).

tion, federal regulations prohibit disclosure of identifying information contained in voluntary MDRs.¹⁶ These statutes have been interpreted to prohibit disclosure of any information obtained from voluntary MDRs or the discovery of other documents that rely on information contained in such reports.¹⁷

Certain MDRs fall outside the protection afforded by the Code of Federal Regulations, however. With respect to these reports, the bases for excluding evidence of MDRs at trial parallel those discussed above regarding ADEs.

III. SUBSEQUENT REMEDIAL MEASURES

From time to time, drug and medical device manufacturers can find themselves “between a rock and a hard place.” These businesses strive to develop and manufacture drugs and medical devices that address continuing health conditions and disease. Operating in a constantly changing environment, these drug and medical device manufacturers obtain new safety information about their products nearly every day. At times, new safety information warrants voluntary action to recall a drug or medical device from the market, or to revise package inserts, labels, or dosage levels. Such activities generate documents, conveying this new safety information, that are widely disseminated (both in printed form and on the Internet) to physicians and patients. Recall notices and modifications to package inserts or labels are not “bad” company documents per se. They may constitute evidence that drug and medical device manufacturers continue to evaluate their products, ready to make changes in availability, information, and dosage levels when appropriate. Notwithstanding their salutary effect, in the hands of a skilled adversary, documents resulting from such voluntary conduct may be used at trial to suggest to the jury that the product was defective and inherently dangerous, and that the manufacturer should be held accountable.

The Federal Rules of Evidence likewise offer a basis for excluding evidence of recall notices and changes in package inserts, labels, and dosage at trial. Under one such rule, evidence of subsequent remedial measures is not admissible to show “negligence, culpable conduct, a defect in a product, a defect in a product’s design, or a need for a warning or instruction.”¹⁸ Accordingly, when activities that include product recall or label change oc-

¹⁶ 21 C.F.R. § 20.63(f) (1995).

¹⁷ See *In re Medtronic, Inc.*, 184 F.3d 807, 808-11 (8th Cir. 1999) (court order compelling disclosure of reports covered by 21 U.S.C. § 360i(b)(3) was improper and violated the statute); *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1074 (W.D. Ark. 1999) (finding that voluntary MDRs were not discoverable under 21 C.F.R. § 20.63(f)).

¹⁸ FED. R. EVID. 407.

cur after the plaintiff’s injury, documentary evidence of such voluntary activities is inadmissible.¹⁹

Nevertheless, timing issues sometimes create obstacles to the admissibility protection offered by Federal Rule of Evidence 407. Thus, it may be necessary to invoke additional grounds for excluding this evidence, such as irrelevance and the danger of unfair prejudice or confusion of the issues.²⁰ Evidence of a voluntary recall or changes to package inserts, labels, or dosage levels is not relevant to assess liability because the issue is properly framed as whether the product was defective at the time it was sold.²¹ Further, it is likely that the prescribing or implanting physician did not rely on any recall notice or change to a package insert, label, or dosage to obtain information about the product. Rather, physicians commonly rely on published medical literature and presentations at product conferences. When post-sale activities are not relevant to any issue in the case, this evidence is properly excluded under Federal Rule of Evidence 402.²²

To the extent that an adversary is able to establish the relevance of post-sale activities, an alternate basis for exclusion of voluntary recalls or changes to package inserts, labels, and dosage levels is available under Federal Rule of Evidence 403.²³ The risk that a jury would unfairly use evidence of a voluntary recall as an admission of liability or use evidence of changes to package inserts or labels as evidence of a product defect substantially outweighs any probative value. The potential for unfair prejudice from introduction of this evidence at trial warrants its exclusion.²⁴

¹⁹ See *Chase v. General Motors Corp.*, 856 F.2d 17, 19-21 (4th Cir. 1988); *Werner v. Upjohn Co.*, 628 F.2d 848, 853-56 (4th Cir. 1980) (evidence of revised drug warning issued after plaintiff’s injury was inadmissible under Federal Rule of Evidence 407); *Wolf v. Proctor & Gamble Co.*, 555 F. Supp. 613, 623-24 (D.N.J. 1982) (Federal Rule of Evidence 407 barred admission of voluntary recall evidence to show defect or causation).

²⁰ FED. R. EVID. 402, 403.

²¹ See *Grenada Steel Indus. Inc. v. Alabama Oxygen Co.*, 695 F.2d 883, 888 (5th Cir. 1983).

²² See *In re Richardson-Merrell, Inc. “Bendectin” Prod. Liab. Litig.*, 624 F. Supp. 1212, 1239 (S.D. Ohio 1985), *aff’d*, 857 F.2d 290 (6th Cir. 1986) (evidence of defendant’s discontinued sale of Bendectin was not relevant under Federal Rules of Evidence 401 and 402); *Kociemba v. G.D. Searle & Co.*, 683 F. Supp. 1579, 1581-82 (D. Minn. 1988) (excluding evidence of manufacturer’s voluntary discontinuation of intrauterine device on relevancy grounds); *cf.*, *Figueroa v. Boston Scientific Corp.*, No. 00-Civ-7922, 2003 WL 21488012, at * 1, *4-5 (S.D.N.Y. June 27, 2003) (denying motion in limine to exclude evidence of a voluntary recall that occurred before the plaintiff suffered injury from defendant’s medical device).

²³ See FED. R. EVID. 403.

²⁴ See *Kociemba*, 683 F. Supp. at 1581-82 (granting manufacturer’s motion to exclude evidence of a voluntary drug recall because of the danger of unfair prejudice that it would be considered by the jury as an admission of liability); *In re Richardson-Merrell*, 624 F. Supp. at 1239 (applying Federal Rule of Evidence 403 to manufacturer’s withdrawal from intrauterine device market).

IV. DIRECT ADVERTISEMENTS — PRINT, MEDIA, AND THE INTERNET

An adversary also may attempt to admit a company's direct advertising into evidence to show that the company failed to adequately warn the plaintiff about product-related risks. Direct advertising is fertile ground for the creation of "bad" company documents that may be used by a skilled adversary against a product manufacturer at trial. Television advertisements typically are short and use creative metaphors to imply effectiveness. Print advertisements usually include product-related risk information in smaller type, located somewhere other than in the primary advertising space. Even if displayed more prominently, approved summaries of product-related risks may be difficult for the average consumer to understand.

For many years, the learned intermediary doctrine has shielded drug and medical device manufacturers from liability for failure to warn claims.²⁵ Under this doctrine, a drug or medical device manufacturer has a duty to provide product warnings only to the prescribing physician.²⁶ The learned intermediary doctrine is premised upon the physician-patient relationship. Because patients rely on physicians to recommend and select treatment options based upon individual assessments, the physician (and not the manufacturer) is in the best position to warn the patient about any risks associated with the product.

At least one state court, however, has carved out a new exception to the learned intermediary doctrine based on the manufacturer's direct advertising. The New Jersey Supreme Court in *Perez v. Wyeth Labs., Inc.*,²⁷ held that the learned intermediary doctrine did not apply to a drug manufacturer because of its direct advertising activities. Instead, the manufacturer had a direct duty to warn consumers of product-related risks.²⁸ The result of recent challenges to the learned intermediary rule based on direct advertising remains uncertain.²⁹

²⁵ *Infra* note 26.

²⁶ See *Odom v. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) ("[T]he manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device."); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992) (applying learned intermediary doctrine to acne medication, Accutane); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231-32 (4th Cir. 1984) (applying learned intermediary doctrine to pacemaker); *Willet v. Baxter Int'l Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991) (applying learned intermediary doctrine to artificial heart valve); *Padgett v. Synthes, Ltd.*, 677 F. Supp. 1329, 1335 (W.D.N.C. 1988), *aff'd*, 872 F.2d 418 (4th Cir. 1989) (applying learned intermediary doctrine to compression plate for tibia).

²⁷ 734 A.2d 1245 (N.J. 1999).

²⁸ *Perez*, 734 A.2d at 1257-64; *cf.* *In re Norplant*, 165 F.3d 374, 379-80 (5th Cir. 1999) (rejecting proffered "aggressive" direct advertising exception to learned intermediary doctrine and applying doctrine in case to manufacturer of Norplant).

²⁹ See, e.g., *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 841-42 (Neb. 2000) (applying learned intermediary doctrine to failure to warn claim involving acne drug, Accutane); *Tracy v. Merrell-Dow Pharm. Inc.*, 569 N.E.2d 875, 879 (Ohio 1991) (learned intermediary doctrine applied to manufacturer of Nicorette chewing gum).

Notwithstanding increased direct advertising by drug and medical device manufacturers, the learned intermediary doctrine continues to be recognized in the vast majority of jurisdictions.³⁰ Drug and medical device manufacturers should continue to defend against admission of direct advertising into evidence based on irrelevance and the danger of unfair prejudice under the Federal Rules of Evidence.³¹ Exclusion of such evidence is proper since the communication of warnings to the individual patient is irrelevant when the proper liability analysis applies only to physicians.

Given the emergence of an exception to the learned intermediary doctrine, however, other defenses to the admissibility of direct advertising or Internet evidence deserve consideration. First, direct advertising by drug and device manufacturers implicates commercial speech protected by the First Amendment. Furthermore, the implicit authorization for patients to rely on sources other than physicians for product-related risks threatens the patient-physician relationship. Without the involvement of a physician to explain the information and to discuss product-related risks, patients may improperly substitute advertising promises for the judgment of their physicians.³²

V.

PETITIONING FOR GOVERNMENT REDRESS

Drug and medical device manufacturers frequently interact to seek redress from the government, including the FDA. Skilled adversaries may seek to admit documentary evidence of these government petitions to show improper conduct or improper motives. Since these efforts by product manufacturers are likely to be chilled if admitted into evidence against them, the balancing test of Federal Rule of Evidence 403 and the *Noerr-Pennington* doctrine³³ favor exclusion of the evidence.

Efforts by a product manufacturer to petition the government are generally immune from antitrust liability under the *Noerr-Pennington* doctrine. The *Noerr-Pennington* doctrine was first recognized in *Eastern Railroad Presidents' Conference v. Noerr Motor Freight, Inc.*,³⁴ and *United Mine Workers of America v. Pennington*,³⁵ as a limit to the scope of

³⁰ Tracey Bateman Farrell, *Products Liability: Statements in Advertising as Affecting Liability of Manufacturers and Sellers for Injury Caused by Product Other Than Tobacco*, 93 A.L.R. 5TH 10 (2004).

³¹ FED. R. EVID. 402, 403.

³² See *Swayze v. McNeil Labs. Inc.*, 807 F.2d 464, 471 (5th Cir. 1987) (“When the physician-patient privilege does exist, as here, we hesitate to encourage, much less require, a drug manufacturer to intervene in it.”).

³³ *Infra* notes 34, 35.

³⁴ 365 U.S. 127 (1964).

³⁵ 381 U.S. 657 (1965).

antitrust laws as they affect constitutionally protected speech. The doctrine is intended to remove the chill to free speech posed by the threat of potential liability.³⁶

The doctrine has been applied in contexts other than antitrust, including products liability.³⁷ The *Noerr-Pennington* doctrine also has been applied in cases involving claims against a drug manufacturer for alleged anticompetitive conduct premised upon government petitioning activity.³⁸

Although not a rule of evidence precluding admissibility, the *Noerr-Pennington* doctrine buttresses arguments for excluding evidence of government petitioning activities by drug and device manufacturers under Federal Rule of Evidence 403. Despite their marginal relevance to the case, documents regarding these efforts by manufacturers can contribute to an impermissible inference of liability drawn by a jury that implies improper motive or conduct from the evidence. Courts have considered evidence of petitioning activities directed to the government presumptively prejudicial to a defendant's First Amendment rights.³⁹ As such, any probative value that attaches to this evidence is substantially outweighed by the danger of unfair prejudice, confusing the issues, consuming time, or misleading the jury.

VI. DOCUMENTS FROM OTHER LAWSUITS OR CLAIMS

Although not created by companies or company employees, another category of "bad" evidence may include judgments, pleadings, depositions, or other documents drawn from other lawsuits or claims involving a drug or medical device. When discovered by an adversary, such documents may be offered to suggest improperly that the drug or device at issue is defective and caused the alleged injuries because it was found to be defective or the cause of injury in other claims or lawsuits. There exist several bases for excluding these documents. Pleadings and other papers filed in other actions may constitute inadmissible

³⁶ Fed. Prescription Serv., *Inv. v. Am. Pharm. Ass'n*, 663 F.2d 253, 262 (D.C. Cir. 1981).

³⁷ See, e.g., *Cipollone v. Liggett Group, Inc.*, 668 F. Supp. 408 (D.N.J. 1987) (applying the *Noerr-Pennington* doctrine in the tobacco products liability context).

³⁸ See *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 120-27 (3rd Cir. 1999) (applying *Noerr-Pennington* doctrine to petitioning activities of ibuprofen manufacturer in antitrust case); *Mylan Labs., Inc. v. Akzo, N.V.*, 770 F. Supp. 1053, 1063-64 (D. Md. 1991) (finding generic drug manufacturers immune from antitrust liability under *Noerr-Pennington* regarding FDA petitioning activities).

³⁹ See *Feminist Women's Health Ctr., Inc. v. Mohammad*, 586 F.2d 530, 543 n.7 (5th Cir. 1978) (recognizing that when evaluating admissibility, evidence of government petitioning efforts should be considered presumptively prejudicial).

hearsay when offered to prove the truth of the information.⁴⁰ Furthermore, the documents may not involve identical drugs or devices. The other lawsuits or claims frequently involve vastly different factual situations and issues, especially those regarding causation, exposure, product type, and injury. Thus, the existence, evidence used or outcome of another lawsuit or claim often has no bearing whatsoever on the issues presented in the pending action. In this context, documents from other lawsuits or claims are simply not relevant and should be excluded under Federal Rule of Evidence 401.⁴¹

Even if an adversary somehow establishes the relevance of documentary evidence from other lawsuits or claims, exclusion of such evidence is warranted under Federal Rule of Evidence 403.⁴² When used to show improper conduct, improper motives, product defect, or liability, any probative value that attaches to this evidence is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the jury, or undue delay. The admissibility of such documents would be highly prejudicial because such evidence focuses the jury’s attention on other alleged misconduct, rather than allowing the jury to determine whether liability is appropriate under the facts of the pending lawsuit.⁴³ The danger of prejudice, confusion of the issues, or misleading the jury is implicated particularly when the prior action was resolved by settlement.⁴⁴

⁴⁰ See FED. R. EVID. 801; *Stevenson v. Hearst Consol. Publ’n*, 214 F.2d 902, 907 (2nd Cir.), *cert. denied*, 348 U.S. 874 (1954).

⁴¹ See FED. R. EVID. 401; *see, e.g., Grenier v. Med. Eng’g Corp.*, 243 F.3d 200, 204-05 (5th Cir. 2001) (refusing to adopt by reference opinion in different action involving a different type of product and different injuries to show existence of defect).

⁴² See FED. R. EVID. 403.

⁴³ See *Figueroa v. Boston Scientific Corp.*, No. 00-CV-7922, 2003 WL 21488012, at *4 (S.D.N.Y. June 27, 2003) (granting motion to exclude evidence of 720 other lawsuits involving same medical implant because any probative value was substantially outweighed by the danger of unfair prejudice, confusion of the issues, and waste of time); *Johnson v. Colt Indus. Operating Corp.*, 797 F.2d 1530, 1534 (10th Cir. 1986) (even if relevant, a judicial opinion concerning the very product at issue performing under similar circumstances was not admissible because the jury would be likely to give it undue weight).

⁴⁴ See *Wilson v. Bicycle South, Inc.*, 915 F.2d 1503, 1510 (11th Cir. 1990) (affirming exclusion of evidence of a prior settled claim involving a similar product based on Federal Rule of Evidence 403 considerations); FED. R. EVID. 408 (evidence of an offer to settle or acceptance of such offer “is not admissible to provide liability for or invalidity of the claim or its amount”).

VII. CONCLUSION

Despite their marginal relevance to the case, preventing the facts contained in “bad” company documents from becoming influential evidence at trial is an uphill battle. After a “bad” company document is admitted into evidence by an adversary, innocuous facts and activities can be developed into compelling evidence of a product defect or grounds for liability against a given manufacturer. Defense counsel must identify and critically examine “bad” company documents as early as possible to identify strategic legal grounds upon which to bar their admission at trial.

Proportionate Liability in Australia[†]

Oscar Shub
Mark Lindfield

I.

INTRODUCTION

Joint and several liability means that any tortfeasor liable to a plaintiff for the same harm may be sued for the whole amount of the plaintiff's loss, irrespective of whether other persons are also liable. Traditionally there has been no right of contribution between or among joint tortfeasors because of the principle that tortfeasors ought not to be allowed to found a cause of action on their own wrongdoing. However, statutory reforms in each State and Territory of Australia were introduced in the 1940s and 1950s that made it possible for one joint tortfeasor to claim contribution from another who is, or would if sued, also be liable in respect of the plaintiff's claim.

The introduction of the principles of proportionate liability to certain damages claims is one of the controversial aspects of the recent wide-ranging legislative reforms to civil liability laws in the Australian jurisdictions. Unlike joint and several liability, under proportionate liability each tortfeasor's liability is limited, having regard to an assessment of the extent of their contribution to the plaintiff's loss. The plaintiff therefore bears the risk that some tortfeasors may become insolvent or disappear. Although the issue of proportionate liability was examined in Australia repeatedly in the 1990s in respect of liability for both property and personal injury damage, it was not adopted. The concept arose again in early 2002 as part of the wave of tort law reform following what is often referred to as the "liability insurance crisis" in Australia.

This article seeks to outline some of the legislation passed in Australia and to examine how they might be implemented. It is intended to give some insights into possible issues arising for those overseas insurers insuring into Australia where contribution issues might arise between defendants.

[†] Submitted by the authors on behalf of the FDCC Professional Liability Section.



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eral on alternatives to litigation.

II.

RECENT REFORMS¹

As part of the tort law reform, each Australian jurisdiction has introduced legislation intended to apply proportionate liability to claims other than personal injury claims. The detail of that legislation is considered below, followed by an analysis of key differences between the jurisdictions.

A. Commonwealth

At the Commonwealth level the relevant provisions of the *Corporate Law Economic Reform Program (Audit Reform and Corporate Disclosure) Act 2004* (Cth) commenced on July 26, 2004 and apply to all causes of action that arise after that date.

Schedule 3 to the Act contains amendments that have now been made to the *Trade Practices Act 1974* (Cth) (the "TPA"), the *Corporations Act 2001* (Cth) (the "CA") and the *Australian Securities and Investments Commission Act 2001* (Cth) (the "ASIC Act"), which are important legislation of particular significance to corporate defendants engaged in trade or commerce. These amendments provide for contributory negligence and also abolish joint and several liability in certain cases.

The provisions only operate in respect of the misleading and deceptive conduct provision of the TPA² and the equivalent provisions in the ASIC Act³ and the CA.⁴

¹ This article is up-to-date in respect of proportionate liability reforms as at 1 October 2005.

² *Trade Practices Act*, 1979, c. 52 (Austl.).

³ *Securities & Investment Commission Act*, 2001, c. 12DA (Austl.).

⁴ *Corporations Act*, 2001, c. 1041H (Austl.).



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The first amendment relates to the TPA requirement that provides for a civil action for damages arising from conduct in contravention of certain provisions of the TPA.⁵ This amendment has the effect of creating a defense of contributory negligence to allegations by a plaintiff that a defendant has breached the misleading and deceptive conduct prohibition of the TPA. However, contributory negligence does not apply when such a breach was intentional or fraudulent.

The new sections introduced to the TPA⁶ comprise the amendments to introduce proportionate liability. These provisions apply in respect of claims for damages for economic loss and property damage caused by misleading and deceptive conduct again other than intentional or fraudulent conduct.

Under the amendments, “the liability of a defendant who is a concurrent wrongdoer in relation to [the] claim is limited to an amount reflecting that proportion of the damage or loss claimed that the court considers just having regard to the extent of the defendant’s responsibility for the damage or loss”⁷

The legislation allows apportionment even if all concurrent wrongdoers are not joined as parties to the proceedings, and it provides for mechanisms for the notification by defendants of information relating to potential concurrent wrongdoers and provisions for joinder of those parties.

The amendment does not affect vicarious liability, liability of partners between each other or the imposition of several liability under any other Act. The proportionate liability

⁵ *Trade Practices Act*, 1979, c. 82 (Austl.).

⁶ *Id.*, c. 87CB-87CI.

⁷ *Id.*, c. 87CD(1)(a).

provisions also do not address other more specific provisions of the TPA, the CA or the ASIC Act that can give rise to a civil liability in circumstances that will also attract liability under the misleading and deceptive conduct provision of the TPA. Where plaintiffs are able to rely on any of these more specific provisions, proportionate liability will not apply.

B. *New South Wales (NSW)*

The proportionate liability provisions passed in NSW commenced on December 1, 2004.⁸

Under the NSW provisions proportionate liability applies to claims for economic loss or damage to property in an action for damages arising from:

- a failure to take reasonable care (whether the claim is made in contract, tort or otherwise); or
- a contravention of the misleading and deceptive conduct prohibition in NSW's fair trading legislation.⁹

Any claim arising out of personal injury is expressly excluded from the scope of the proportionate liability provisions.

Under the proportionate liability provisions, the liability of a defendant who is a concurrent wrongdoer in respect of a claim will be limited to an amount that reflects the proportion of the damage or loss claimed that the court considers just, having regard to the extent of that defendant's responsibility for the damage or loss. A "concurrent wrongdoer" is defined as one "who is one of two or more persons whose acts or omissions . . . caused, independently of each other or jointly, the damage or loss that is the subject of the claim."¹⁰

Under the NSW proportionate liability provisions there is a single apportionable claim in proceedings in respect of the same loss or damage even if the claim for that loss or damage is based on more than one cause of action.¹¹ This means that an economic loss claim that alleges negligence, breach of contract and breach of statutory duty against several concurrent wrongdoers will attract the operation of the proportionate liability provisions regardless of the different causes of action.

Exemptions from the proportionate liability provisions apply in respect to intentional and fraudulent wrongdoers and the legislation also expressly does not displace the law in relation to vicarious liability, the several liability of partners or several liability imposed by any statute.

⁸ The NSW proportionate liability provisions are set out in *Civil Liability Act, 2002*, Part 4 (NSW).

⁹ *Fair Trading Act, 1987*, c. 42 (NSW), which is the equivalent of the misleading and deceptive conduct provision of the TPA.

¹⁰ *Civil Liability Act, 2002*, c. 34(2) (NSW).

¹¹ *Id.*, c. 34(1A).

Further, the provisions impose an obligation on a defendant to give notice to the plaintiff of other concurrent wrongdoers when the defendant has reasonable grounds to believe that a particular person may be a concurrent wrongdoer.¹² It is notable that the plaintiff is not obliged to join such a concurrent wrongdoer, nor does the court have the power to order a joinder.

The NSW proportionate liability provisions do not apply in respect to proceedings commenced before December 1, 2004 or any civil liability that arose before July 26, 2004 (the date of commencement of proportionate liability provisions under the TPA).

C. *Western Australia*

The WA proportionate liability provisions also came into force on December 1, 2004 and do not apply to causes of action that accrued prior to that date.¹³

The WA model adopts a similar approach to the NSW proportionate liability provisions. “Apportionable claim,” “concurrent wrongdoer” and the application of the provisions by the courts are set out substantially on the same terms in the WA legislation as in NSW. One point of difference is that the WA legislation requires the court to have regard to the proportionate liability of persons who are not joined to an action. In NSW, the court “may” have regard to the liability of those persons. The importance of this distinction may not be made clear until the courts are asked to determine this issue.

The WA provisions also impose an obligation on defendants to give notice to the plaintiff of other concurrent wrongdoers.

D. *Queensland*

The Queensland’s proportionate liability provisions¹⁴ commenced on March 1, 2005 and apply to claims for economic loss or damage to property in an action for damages arising from a breach of a duty of care, or for a breach of the misleading and deceptive conduct prohibition of Queensland’s fair trading legislation.¹⁵ This is subject to the exception of claims made “by a consumer.”

A “consumer” means an individual whose claim is based on rights relating to goods or services, or both, in circumstances in which goods or services are being acquired for personal domestic or household use or consumption. They also relate to advice given by a professional to the individual for the individual’s use, other than for a business carried on by the individual.

¹² *Id.*, c. 35A.

¹³ The WA proportionate liability provisions are contained in Part 1F of the *Civil Liability Act 2002* (WA).

¹⁴ The Queensland’s proportionate liability provisions are contained in the Chapter 2 Part 2 of the *Civil Liability Act, 2003* (Qld).

¹⁵ *Fair Trading Act, 1989*, c. 38 (Qld).

The Queensland proportionate liability provisions contain an unusual requirement to the effect that a concurrent wrongdoer who breaches the misleading and deceptive conduct provisions of Queensland's fair trading legislation is "severally liable for the damages awarded against any other concurrent wrongdoer to the apportionable claim."¹⁶ The intent of this provision is unclear. If a person is misleading or deceptive and thereby contributes to another's economic loss, the Act states that they are proportionately liable. However, they are also "severally liable" for the wrongdoing of all concurrent wrongdoers.¹⁷

Further, the Queensland proportionate liability provisions state that in any proceedings involving a claim that is covered by the Act:

the liability of a defendant who is a concurrent wrongdoer in relation to the claim is limited to an amount reflecting that proportion of the loss or damage claimed that the court considers just and equitable having regard to the extent of the defendant's responsibility for the loss or damage¹⁸

In apportioning liability between defendants in a proceeding, the court may have regard to the comparative responsibility of any concurrent wrongdoer who is not a party to the proceedings.¹⁹

A "concurrent wrongdoer" is defined as "a person who is 1 of 2 or more persons whose acts or omissions caused, independently of each other, the loss or damage that is the subject of the claim."²⁰

This definition causes some concern as it represents a significantly different position to the legislation introduced by the other Australian jurisdictions. In each other relevant Act "concurrent wrongdoer" includes persons whose actions jointly caused the loss or damage claimed. The Queensland Act, however, appears to require that the conduct of each person by itself would have been sufficient to cause the loss or damage.

E. *Victoria*

The provisions relating to proportionate liability in Victoria commenced on December 3, 2003.²¹ They apply to proceedings commenced from January 1, 2004, regardless of when the facts giving rise to the litigation occurred.

¹⁶ *Civil Liability Act*, 2003, c. 32F (Qld).

¹⁷ *Id.*

¹⁸ *Id.*, c. 31(1)(a).

¹⁹ *Id.*, c. 31(3).

²⁰ *Id.*, c. 30(1).

²¹ The Victorian proportionate liability provisions are contained in Part IVAA of the *Wrongs Act*, 1958, (VIC).

As with the New South Wales and Commonwealth legislation, the provisions apply to claims for economic loss or property damage. One significant difference is that when apportioning responsibility between defendants, a court must not have regard to the comparative responsibility of any person who is not a party to the proceedings unless that person is dead or, in the case of a corporation, has been wound-up.²² Another is that the Victorian provisions do not require a defendant to notify the plaintiff of concurrent wrongdoers.

F. *South Australia*

South Australia has most recently enacted proportionate liability legislation, its provisions commencing on October 1, 2005²³ and applying to causes of action arising on or after that date.

The legislation is similar to that enacted in other jurisdictions with two important exceptions. First, the South Australian legislation includes an unusual provision similar to that in Queensland requiring that the concurrent wrongdoers that are the subject of the apportionable claim must not have been acting jointly.²⁴ This provision is inconsistent with the legislation enacted in jurisdictions other than Queensland. Second, the legislation contains a potentially useful provision to the effect that in subsequent actions by a plaintiff against other concurrent wrongdoers, the first judgment given against the wrongdoers who were first sued is to determine the quantum of damages and liability of each of the parties to the first action for the purposes of all subsequent litigation.²⁵

G. *Tasmania*

Tasmania enacted proportionate liability legislation with effect from June 1, 2005²⁶ and applying to causes of action arising on or after that date.

There are no significant differences between the Tasmanian legislation and the equivalent provisions of the New South Wales legislation.

H. *Australian Capital Territory*

The ACT has also enacted proportionate liability legislation.²⁷ The provisions relating to proportionate liability apply to causes of action arising on or after March 8, 2005 and, as in other jurisdictions, apply to claims arising from property damage and economic loss.

²² *Id.*, c. 24AI(3).

²³ The South Australian proportionate liability provisions are contained in the *Law Reform (Contributory Negligence and Apportionment of Liability) Act*, 2001 (SA).

²⁴ *Id.*, c. 3(2).

²⁵ *Id.*, c. 11.

²⁶ The Tasmanian proportionate liability provisions are contained in Part 9A of the *Civil Liability Act*, 2002 (Tas).

²⁷ Chapter 7A of the *Civil Law (Wrongs) Act*, 2002 (ACT).

The ACT provisions draw both from the NSW and Queensland proportionate liability reforms. Just as the NSW and Queensland provisions, it generally applies to claims for economic loss or damage to property in an action for damages (whether in tort, under contract or otherwise) arising from a failure to take reasonable care or a breach of the unfair practices provisions of the ACT's fair trading legislation, including misleading and deceptive conduct.²⁸ It is notable that while the Queensland provisions are limited in their application to the misleading and deceptive conduct provisions of the Queensland fair trading legislation, the ACT proportionate liability reforms extend to all unfair practices contained in the ACT fair trading legislation.²⁹ The ACT, as Queensland, exempts claims made by a "consumer."

The ACT provisions also call for notification of the plaintiff by the defendant of other wrongdoers.

I. *Northern Territory*

Northern Territory has also enacted proportionate liability legislation, its provisions commencing on June 1, 2005³⁰ and applying to causes of action arising on or after that date.

The legislation is effectively similar to that enacted in the ACT, except that the carve-out for consumer claims in the Northern Territory legislation is based upon whether the plaintiff's action arises from a breach of consumer product safety and product information legislation in the Northern Territory.³¹

III.

SOME SIGNIFICANT ISSUES ARISING FROM THE REFORMS

A. *Misleading and Deceptive Conduct*

A plaintiff's contributory negligence can now be taken into account for the purposes of determining the total amount of damages that may be awarded to the plaintiff. Accordingly, the High Court of Australia's recent ruling,³² that a court cannot reduce damages for misleading or deceptive conduct because the person relying on the misleading or deceptive conduct has acted carelessly in doing so, has been superseded.

²⁸ Part 2 of the *Fair Trading Act*, 1992 (ACT).

²⁹ *Id.*

³⁰ The Northern Territory proportionate liability provisions are contained in the *Proportionate Liability Act*, 2005 (NT).

³¹ Contained in Part 4 of the *Consumer Affairs and Fair Trading Act*, (NT).

³² *Henville v. Walker* (2001) 206 CLR 459; *I & L Securities Pty Ltd. v. HTW Valuers (Brisbane) Pty Ltd.* (2002) 192 A.L.R. 1.

B. *Obligation to Notify Plaintiff of Concurrent Wrongdoers*

The obligation imposed on a defendant by the legislation in most jurisdictions to provide details in relation to concurrent wrongdoers has significant potential to create controversy and further dispute.

Firstly, the notice test to be applied appears to have a fairly low threshold. For example, NSW legal practitioners are required to file a certificate with the court in any damages claim (and any defence to a damages claim) that the claim (or defence) has reasonable prospects of success based on “provable facts and a reasonably arguable view of the law.”³³ In contrast, the proportionate liability legislation requires only that if a defendant has “reasonable grounds to believe” that another party is liable for the plaintiff’s damage, the defendant must provide the plaintiff with the identity of all alleged concurrent wrongdoers, together with circumstances from which their liability allegedly arises.³⁴

Secondly, when a party is identified by a defendant as being a concurrent wrongdoer and the circumstances on which the allegation of wrongdoing is based are provided to a plaintiff or plaintiffs, there are potential reputational issues for the named party. In addition, potentially damaging allegations may be made in the course of the hearing and, unless the non-party is joined to the proceedings or unless the plaintiff brings a subsequent action against it, the non-party will not have the opportunity to defend those allegations.

C. *Intentional Wrongdoers*

As we have noted, intent to harm on the part of a wrongdoer disqualifies that wrongdoer from relying on the operation of the proportionate liability provisions. However, it is not clear what effect, if any, proof of dishonesty on the part of one concurrent wrongdoer will have on the proportion of loss allocated to any other (non-fraudulent) concurrent wrongdoers. Other things being equal, the extent of responsibility attributable to innocent wrongdoers would be diminished when another party is proven to have acted dishonestly. It remains to be seen how this will be applied in practice, given that the court has considerable discretion in the allocation of responsibility. In some cases defendants may have an incentive to prove dishonesty on the part of co-defendants so that they are able to reduce their proportions. However, a consequence of proving the dishonesty will generally be that any directors’ and officers’ liability insurance coverage or other applicable insurance coverage held by the wrongdoer may be able to be avoided by the insurer. Accordingly, in practice, plaintiffs may be reluctant to allege dishonesty.

D. *Consequence of Not Joining All Concurrent Wrongdoers*

As we have noted, the consequence of not joining all concurrent wrongdoers is that the plaintiff will risk not being able to recover fully the extent of its loss or damage. Plaintiffs may seek to address this issue by:

³³ Legal Profession Act 2004, c. 345(1) (NSW).

³⁴ Civil Liability Act 2002. c. 35A(1) (NSW).

- (a) attempting to establish that the proportionate liability provisions do not apply to the defendant – such as by proving there was intentional or fraudulent conduct, or by showing that there are no other concurrent wrongdoers; or
- (b) making thorough enquiries at an interlocutory stage in relation to potential future parties to the litigation – on this point, it might be expected that a consequence will be the wider use of devices such as preliminary discovery, interrogatories and so on, which is likely to add to the cost of claims and can further delay their resolution.

Under proportionate liability a plaintiff will have greater incentive to join all potentially liable defendants to an action. However, it will not be obliged to do so. From the defendant's perspective, it will not necessarily be in its interest to join a concurrent wrongdoer. The defendant may instead prefer to wait until the hearing and then seek to adduce evidence that a party who is not present (and in respect of whom the defendant previously provided details to the plaintiff but with no joinder following) bears a greater share of the liability for the plaintiff's loss. The absent party will not be present at the hearing to counter such arguments, and it is notable that the court cannot compel a joinder.

E. *Differences between Jurisdictions*

Although there is, on the whole, a significant degree of consistency between the proportionate liability provisions of each jurisdiction, there are nevertheless some potentially important and difficult discrepancies that have the potential to produce anomalous results, particularly when wrongs have been committed, or damage sustained, across State borders.

There are five principal areas of difference between the legislation as introduced or enacted in each jurisdiction:

(a) Consumer carve-out

The Queensland and ACT (and, to a lesser extent, the Northern Territory) provisions are the only statutes to contain a carve-out from proportionate liability for consumer claims. The term "consumer claims" is defined by the relevant legislation although there are some differences in that regard also. No other State excludes actions arising from the goods or services acquired for personal, domestic or household use.

(b) Obligation to provide notice of concurrent wrongdoers

The obligation to provide such a notice is not uniform throughout all jurisdictions. In Victoria, there is no obligation on the part of a defendant to notify a plaintiff of persons believed to be concurrent wrongdoers. This adds to the incentive for plaintiffs in that jurisdiction to plead allegations of misleading and deceptive conduct under the TPA in order to trigger the obligation to no-

tify that exists under the Commonwealth proportionate liability provisions. In South Australia and Queensland, there is a positive obligation on a defendant to provide the plaintiff with details of concurrent wrongdoers. However, in the other jurisdictions there is not so much a positive obligation as a potential costs penalty for failing to do so.

(c) Having regard to the liability of non-parties

In Western Australia and South Australia, the legislation provides that a court *is* to have regard to the proportionate liability of persons who are not parties to the litigation. By contrast, Victorian legislation expressly prohibits a court from having regard to the liability of non-parties unless they are insolvent or deceased. In the remainder of the Australian jurisdictions, the legislation states that the court *may* have regard to the liability of those non-parties. In practice, this may make little difference, but until the courts begin to apply the legislation, it remains to be seen whether, and if so in what circumstances, the courts will consider themselves bound to have regard to these matters.

(d) Meaning of “concurrent wrongdoers”

As noted earlier, in Queensland and South Australia, the definition of “concurrent wrongdoer” contained in the legislation does not include persons whose actions “jointly cause” the loss or damage claimed. The purpose of excluding such claims is unclear. It is possible to imagine many circumstances in which it will not be obvious whether the conduct of two or more defendants can be said to have jointly caused the loss or independently did so, particularly in professional negligence cases where the negligent advice or services of more than one professional has been relied on to the plaintiff’s detriment. It is difficult to see why jointly committed torts ought to be excluded from proportionate liability, given the courts’ wide discretion to take into account all relevant circumstances in determining what apportionment is just.

(e) Contracting out of proportionate liability

In New South Wales, Western Australia and Tasmania, there is an express provision permitting parties to contract out of the proportionate liability provisions. No such provision exists in the Commonwealth, Victorian, South Australia, Northern Territory or ACT legislation. In Queensland, there is an express prohibition against contracting out in relation to proportionate liability.

The foregoing differences create the potential for confusion and unexpected results in claims when causes of action cross borders.

It has been suggested by some commentators that differences in civil liability provisions between States and Territories may provide an opportunity for forum shopping.

In June 2000 the High Court of Australia found that the assessment of damages and other matters of substance in interstate tort cases are to be determined in accordance with the law of the place of the wrong and not the law of the forum in which proceedings had been commenced.³⁵ The judgment has the potential to reduce, if not eliminate, the incentive for parties to forum shop for favorable damages awards. The High Court also held that laws relating to limitation periods and assessment of damages deal with questions of substance and not procedure.

In order to understand and identify the potential for forum shopping in the context of proportionate liability legislation, it is necessary to consider whether any conflicting aspects of the legislation are procedural or substantive. If they are merely procedural, then they will be determined by reference to the place where the action is commenced. However, if they are substantive (and it now appears that many of the provisions will be substantive), then they will be determined by the law of the place where the tort was committed, and there will be no opportunity for forum shopping.

Consider, for example, proceedings concerning allegations of misleading and deceptive conduct and also of negligence that are commenced in Victoria (where the plaintiff has suffered loss) in respect of a tort committed by the defendant in Queensland:

- (a) First, the consumer carve-out applies in Queensland. That would seem to be a substantive matter rather than a procedural one (although it is less than clear cut), so it ought to be determined by the law of Queensland. If the plaintiff's claim falls within the description in the Queensland legislation, then proportionate liability may not apply at all.
- (b) Second, the obligation to notify the plaintiff of concurrent wrongdoers seems likely to be a procedural rather than substantive matter, so that should be determined by the law of Victoria. In Victoria, there is no such notification requirement.
- (c) Third, the question of whether a court is to have regard to the liability of non-parties seems to be more than a matter of procedure but a matter that goes to the substance of the action. On that basis, it should be determined by the law of Queensland, where the tort was committed, and might foreseeably result in a reduction of the damages to which the plaintiff is otherwise entitled.

³⁵ John Pfeiffer Pty Ltd. v. Rogerson (2000) 203 CLR 503.

IV.
CONCLUSION

Similar issues can arise even when there is no cross-border dispute but when causes of action are pleaded concurrently based on State and Commonwealth proportionate liability legislation.

As indicated in this article, the position is by no means clear. Clarity may emerge over the coming months as the legislation is used in litigation to apportion liability. However that remains to be seen, as we have yet to see any significant reported decision applying the principles contained in the legislation.

FUTURE MEETINGS

2006

WINTER 2006

Sunday, March 5 – Sunday, March 12

Hyatt Regency Lake Las Vegas Resort, Spa & Casino
Las Vegas, Nevada

ANNUAL 2006

Sunday, July 23 – Sunday, July 30

Fairmont Southampton
Southampton, Bermuda

WINTER 2007

Sunday, February 25 – Sunday, March 4

Fairmont Scottsdale Princess
Scottsdale, Arizona

ANNUAL 2007

Sunday, July 22 – Sunday, July 29

Sun Valley Resort
Sun Valley, Idaho

2007

Prospective Juror Questionnaires Made Easy[†]

John P. Daniels
Annie L. Knafo

I. INTRODUCTION

Traditionally, attorneys have relied upon oral voir dire to elicit information from potential jurors. Because these questions are asked in the presence of the judge, counsel and other potential jurors, potential jurors may be hesitant or embarrassed to answer the questions truthfully. As a result, questions about sensitive issues such as economic status, physical health, mental health and prejudices or biases are very hard for attorneys to address for fear of embarrassing the potential juror. However, some of this information can be invaluable to attorneys when selecting the best jurors for the case.

Consequently, in some cases, courts allow the use of Prospective Juror Questionnaires. The questionnaires are used to gather information about potential jurors for use in jury selection. In addition to background information, the questionnaires address a variety of aspects of the jurors' lives including, household income, political affiliations, membership in community organization, knowledge of the witnesses, attorneys or parties, knowledge of the case and pre-existing opinions. The questionnaires also address the juror's opinions relevant to the case (e.g., views on negligence, liability, oral contracts, punitive damages, victim compensation).

[†] Submitted by the authors on behalf of the FDCC Trial Tactics, Practice and Procedures Section.



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ABOTA Los Angeles Trial Academy since 1988.

II. DESIGN OF QUESTIONS

The questions are designed to help the court and the attorneys learn about the jurors' background, their views, personal experiences and their family members' experiences on issues that may be related to the case or effect their opinion on the case. In short, the questionnaires are to make certain that the juror can be fair and impartial. Because many people are uncomfortable speaking publicly, when asked questions during oral voir dire they only provide cursory information. But, on a written questionnaire, jurors are more likely to provide more insightful information more accurately reflecting any prejudices, biases or pre-existing opinions than they would provide verbally in court. Additionally, the use of questionnaires also gives jurors time to provide more thoughtful answers.

The most effective juror questionnaires will identify the characteristics making a juror risky or favorable. In some cases, these characteristics are readily observable (e.g., employment-related variables, income levels and ethnicity). In other cases, these predictive variables are represented by deeper beliefs, values and attitudes held by the individual.

Most importantly, juror questionnaires save time in oral voir dire by eliminating the repetition of generic questions. The questionnaires identify the specific areas of potential bias, so that the voir dire process can be more focused and the follow-up questions more effective.

Typical juror questionnaires are approximately ten to fifteen pages, containing both yes/no answer questions and questions that require narrative answers. However, the length



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of the questionnaire varies depending on the complexity or publicity of the trial. In some cases the questionnaires can be as short as three to five pages. In the O.J. Simpson trial the questionnaire was approximately eighty pages. After the proposed questionnaires have been submitted to the judge, they can either be mailed out prior to jury selection or can be completed when jurors are assembled for trial. However, regardless of what approach is taken, there needs to be a sufficient amount of time between the completion of the questionnaire and the beginning of oral voir dire for the parties to have an opportunity to review the answers.

III.

SAMPLE QUESTIONNAIRE

The following is a sample of a jury questionnaire for a civil case. Notice that the first half of the questionnaire is generic background information, helpful in all cases: questions regarding education, work, economic status, affiliations, jury experience and involvement in lawsuits. The second half of the questionnaire is more case specific. In the particular instance, the questions are regarding the potential juror's opinions on contracts, investments, real estate and punitive damages. In examining what follows, be aware that the space for some answers has been limited for this article to less than would ordinarily be provided to a perspective juror.

Jury Questionnaire

1. Age: ____
2. Place of Birth: _____
3. Marital Status: ___Single, ___Currently Married, ___Divorced, ___Widowed, ___Live with non-marital partner, ___Other
4. Is English your first language? ___Yes, ___No. If NO, what is? _____
5. How long have you lived in the area? ____
6. Do you: ___Rent, ___Own, ___Live with others & do not pay rent
7. What is the highest level of education you completed? ___Some High School, ___High School Graduate, ___Technical/Vocational, ___Some College (Major)_____, ___College Graduate (Major) _____, ___Postgraduate study (Field) _____
8. If you plan to attend or are currently attending school, describe: _____
9. What is the highest level of education your spouse/significant other has completed? ___Some high school, ___High school graduate, ___Technical/Vocational, ___Some college (Major) _____, ___College graduate (Major) _____, ___Postgraduate degree (Field) _____, ___Other
10. Would you say that in the past few years your economic situation has: ___Gotten better, ___Stayed the Same, ___Gotten Worse
11. Your present employment status (check all that apply): ___Employed Full-time, ___Employed Part-time, ___Temporarily laid off, ___Unemployed & looking for work, ___Unemployed & not looking for work, ___Self-employed, ___Student, ___Part-time student, ___Working more than one job, ___Retired
12. Your current or most recent occupation: _____
13. Name of your current or most recent employer, or if a student your school: _____
14. Please list all other employment you have had in the past and for how long: _____
15. How many employers have you had over the past 10 years? _____. What are your specific duties and responsibilities on the job? _____
16. Have you or has any member of your family ever owned or run a business: ___Yes, ___No. If YES, please describe business: _____
17. Are you involved in the hiring and firing of other employees? ___Yes, ___No

18. Are you involved in evaluating the job performance of other employees?
 Yes, No
19. Please list all full-time employment of your spouse/former spouse (and for how long): _____
20. Please list employment of any other adult who lives in your home (and for how long): _____
21. In general, do you support the goals and activities of unions nowadays? Yes, No
22. If you or your current spouse or partner have ever served in the military please list for each the brand of service and the dates of service: _____
23. What is your main source of news? Television, Radio, Internet, Newspapers, News Magazines, Word of mouth, friends.
24. What social, civic, civil rights, trade, or other organizations are you affiliated with or do you give money to if any? _____
25. Describe any offices you have held in organization listed above: _____
26. What magazine or newspapers, if any do you read regularly? _____
27. How frequently have you been a group leader? Very frequently, Occasionally, Sometimes, Never
28. Have you or any of your family members ever sued or been sued by anyone? Yes, No. If YES, please explain.
29. If you or anyone close to you has ever filed a lawsuit or made any type of claim for damages, explain: _____
30. Have you ever considered suing someone but did not for any reason? Yes, No. If YES, please explain.
31. If a claim for money damages or a lawsuit has ever been brought against you or anyone close to you, explain the circumstances: _____
32. Do you know anyone on this jury panel? Yes, No. If YES, please explain _____.
33. On how many cases have you served on a jury? 0, 1, 2, More than 2. Where did you serve on a jury? _____.
 What kinds of cases did you hear while serving: Civil, Criminal, Both civil and criminal. In how many of those cases did the jury reach a verdict? _____. In how many of those cases did you serve as the jury foreperson? _____. Was your jury service a positive or negative experience? Positive, Negative. Explain: _____

34. If you have been to court for any other reason explain: _____
35. Have you, a member of your family, or close friend ever had any legal training or worked with lawyers? ___ Yes, I have, ___ Yes, someone close to me has, ___ No. If YES, please explain what type of training or experience and when: _____
36. If you have relatives or close personal friends who are judges or attorneys or court personnel, what are their names, relationship to you, and their position?
37. An important function of juries in America is to send messages to corporations and individuals to improve their behavior: ___ Strongly disagree, ___ Disagree, ___ Agree, ___ Strongly agree.
38. People who file lawsuits are trying to place responsibility where it belongs: ___ Strongly disagree, ___ Disagree, ___ Agree, ___ Strongly agree.
39. What a contract says is more important than what the parties intend it to mean: ___ Strongly disagree, ___ Disagree, ___ Agree, ___ Strongly agree.
40. In a trial, I would believe what a document says over what a witness says: ___ Strongly disagree, ___ Disagree, ___ Agree, ___ Strongly agree.
41. Punitive damages are sometimes used to punish corporations and individuals for past behavior and to deter similar behavior in the future. What is your general attitude toward awarding punitive damages? _____
42. Have you ever been denied compensation that was owed to you? ___ Yes, ___ No. If YES, please explain.
43. Have you ever loaned a large amount of money to someone? ___ Yes, ___ No. If YES, please explain.
44. Have you ever signed a formal business agreement? ___ Yes, ___ No. If YES, please explain.
45. Have you ever been involved in a dispute over a contract or suffered negative consequences because of a contract? ___ Yes, ___ No. If YES, please explain.
46. Have you ever been an employee for a company that was involved in a contract dispute? ___ Yes, ___ No. If YES, please explain.
47. Do you have any special training or experience with contracts (administration, negotiation, writing, etc)? ___ Yes, ___ No. If YES, please explain.
48. Do you think that an oral contract is as binding or legal as a written contract? ___ Yes, ___ No, ___ Unsure
49. Do you think that an oral agreement should be honored under any circumstances? ___ Yes, ___ No, ___ Unsure

50. Have you, or has anyone close to you, ever been a party to an oral contract involving a large amount of money? ___Yes, ___No. If YES, please explain.
51. How would you rate your level of knowledge about the real estate market? ___Very Knowledgeable, ___Somewhat knowledgeable, ___No Knowledge
52. How would you rate your level of knowledge about investments or financial matters? ___Very Knowledgeable, ___Somewhat knowledgeable, ___No Knowledge
53. How would you describe your general investment strategy? ___Very risky, ___Somewhat risky, ___Very conservative, ___Somewhat conservative, ___I do not make investments.
54. Have you ever lost a significant amount of money in an investment? ___Yes, ___No. If YES, please explain.
55. Have you ever felt cheated in an investment, business situation or consumer transaction? ___Yes, ___No. If YES, please explain.
56. To what extent do you trust stockbrokers, real estate brokers and other people who invest money for others? ___Not at all, ___Not too much, ___Somewhat, ___Quite a bit
57. Have you or has anyone close to you, ever been involved in making investments for other people? ___Yes, ___No. If YES, please explain.
58. Have you or has anyone close to you had any training or work experience in any of the following: Accounting, Banking, Business Management, Construction, Insurance, Mental Health or Medicine, Real Estate Appraisal, Real Estate Lending or Borrowing. ___Yes I have, ___Yes, someone close to me has, ___No. If YES, please explain.
59. Which of the following attitude best describes how you feel about business nowadays? ___Buyer beware, ___Seller be fair
60. Have you or has anyone close to you ever been involved in purchasing or managing real estate as an investment? ___Yes, ___No. If YES, please explain.
61. Have you or has anyone close to you, ever worked or had any experience with partnerships or other business ventures or investments with other people? ___Yes, ___No. If YES, please explain.
62. Do you believe that people who lost money on an investment should be reimbursed? ___Yes, ___No. If YES, please explain.
63. Have you or a close family member ever filed for bankruptcy? ___Yes, ___No. If YES, please explain.

64. Have you, or has anyone close to you, ever suffered significant losses in the real estate market? ___Yes, ___No. If YES, please explain.
65. Do you have any ethical, religious, political or other beliefs that may prevent you from serving as a juror? ___Yes, ___No. If YES, please explain.
66. Describe any problems (vision, hearing, language difficulty or other medical problems) that may affect your jury service: _____
67. Describe any medication you are currently taking: _____
68. If there is any matter, not covered by this questionnaire that could affect your ability to be a fair and impartial juror, please explain: _____

IV.

PROCEDURE FOR USE

The most common practice is that the questionnaires are to be distributed and filled out by the jurors on the first day of trial. After the questionnaires are collected, the attorneys have the afternoon and evening (if they are lucky) to assimilate the information into a usable form. It is extremely important for the attorney to have a group of attorneys help him assimilate the information. This involves establishing the most important factors/characteristics, determining what needs to be asked in oral voir dire and organizing the questionnaires into a usable form. A common method is using a highlighter or “post its” to tag questions or answers that the attorney wants to follow up on during oral voir dire. One of the biggest benefits of the questionnaire is that the attorney already has an abundance of information on each juror to prepare questions to ask and what issues to focus on during oral voir dire. For example, a follow up question could now be, “Mr. Jones, I see here that you have been involved in a contract dispute. Could you please tell us about it.” The jury questionnaire can be tremendously helpful, but if the attorney does not get the information into a workable form, the lawyer will have great difficulty trying to read through the questionnaires during voir dire.

The jury questionnaires provide attorneys with an abundance of information that can assist them in the selection process. However, because there is *so much* information, it is often unmanageable. Therefore the information in the questionnaires must be reduced into a manageable form. Fortunately, a ranking system of “jury codes” has been developed to assist attorneys with this very problem. The most efficient way to use jury questionnaires is to first establish which characteristics/factor are the most predictive and use questions that will gather information or the juror’s opinions relative to those factors. Then create a checklist that contains all of those factors and attach a copy of the checklist to each completed questionnaire. The following is a sample checklist with 67 factors/characteristics that can be taken into consideration when selecting a juror. Each factor on the list below correlates to a question in the sample questionnaire.

V. JUROR SELECTION

Below is a list of all of the various factors/characteristics that can taken into consideration when selecting a juror. A sample juror questionnaire has also been provided. Each factor on the list below correlates to a question in the sample questionnaire. Obviously not all of the factors below are relevant in every case and some cases may require additional factors to be taken into consideration.

Potential Juror Characteristics

- 1) Age (A)
- 2) Marital Status (M)
- 3) Whether English is their first language (LANG)
- 4) How long they have been a resident in the area in which they live (R)
- 5) Ownership vs. rental of residence/property (OWN)
- 6) Satisfaction with living arrangement/area (SAT)
- 7) Highest level of education the juror has completed (ED)
- 8) Whether the juror currently attends school or plans to attend school (SCHOOL)
- 9) Highest level of education of juror's spouse or significant other has completed (HI-ED)
- 10) Juror's Economic Situation (improved or gotten worse over the past few years) (ECON)
- 11) Juror's current Employment Status (full-time/part-time/unemployed/student/working more than one job (EMP)
- 12) Juror's current or most recent occupation (JOB)
- 13) Name of current or most recent employer (EMPLYR)
- 14) Juror's past employment (EMPHIS)
- 15) Number of employers over the past 10 years (#EMP)
- 16) Experience in ownership or running of business (BUS)
- 17) Involvement in hiring and firing other employees (HIRE)
- 18) Involvement in evaluating the job performance of other employees (EVAL)
- 19) Spouse's and/or former spouse's employment history (SPSE EMPLYR)
- 20) Employment of other adults living in the juror's home (EMP CHILD)

- 21) Juror's support of goals and activities of unions (UNION)
- 22) Juror or spouses service in the military (MIL)
- 23) Juror's main source of news (NEWS)
- 24) Juror's social, civic, civil rights, trade or other organizational affiliations (SOCIALIZE)
- 25) Juror's offices in any of the above mentioned organizations (OFF)
- 26) Magazines or newspapers regularly read by juror (MAGS)
- 27) Juror's frequency of being a group leader (LEADER)
- 28) Juror's or family member's previous experience being sued (SUED)
- 29) Juror or anyone close to juror's previous experience in filing a lawsuit or making a claim for damages (LAWSUIT)
- 30) Juror's consideration of suing someone, then deciding not to (CLAIM)
- 31) Claim for money damages or a lawsuit brought against juror or someone close to him/her (MONEY)
- 32) Knowledge of someone else on the jury panel (JURY)
- 33) Past experience as a juror (how many times, where, civil/criminal, positive/negative experience) (JD)
- 34) Any other reason the juror may have been to court (COURT)
- 35) Juror's or someone close to the juror's legal training or work with lawyers (LEGAL)
- 36) Relatives or friends that are judges, attorneys or court personnel (ATTY)
- 37) Juror's opinion about juries' function of sending messages to corporations and individuals to improve their behavior (agree/disagree) (JURY FUNC)
- 38) Juror's opinion regarding plaintiffs filing lawsuits to place responsibility where it belongs (agree/disagree) (RESP)
- 39) Juror's opinions about contracts: What's more important, what the contract says vs. what parties intended it to mean (K)
- 40) What the juror is more likely to believe, what a document says vs. what a witness says (K vs. O)
- 41) General attitude towards awarding punitive damages (PUNI)
- 42) Past denial of compensation that was owed to juror (DCOMP)

- 43) Previous loans the juror gave, were they repaid? (LOAN)
- 44) Juror's experience in signing a formal business agreement (SIGN-B)
- 45) Jurors involvement in a dispute over a contract (did juror suffer negative consequences of the contract) (DIS-K)
- 46) Juror's employment for a company that was involved in a contract dispute (EMP-K)
- 47) Special training or experience with contracts, administration or negotiation (TRAIN-K)
- 48) Opinions on oral contracts: Are they as binding as written contracts (OK vs. WK)
- 49) Juror's opinion whether oral agreements always be honored (ORAL)
- 50) Juror's involvement in an oral contract involving a large amount of money (ORAL-K-MON)
- 51) Juror's level of knowledge about the real estate market (very knowledgeable/ no knowledge) (RE)
- 52) Juror's level of knowledge about investments or financial matters (FIN)
- 53) Juror's general investment strategy (very risky/very conservative) (INVEST STRAT)
- 54) Juror's loss of significant amount of money in an investment (LOST)
- 55) Juror's feelings about being cheated in an investment, business situation or consumer transaction (CHEAT)
- 56) Juror's trust of stockbrokers, real estate brokers, and other people who invest money (BROKERS)
- 57) Juror's involvement in making investments for other people. (IN-OTHERS)
- 58) Juror's or someone close to the juror's experience or training in Accounting, Banking, Business Management, Construction, Insurance, Mental Health or Medicine, Real Estate Appraisal, Real Estate Lending or Borrowing (PROF)
- 59) Juror's attitudes towards business (Seller be fair vs. Buyer beware) (BUS-ATTID)
- 60) Juror's or someone close to the juror's involvement in purchasing or managing real estate as an investment (RE)
- 61) Juror's or someone close to the juror's experience in partnerships or other business ventures or investments (PTRSHIP)

- 62) Juror's opinion on whether people who lose money on an investment should be reimbursed (REIMB)
- 63) Juror or someone close to the juror filing for bankruptcy (BK)
- 64) Juror's or someone close to the juror's significant losses in the real estate market (LOSS)
- 65) Juror's ethical, religious, political or other beliefs that might prevent juror from serving on a jury (REL)
- 66) Juror's vision, hearing, language difficulty, or other medical problems that may affect their jury service (MED)
- 67) Any medications the juror is currently taking (MEDS)

When reviewing the juror's answers to each question, assign a number 0-5 (see below for coding system) to that factor and write the number of the checklist next to that factor. Obviously, the most favorable jurors will be the potential jurors with the highest numbers and the riskiest jurors will be the ones with the lower numbers.

Coding System

- 5 = Yes! Lets Roll
- 4 = Likely
- 3 = Less Likely
- 2 = Unlikely
- 1 = Desperate
- 0 = No way, Jose!

For example, a plaintiff is suing a defendant real estate broker for fraud in connection with a piece of investment property. The plaintiff is claiming that the defendant misrepresented that the property had the proper zoning for its intended use. Question 59 on the questionnaire says, "Which of the following attitudes best describes how you feel about business nowadays – Buyer beware or Seller be fair?" If potential juror #1 responds, "Seller be fair", the plaintiff's attorney is likely to put a "4" or "5" next to "59- Business attitudes" on the checklist, while the defendant's attorney is more likely to put a "2" or "3."

Another example might be a disgruntled investor suing a brokerage firm for fraud because the broker allegedly failed to meet his duty of due diligence and the investor subsequently lost all of his money. Questions 52 through 57 specifically address questions about the juror's investment strategies and opinions about brokers. For example, Question 52 asks, "How would you rate your level of knowledge about investments or financial matters?" Juror #1 responds that he is "very knowledgeable" and Juror #2 responds that he has "no knowledge." The plaintiff may give Juror #1 a "2" or "3" and give Juror #2 a "4."

Juror #1 might be less sympathetic with the plaintiff because the plaintiff did not know about his own investments, while Juror #2 might be more sympathetic because he himself doesn't know about financial matters either.

The next question, 53, on the questionnaire says, "How would you describe your general investment strategy?" Juror #1 says, "very risky" while Juror #2 says, "very conservative." Once again, the plaintiff might give Juror #1 a lower score like a "2" or "3" because he is willing to take risks and may not sympathize with the plaintiff for losing all his money, while, Juror #2 might get a higher number because he might be more sympathetic. Question 55 asks, "Have you ever felt cheated in an investment, business situation or consumer transaction?" If Juror #2 answers "No," this doesn't necessarily mean that the plaintiff should give him a really low number like "0." However, if he answers "yes" the plaintiff would definitely give him a "4" or "5."

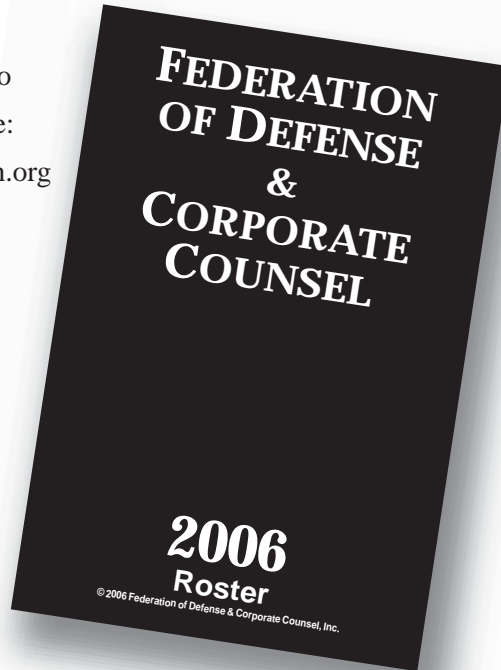
Obviously, one of the most helpful questions will be Question 56, "To what extent do you trust stockbrokers, real estate brokers, and other people who invest money for others?" The plaintiff would give Juror #1 who says, "Quite a bit" a lower number and give Juror #2 who says "Not at all" a higher number. Overall, potential juror #2's numbers were higher than potential juror #1 and would be a better choice for the plaintiff. Now that the attorney has a better idea of the juror's background views and opinions, the voir dire process will be more effective because the attorney can follow up on specific issues like how they lost their money in investments or why they have a low opinion of brokers.

VI. CONCLUSION

There is no doubt that that juror questionnaires are an extremely helpful tool for trial attorneys. However, without a method of condensing the information into a manageable format, an attorney could get lost in the sea of information. This code system allows the attorney to reduce all of the information into numbers for each potential juror. Such a system is extremely beneficial and can maximize the effectiveness of the juror questionnaires.

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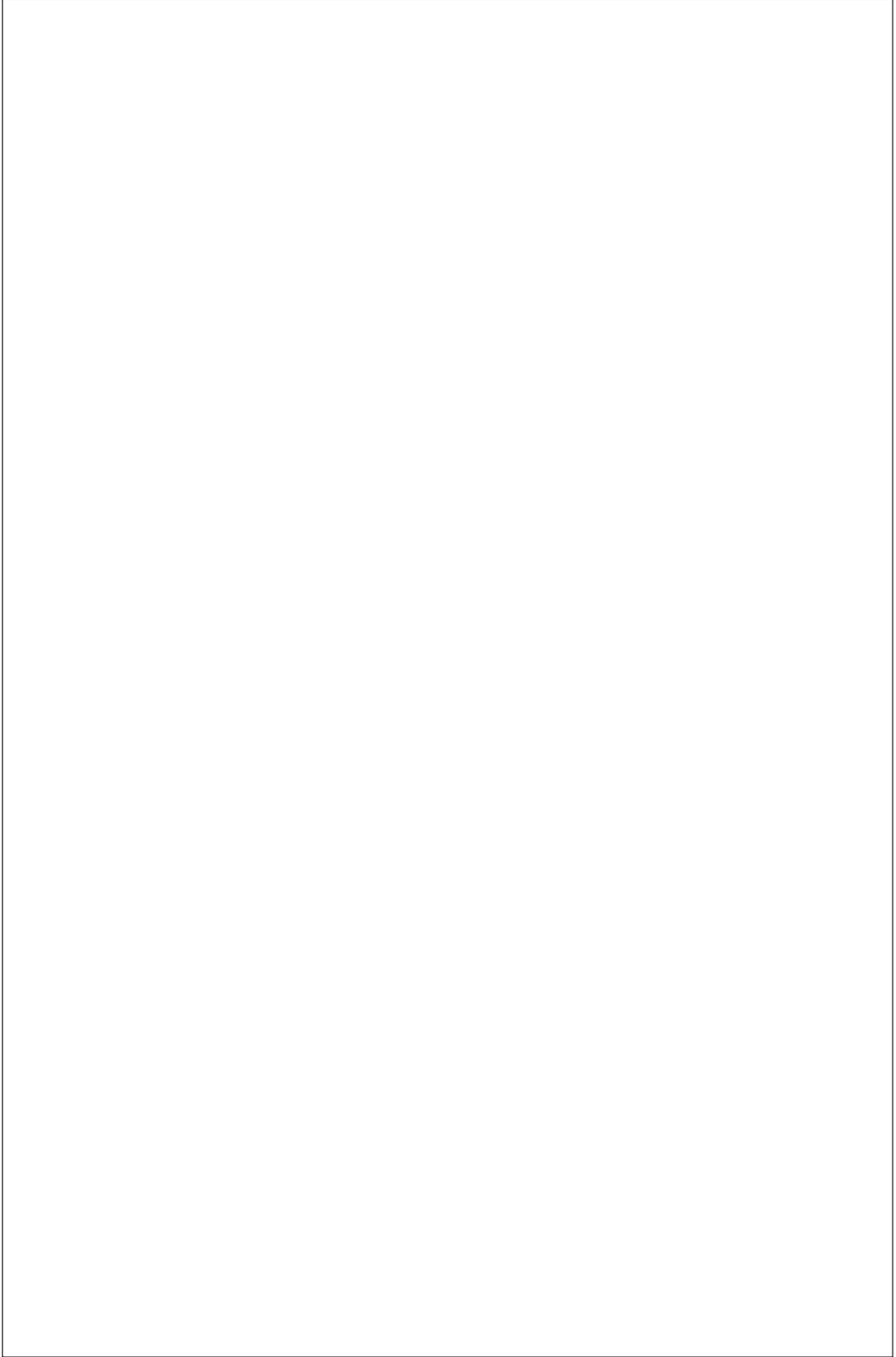
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