# PRODUCT LIABILITY

LAW SECTION • STATE BAR OF GEORGIA

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## Mark Your Calendar

**May 17, 2002**

**The Annual Product Liability Institute**

Swissotel, Buckhead

*Featured luncheon speaker:*

**Clarence Ditlow** of the Center for Auto Safety, Washington, D.C.

## Inside this Issue



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# Proving Up Other Similar Incidents or Claims After *Cooper Tire*


*By Lance A. Cooper and Scott B. Cooper*
*Cooper & Jones*


*Lance A. Cooper*

*Scott B. Cooper*

## I. Introduction

In product liability actions, Georgia courts have long allowed the admission of other similar incidents or claims ("OSIs") to prove various elements of a plaintiff's case. OSIs are admissible and relevant to the issues of whether the subject product is defective, whether the manufacturer had notice or knowledge of the defect, and whether the manufacturer's conduct in the face of this knowledge rises to the level of conscious indifference sufficient to support an award of punitive damages.[1] The manufacturer's knowledge of a product's dangerous propensities can also demonstrate a duty to warn.[2]

The Georgia courts have made it equally clear that other incidents or claims are only admissible if the party offering the evidence can show that these OSIs are "substantially similar" to the incident or claim at

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# *Buckman* Preemption: Drawing the Lines One Year Later


*By Andrew T. Bayman and Amy M. Power*
*King & Spalding*


*Andrew T. Bayman*

*Amy M. Power*

One year ago, the U.S. Supreme Court in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), held that a state law claim alleging a defendant's "fraud-on-the FDA" was impliedly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") and its Medical Device Amendments of 1976 ("MDA"). Plaintiffs in *Buckman* claimed that a regulatory consultant made fraudulent representations to the FDA in connection with seeking approval to market certain orthopedic bone screws. *Id.* at 346-47. Had the company not made those representations, plaintiffs claimed, the FDA would not have approved the bone screws and they would not have

*Continued, p. 9*

# Message from the Chair

*Lee Tarte Wallace*

The product liability section is in its third year of rebirth, and I am proud to say that **we now have more than 471 members, the largest number ever for this section.** Our fall seminar, headed by Dart Meadows, had nearly 100 people in attendance, and was the largest fall seminar the section has ever had.

You will not want to miss our annual Product Liability Seminar, to be held May 17th at the Swissotel in Atlanta. This year's Institute will cover the elements – from discovery through subrogation – that can be involved in a product liability suit. Our featured luncheon speaker will be Clarence Ditlow of the Center for Auto Safety. A number of terrific speakers have been confirmed to date, including Lance Cooper on voir dire, Jeff Pope on subrogation, Laura Shamp on other similar incidents, Charles Beans on subsequent design changes, Jason Crawford on motions in limine, and Allen Willingham on circumstantial evidence of design defect. Bill Lanham will give an actual opening statement and Jim Carter will give a closing argument. Please mark the seminar date on your calendar.

We have added three new benefits for section members this year. First, we hosted our first Brown Bag luncheon for the section. We learned engineering basics in a crash course taught by engineer Dr. Michael Stevenson. Secondly, we are fortunate to have 50 members of the Product Liability section who are in-house counsel for corporations. Stephanie Parker, the section's immediate past president, has begun a Corporate Counsel group, which hosts lunches at which speakers address issues of particular concern to this group. Thirdly, we have begun providing email legislative updates to section members.

This newsletter features three terrific articles on timely topics for product liability lawyers. Andy Bayman and Amy Power of King & Spalding write on preemption; former Georgia professor and now practicing attorney Al Pearson has prepared a chart that explains the elements applicable to expert witnesses under Daubert, and collects the cases related to each element; and Lance and Scott Cooper have written on other similar incidents.

We appreciate your being a member of the section. Please email us with any ideas or suggestions you have for the section. Also, if you know someone who is interested in product liability cases, please tell them about our section.

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## To Join the Product Liability Section

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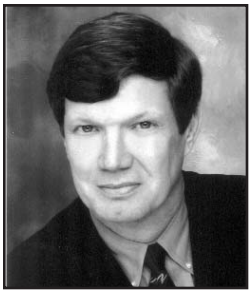

# The Factors Courts Consider Under Daubert

*By Albert M. Pearson, MORAITAKIS, KUSHEL & PEARSON*

## Daubert or FRE 702 Factor

### Are the expert's qualifications adequate and suitable?

The selection of an expert in a products liability case is a preeminently important decision. As the cases noted in connection with this factor reveal, it is critical for your expert to have a scientific or professional background that is closely matched to the issues in the case. This factor is routinely used in product liability cases by defendants, who hope that by getting a plaintiff's expert disqualified on the grounds of inadequate qualifications in one case, the ruling will be a deadly weapon in other cases. There is a strong linkage between an expert's qualifications and the closely related factor of testing. It is possible to overcome some arguable deficiencies in case specific qualifications by compensating with testing data. Defendants have a built-in advantage for this factor: defendants always have the luxury of selecting experts who have previous experience in the industry, whereas plaintiffs have much more difficulty in finding such experts.

### Cases Discussing Factor

**Bonner v. ISP Technologies, Inc.**, 259 F.3d 924 (8th Cir. 2001) (Plaintiff's expert; admission upheld)
**Nemir v. Mitsubishi Motor Sales Of America, Inc**., 248 F.3d 1151 (6th Cir. 2001) (Plaintiff's expert; exclusion reversed)
**Wilson v. Bradlees Of New England, Inc.,** 250 F.3d 10 (1st Cir. 2001) (Plaintiff's expert; exclusion upheld)
**Kron v. Moravia Central School District**, 2001 WL 246072 (2nd Cir. 2001) (Age discrimination; Plaintiff's expert; exclusion upheld)
**United States v. Mathis**, __ F.3d __, 2001 WL 995170 (3rd Cir. 2001) (Criminal defendant's expert; erroneously excluded under Daubert, but exclusion upheld under FRE 403 balancing and harmless error standard)
**Saldana v. KMART Corporation**, 260 F.3d 228 (3rd Cir. 2001) (Plaintiff's expert; exclusion upheld)
**Nelson v. Tennessee Gas Pipeline Company**, 243 F.3d 244 (6th Cir. 2001) (Plaintiff's expert; exclusion upheld)
**Gebhardt v. Mentor Corp**., 2001 WL 868453 (9th Cir. 2001) (Unpublished opinion) (Plaintiff's expert; exclusion upheld)
**United States v. Hansen**, 262 F.3d 1217 (11th Cir. 2001) (Government's expert; admission upheld) (Expert's testimony questioned or excluded in 4 other cases)
**Seatrax, Inc. v. Sonbeck International, Inc.,** 200 F.3d 358 (5th Cir. 2000) (Trademark infringement
and trade secret action; Plaintiff's expert; exclusion upheld)
**Jahn v. Equine Services,** PSC, 233 F.3d 382 (6th Cir. 2000) (Plaintiff's expert; exclusion reversed)
**Pride v. BIC Corporation**, 218 F.3d 566 (6th Cir. 2000) (Plaintiff's experts; exclusion upheld)
**Smith v. Ford Motor Company,** 215 F.3d 713 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed)
**Walker v. SOO Line Railroad Company**, 208 F.3d 581 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed) (Defendant's experts; admission upheld)
**Smith v. Ingersoll-Rand Company**, 214 F.3d 1235 (10th Cir. 2000) (Plaintiff's experts; admission upheld)
**Hynes v. Energy West, Inc.,** 211 F.3d 1193 (10th Cir. 2000) (Plaintiff's expert; admission upheld)
**United States v. Salimonu**, 182 F.3d 63 (1st Cir. 1999) (Defendant's expert; criminal conviction affirmed)
**Oglesby v. General Motors Corp.,** 190 F.3d 244 (4th Cir. 1999) (Plaintiff's expert; exclusion upheld)
In re: UNISYS Savings Plan Litigation, 173 F.3d 145 (3rd Cir. 1999) (Plaintiff's expert; exclusion upheld)
**Curtis v. M&S Petroleum, Inc.,** 174 F.3d 661 (5th Cir. 1999) (Plaintiff's expert; exclusion reversed)
**Tanner v. Westbrook, M.D.,** 174 F.3d 542 (5th Cir. 1999) (Plaintiff's expert; admission reversed)
Allison v. McGhan Medical Corporation, 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld)

### Does the expert have testing and/or can the expert show testability?

This is a hugely important Daubert factor. Again, product liability defendants have an advantage with this factor, because they can show a court extensive product testing. The issue of testing relates not only to the question of defect but also to the issue of reasonable alternative design. It would be extraordinarily difficult for plaintiffs in product liability cases to conduct the kind of testing that product liability defendants can do. Nevertheless, the extent to which an expert can generate test results is going to matter to many trial judges ruling on a Daubert motion. One compensating factor is the ability to secure documents from product liability defendants showing, based on their own internal test results, that a product is defective or that a reasonable alternative design exists.

**Nemir v. Mitsubishi Motor Sales Of America, Inc.,** 248 F.3d 1151 (6th Cir. 2001) (Plaintiff's expert; exclusion reversed)

**Saldana v. KMART Corporation,** 260 F.3d 228 (3rd Cir. 2001) (Plaintiff's expert; exclusion upheld)

**Glastetter v. Novartis Pharmaceuticals Corporation,** 252 F.3d 986 (8th Cir. 2001) (Plaintiff's experts; exclusion upheld)
Pride v. BIC Corporation, 218 F.3d 566 (6th Cir. 2000) (Plaintiff's experts; exclusion upheld)

**Hynes v. Energy West, Inc.,** 211 F.3d 1193 (10th Cir. 2000) (Plaintiff's expert; admission upheld)

**Heller v. Shaw Industries, Inc.,** 167 F.3d 146 (3rd Cir. 1999) (Plaintiff's experts; exclusion reversed in part and upheld in part)
**Allison v. McGhan Medical Corporation**, 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld)

| Daubert or FRE 702 Factor | Cases Discussing Factor |
|---|---|
| **Does the expert have publications, particularly peer reviewed publications?**<br><br>This is a much-mentioned factor, but it does not appear to be as decisive as the previous two factors. Generally speaking, as long as the literature reflects the existence of a reasonable scientific debate, this factor is going to be a wash. Plaintiffs in particular should be alert for situations in which product liability defendants have subsidized professional publications, which are then used to support defenses in product liability cases. This issue should be explored when the qualifications and background of defense experts is examined. While it will probably not suffice to exclude defense expert testimony, "subsidized" defense research can be an effective cross-examination tool. Also be mindful of your expert's testimonial history in connection with a particular defect, as the opposing attorney may well be aware of this history. | **Bonner v. ISP Technologies, Inc.,** 259 F.3d 924 (8th Cir. 2001) (Plaintiff's expert; admission upheld)<br><br>**United States v. Mathis,** __ F.3d __, 2001 WL 995170 (3rd Cir. 2001) (Criminal defendant's expert; erroneously excluded under Daubert, but exclusion upheld under FRE 403 balancing and harmless error standard)<br><br>**Nelson v. Tennessee Gas Pipeline Company**, 243 F.3d 244 (6th Cir. 2001) (Plaintiff's expert; exclusion upheld)<br><br>**Glastetter v. Novartis Pharmaceuticals Corporation,** 252 F.3d 986 (8th Cir. 2001) (Plaintiff's experts; exclusion upheld)<br><br>**Smith v. Ford Motor Company,** 215 F.3d 713 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed)<br><br>**Gebhardt v. Mentor Corp.,** 2001 WL 868453 (9th Cir. 2001) (Unpublished opinion) (Plaintiff's expert; exclusion upheld)<br><br>**United States v. Hansen,** 262 F.3d 1217 (11th Cir. 2001) (Government's expert; admission upheld)<br><br>**United States v. Salimonu,** 182 F.3d 63 (1st Cir. 1999) (Defendant's expert; criminal conviction affirmed)<br><br>**Heller v. Shaw Industries, Inc.,** 167 F.3d 146 (3rd Cir. 1999) (Plaintiff's expert; exclusion reversed in part and upheld in part)<br><br>**Westberry v. Gislaved Gummi AB,** 178 F.3d 257 (4th Cir. 1999) (Plaintiff's expert; admission upheld)<br><br>**Curtis v. M&S Petroleum, Inc.,** 174 F.3d 661 (5th Cir. 1999) (Plaintiff's expert; exclusion reversed)<br><br>**Tanner v. Westbrook, M.D.,** 174 F.3d 542 (5th Cir. 1999) (Plaintiff's expert; admission reversed)<br><br>**Allison v. McGhan Medical Corporation,** 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld) |
| **Does the industry accept the methodology used by your expert?**<br><br>It is critically important for the methodology used by your expert to mirror the methodology or methodologies used in the industry generally. If you cannot win your case without a departure from established analytical methods, be prepared to document the scientific efficacy of the method you ask the court to rely upon. In this vein, you should note the recent decision invalidating the use of fingerprint evidence because of an inability to validate such evidence based on Daubert factors. United States v. Llera Plaza, 179 F. Supp. 2d 492 (E.D. Pa 2002). See also United States v. Harvard, 260 E. 3d 597 (7th Cir. 2001) (upholding admissibility of fingerprint evidence against Daubert challenge.) | **Bonner v. ISP Technologies, Inc.,** 259 F.3d 924 (8th Cir. 2001) (Plaintiff's expert; admission upheld)<br><br>**United States v. Mathis,** __ F.3d __, 2001 WL 995170 (3rd Cir. 2001) (Criminal defendant's expert; erroneously excluded under Daubert, but exclusion upheld under FRE 403 balancing and harmless error standard)<br><br>**Glastetter v. Novartis Pharmaceuticals Corporation,** 252 F.3d 986 (8th Cir. 2001) (Plaintiff's experts; exclusion upheld)<br><br>S.M. v. J.K., 262 F.3d 914 (9th Cir. 2001) (Plaintiff's expert; admission upheld)<br><br>**United States v. Hansen,** 262 F.3d 1217 (11th Cir. 2001) (Government's expert; admission upheld)<br><br>**Jahn v. Equine Services,** PSC, 233 F.3d 382 (6th Cir. 2000) (Plaintiff's expert; exclusion reversed)<br><br>**Pride v. BIC Corporation,** 218 F.3d 566 (6th Cir. 2000) (Plaintiff's experts; exclusion upheld)<br><br>**Smith v. Ford Motor Company**, 215 F.3d 713 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed)<br><br>**Walker v. SOO Line Railroad Company**, 208 F.3d 581 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed) (Defendant's experts; admission upheld)<br><br>**Goebel v. Denver and Rio Grande Western Railroad Company,** 215 F.3d 1083 (10th Cir. 2000) (Plaintiff's expert; admission reversed)<br><br>**Smith v. Ingersoll-Rand Company**, 214 F.3d 1235 (10th Cir. 2000) (Plaintiff's experts; admission upheld)<br><br>**Hynes v. Energy West, Inc.,** 211 F.3d 1193 (10th Cir. 2000) (Plaintiff's expert; admission upheld)<br><br>**Heller v. Shaw Industries, Inc.,** 167 F.3d 146 (3rd Cir. 1999) (Plaintiff's experts; exclusion reversed in part and upheld in part)<br><br>**Westberry v. Gislaved Gummi AB,** 178 F.3d 257 (4th Cir. 1999) (Plaintiff's expert; admission upheld)<br><br>**Allison v. McGhan Medical Corporation,** 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld) |

## Daubert or FRE 702 Factor

## Cases Discussing Factor

### Has the expert made a proper extrapolation from the evidence or is there a lack of "fit"?

This factor is another crunchpoint for experts. Generally, experts face difficulty when their conclusions outstrip the evidence upon which the conclusions are based. Thus, this factor is very similar to the methodology factor but it involves a misuse or misapplication of a methodology that is otherwise acceptable. Some people refer to this as the scientific "leap of faith" factor.

**Bonner v. ISP Technologies, Inc.,** 259 F.3d 924 (8th Cir. 2001) (Plaintiff's expert; admission upheld)
**Nemir v. Mitsubishi Motor Sales Of America, Inc.,** 248 F.3d 1151 (6th Cir. 2001) (Plaintiff's expert; exclusion reversed)
**Wilson v. Bradlees Of New England, Inc.,** 250 F.3d 10 (1st Cir. 2001) (Plaintiff's expert; exclusion upheld)
**Kron v. Moravia Central School District,** 2001 WL 246072 (2nd Cir. 2001) (Age discrimination; Plaintiff's expert; exclusion upheld)
**United States v. Mathis,** __ F.3d __, 2001 WL 995170 (3rd Cir. 2001) (Criminal defendant's expert; erroneously excluded under Daubert, but exclusion upheld under FRE 403 balancing and harmless error standard)
**Saldana v. KMART Corporation,** 260 F.3d 228 (3rd Cir. 2001) (Plaintiff's expert; exclusion upheld)
**Nelson v. Tennessee Gas Pipeline Company,** 243 F.3d 244 (6th Cir. 2001) (Plaintiff's expert; exclusion upheld)
**Glastetter v. Novartis Pharmaceuticals Corporation,** 252 F.3d 986 (8th Cir. 2001) (Plaintiff's experts; exclusion upheld)
**Gebhardt v. Mentor Corp.,** 2001 WL 868453 (9th Cir. 2001) (unpublished opinion) (Plaintiff's expert; exclusion upheld)
**S.M. v. J.K.,** 262 F.3d 914 (9th Cir. 2001) (Plaintiff's expert; admission upheld)
**Jahn v. Equine Services, PSC,** 233 F.3d 382 (6th Cir. 2000) (Plaintiff's expert; exclusion reversed)
**Pride v. BIC Corporation,** 218 F.3d 566 (6th Cir. 2000) (Plaintiff's experts; exclusion upheld)
**Smith v. Ford Motor Company,** 215 F.3d 713 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed)
**Walker v. SOO Line Railroad Company,** 208 F.3d 581 (7th Cir. 2000) (Plaintiff's expert; exclusion reversed) (Defendant's experts; admission upheld)
**Goebel v. Denver and Rio Grande Western Railroad Company**, 215 F.3d 1083 (10th Cir. 2000) (Plaintiff's expert; admission reversed)
**Smith v. Ingersoll-Rand Company**, 214 F.3d 1235 (10th Cir. 2000) (Plaintiff's experts; admission upheld)
**Hynes v. Energy West, Inc.,** 211 F.3d 1193 (10th Cir. 2000) (Plaintiff's expert; admission upheld)
**Oglesby v. General Motors Corp.,** 190 F.3d 244 (4th Cir. 1999) (Plaintiff's expert; exclusion upheld)
In re: UNISYS Savings Plan Litigation, 173 F.3d 145 (3rd Cir. 1999) (Plaintiff's expert; exclusion upheld)
**Heller v. Shaw Industries, Inc.,** 167 F.3d 146 (3rd Cir. 1999) (Plaintiff's expert; exclusion reversed in part and upheld in part)
**Norris v. Ford Motor Company,** 1999 WL 410119, 182 F.3d 909 (4th Cir. 1999) (unpublished opinion) (Plaintiff's expert; exclusion affirmed)
**Westberry v. Gislaved Gummi AB,** 178 F.3d 257 (4th Cir. 1999) (Plaintiff's expert; admission upheld)
**Seatrax, Inc. v. Sonbeck International, Inc.,** 200 F.3d 358 (5th Cir. 2000) (Trademark infringement and trade secret action; Plaintiff's expert; exclusion upheld)
**Curtis v. M&S Petroleum, Inc.,** 174 F.3d 661 (5th Cir. 1999) (Plaintiff's expert; exclusion reversed)
**Allison v. McGhan Medical Corporation,** 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld)

### Can the expert properly account for alternative explanations?

This factor requires experts to address the various alternative explanations for the injury raised by the defendant. It is usually weighed by the trial court in conjunction with other Daubert factors. It will rarely be the sole reason for excluding evidence under Daubert. However, it is important to remind the trial court that the alternative explanations for an event go to the weight of the evidence and should not foreclose consideration of an expert's testimony. If a trial court does not understand the impermissible burden shifting effect that this factor can have, it will weigh the factor too heavily in favor of exclusion.

**Nemir v. Mitsubishi Motor Sales Of America, Inc.,** 248 F.3d 1151 (6th Cir. 2001) (Plaintiff's expert; exclusion reversed)

**United States v. Mathis,** __ F.3d __, 2001 WL 995170 (3rd Cir. 2001) (Criminal defendant's expert; erroneously excluded under Daubert, but exclusion upheld under FRE 403 balancing and harmless error standard)

**Saldana v. KMART Corporation,** 260 F.3d 228 (3rd Cir. 2001) (Plaintiff's expert; exclusion upheld)

**Nelson v. Tennessee Gas Pipeline Company,** 243 F.3d 244 (6th Cir. 2001) (Plaintiff's expert; exclusion upheld)

**Glastetter v. Novartis Pharmaceuticals Corporation,** 252 F.3d 986 (8th Cir. 2001) (Plaintiff's experts; exclusion upheld)

**Jahn v. Equine Services, PSC,** 233 F.3d 382 (6th Cir. 2000) (Plaintiff's expert; exclusion reversed)

**Oglesby v. General Motors Corp.,** 190 F.3d 244 (4th Cir. 1999) (Plaintiff's expert; exclusion upheld)

**Westberry v. Gislaved Gummi AB,** 178 F.3d 257 (4th Cir. 1999) (Plaintiff's expert; admission upheld)

**Curtis v. M&S Petroleum, Inc.,** 174 F.3d 661 (5th Cir. 1999) (Plaintiff's expert; exclusion reversed)

**Allison v. McGhan Medical Corporation,** 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld)

| Daubert or FRE 702 Factor | Cases Discussing Factor | |
|---|---|---|
| **Does the expert base his opinion on independent research or is the opinion litigation-based?**<br><br>To the extent that an expert can tie his opinions and conclusions to a wider body of research that is unrelated to litigation, it will always be helpful. Product liability defendants enjoy pointing out how plaintiff's experts have fashioned their opinions for a particular litigation constituency. Sometimes judges are impressed with this argument. On the other hand, as previously noted, defense experts often are relying upon "subsidized" research, or speak for a litigation constituency as well, as in the tobacco litigation. | **Wilson v. Bradlees Of New England, Inc.,** 250 F.3d 10 (1st Cir. 2001) (Plaintiff's expert; exclusion upheld)<br><br>**Nelson v. Tennessee Gas Pipeline Company,** 243 F.3d 244 (6th Cir. 2001) (Plaintiff's expert; exclusion upheld)<br><br>**United States v. Hansen,** 262 F.3d 1217 (11th Cir. 2001) (Government's expert; admission upheld) | **Pride v. BIC Corporation,** 218 F.3d 566 (6th Cir. 2000) (Plaintiff's experts; exclusion upheld)<br><br>**Allison v. McGhan Medical Corporation,** 184 F.3d 1300 (11th Cir. 1999) (Plaintiff's expert; exclusion upheld) |
| **In reaching opinions for this case, has the expert used the same degree of care as for non-litigation work?**<br><br>As noted above, if the trial court thinks that an expert is using a relaxed scientific standard or methodology for litigation work as opposed to other professional work, the court will not be favorably impressed. | **Seatrax, Inc. v. Sonbeck International, Inc.,** 200 F.3d 358 (5th Cir. 2000) (Trademark infringement and trade secret action; Plaintiff's expert; exclusion upheld) | **Tanner v. Westbrook, M.D.,** 174 F.3d 542 (5th Cir. 1999) (Plaintiff's expert; admission reversed) |
| **Is the expert's field known for reliable results?**<br><br>There are actually a number of professional fields where the science is "soft." In the product liability field this would include a lot of the research in the warnings and human factors areas. You will rarely be able to get evidence excluded because of the "softness" of the data in the field, but you may have fertile lines of cross-examination. | **United States v. Mathis,** __ F.3d __, 2001 WL 995170 (3rd Cir. 2001) (Criminal defendant's expert; erroneously excluded under Daubert, but exclusion upheld under FRE 403 balancing and harmless error standard)<br><br>**S.M. v. J.K.,** 262 F.3d 914 (9th Cir. 2001) (Plaintiff's expert; admission upheld) | **United States v. Salimonu,** 182 F.3d 63 (1st Cir. 1999) (Defendant's expert; criminal conviction affirmed)<br><br>**Westberry v. Gislaved Gummi AB,** 178 F.3d 257 (4th Cir. 1999) (Plaintiff's expert; admission upheld). |
| **What is the error rate for the expert's work?**<br><br>This factor was mentioned prominently in the Daubert decision itself, but it is not a factor that receives much attention in the cases. | **United States v. Salimonu,** 182 F.3d 63 (1st Cir. 1999) (Defendant's expert; criminal conviction affirmed) | |
| **Does the expert have proof of similar failures or accidents?**<br><br>This factor is a potent line of evidence for plaintiff's experts. It tends to validate an expert's opinions and methodology. To the extent that product liability manufacturers take this type of data into account, it tends to neutralize their attacks on the methodology of plaintiff's experts. | **Nemir v. Mitsubishi Motor Sales Of America,** Inc., 248 F.3d 1151 (6th Cir. 2001) (Plaintiff's expert; exclusion reversed) | **Smith v. Ingersoll-Rand Company,** 214 F.3d 1235 (10th Cir. 2000) (Plaintiff's experts; admission upheld) |

issue in the case. "Without a showing of substantial similarity, the evidence is irrelevant as a matter of law."[3] The admissibility of this evidence then turns on the definition of substantially similar.

The Georgia Supreme Court last year addressed the issue of substantial similarity as it applies to product liability cases in *Cooper Tire & Rubber Co. v. Crosby*.[4] In *Cooper Tire*, the tread separated from the left rear tire on the Crosby's Ford Bronco II. This caused Bobby Crosby to lose control of the vehicle, which ultimately rolled over, killing Bobby and seriously injuring his wife and daughter.[5]

At trial, the plaintiff sought to introduce evidence of Cooper Tire's adjustment statistics for the previous nine years at the plant where Cooper Tire manufactured the accident tire.[6] "Adjustments" are consumer claims that are honored by the manufacturer, and adjustment statistics usually show the total number of adjusted tires and the ratio of the number of tires adjusted to the number of tires manufactured.

The trial court excluded the Crosby's adjustment evidence, and the jury returned a defense verdict. The Court of Appeals reversed and remanded, holding that the trial court erred in excluding the adjustment statistics. The Supreme Court subsequently reversed the Court of Appeals on the ground that the plaintiff did not make the requisite "substantial similarity" showing with respect to the adjustment data.[7]

## II. The *Cooper Tire* Factors

In its opinion, the Court listed three deficiencies in plaintiff's proof with respect to the adjustment data. According to the Court, plaintiff failed to meet the substantial similarity test because "the adjustment evidence was proffered at trial without any showing that: (1) Crosby's tires and the adjusted tires shared a common design and manufacturing process; (2) suffered from a common defect; and (3) that any common defects shared the same causation."[8] Based on these enumerated deficiencies, the Court held that the trial court had not abused its discretion in excluding the evidence from trial.

It is not clear whether the Court meant to establish these as new factors by which to analyze all future OSI evidence in product liability cases or whether it was simply citing to those factors as shortcomings specific to that case.[9] Nevertheless, based on the opinion, it would be prudent for all plaintiffs offering OSIs to marshal the evidence necessary to make these showings in preparation for the inevitable motion in limine to exclude the OSIs. According to the *Cooper Tire* language, the plaintiff should be prepared to show:

a. The product at issue in the case shares a common design and manufacturing process with the products involved in the other incidents or claims;
b. The products suffered from a common defect; and
c. Any common defects shared the same causation.

As with virtually all product liability claims, it will almost always be necessary to retain an expert witness to assist in making these showings to the trial court. Through either affidavits or, if necessary, live testimony, the expert can explain to the Court how the product in your case and those at issue in the OSIs meet each similarity showing enumerated in *Cooper Tire*.

### A. Common Design and Manufacturing Process

With respect to this first factor, it is important to note that the products do not have to be the same as long as the design and manufacturing processes are the same. A search for OSIs, therefore, should not be limited to the particular product that is at issue in your case. For instance, identical cars may be sold under different model names or even different brands. As another example, a single tire manufacturing plant will usually produce many different lines of tires, some or all of which may share common design and manufacturing processes. Lawyers pursuing product liability claims need to thoroughly investigate all potentially similar products and not focus on just the product that failed.

You can establish a common design and manufacturing process through a number of sources. Through written discovery, you can obtain documents and admissions about the design and manufacturing process, as well as what other products are made in a similar manner. You can also take Rule 30(b)(6) corporate representative depositions of people familiar with the design and manufacture of the products at issue. If your case warrants it, an inspection of the manufacturing plant under Rule 34 often leads to helpful information. You should also conduct an independent investigation, which can include finding and interviewing ex-employees or others in the industry and reviewing the website of the manufacturer, which oftentimes reveals a surprising amount of information about the company and its products.

### B. A Common Defect

The important word used in this second factor is "a" -- the products must share "a" common defect. This is significant because the products being litigated are often complex, and plaintiffs will frequently assert multiple defects in support of their claims. The defense may try to capitalize on that fact and argue that the other products do not share all of the same defects alleged in the product at issue in the case. According to the Cooper opinion, the plaintiff need only show a single common defect among the various products to meet this element of substantial similarity.

Demonstrating this common defect requires thorough discovery and investigation of the type discussed above. With respect to design defect claims, establishing the first element (a common design) will usually satisfy the second. If you have evidence that the design of a product or one of its components is defective, and you can show that the other similar products share the same design,

then you can argue you have shown a common defect. Claims based on a manufacturing defect are, by their nature, more specific to each product. If, however, you can uncover evidence of a pattern of shoddy manufacturing practices at a particular plant that would have affected all products produced there, you can go a long way toward proving the common manufacturing defect.

### C. Any Common Defects Shared the Same Causation

This is perhaps the most important, and potentially most misunderstood, aspect of the Court's ruling. The Court found that Crosby failed to show "that any common defects shared the same causation."[10] In other words, the analysis is not whether the defect caused the other incident (the product failure or the accident). The similarity of causation required by *Cooper Tire* is focused instead on the defects.

Tire tread separations provide a good illustration of this distinction. Defects in tires can and do cause tread separations, and tread separations can and do cause accidents. In order to offer other similar tires into evidence, however, you need not prove that the defects in those tires actually caused a tread separation or an accident. Under *Cooper Tire*, you only need to show that those other tires had a common defect as the subject tire and that the common defect shared the same causation. In other words, whether the same design or manufacturing deficiency caused the defect.

This analysis is consistent with the purposes for admitting OSIs – to prove a defect and the manufacturer's knowledge of the defect. It is not necessary that the defect in the other similar tires actually causes an "incident." The relevant facts are that the defect exists and the manufacturer knows of it. Suppose, for example, that a tire is brought back to the manufacturer, and the manufacturer determines that the tire had begun to separate internally, but that internal separation had not yet caused an actual tread separation or accident. Under *Cooper Tire*, that other similar tire is still admissible because it provides evidence of a common defect and the manufacturer's knowledge of that defect.

As for proving the shared causation, that will again be the result of investigation, discovery, and consultation with your expert witness. As with the common defect, however, once you are able to prove a common design process, you have gone a long way towards proving shared causation.

## III. Cooper Tire Applies to All Statistical Evidence

The analysis in *Cooper Tire* is generally seen as making it more difficult for plaintiffs to present OSI or claims at trial. The underlying reasoning of the case, however, applies equally to defense evidence. For example, the defense in a products case will oftentimes offer statistical evidence to show that its product performs better, or at least no worse than, comparable products in the marketplace. Although all of the *Cooper Tire* factors may not apply to every case, statistical evidence offered to defend a product should be put through no less scrutiny than any comparable statistical evidence the plaintiff offers. This should not only alert defense counsel to be prepared to defend their statistical evidence on substantial similarity grounds, it should also remind plaintiff's counsel to challenge defense statistical evidence on this often overlooked theory.

## IV. Conclusion

Many people, including the dissenting justices, have read *Cooper Tire* as imposing a higher standard for the admissibility of similar occurrences in product liability actions.[11] Time will tell how rigorously the *Cooper Tire* factors will be applied outside of the tire adjustment context.[12] Nevertheless, even if those factors are strictly applied in other product liability cases, the burdens are by no means insurmountable.[13] With a thorough investigation, exhaustive discovery, and an organized presentation to the trial court, the party offering the evidence can meet these standards and use this powerful evidence at trial.

## ENDNOTES

1. *Rose v. Figgie Int'l, Inc.*, 229 Ga. App. 848, 850, 495 S.E.2d 77 (1997); *Skil Corp. v. Lugsdin*, 168 Ga. App. 754, 755-56, 309 S.E.2d 921 (1983).
2. *Rose*, 229 Ga. App. at 850.
3. *General Motors Corp. v. Moseley*, 213 Ga. App. 875, 877, 447 S.E.2d 302 (1994); *Mack Trucks, Inc. v. Conkle*, 263 Ga. 539, 544, 436 S.E.2d 635 (1993).
4. 273 Ga. 454, 543 S.E.2d 21 (2001).
5. *Id.* at 454.
6. *Id.* at 454-55.
7. *Id.* at 455-56.
8. *Id.* at 456.
9. This article will not analyze the whether the Cooper Tire Court was correct in its conclusions or in its criticisms of the Court of Appeals decision. The opinion has, however, been questioned elsewhere. See, e.g., Deron R. Hicks and Jacob E. Daly, Torts, 53 Mercer L. Rev. 441, 465-67 (2001).
10. *Cooper Tire*, 273 Ga. at 456.
11. *Id.* at 461 (Hunstein, J., dissenting).
12. As of the writing of this article, *Cooper Tire* has not been cited in another published case regarding the admissibility of other similar incident evidence.
13. In a recent trial in Fulton County State Court involving a General Tire tread separation and a Ford Bronco II rollover, Judge Myra Dixon, applying the Cooper Tire factors, admitted evidence of (1) twenty-five similar tread separation/rollover accidents and (2) adjustment data for tire lines that were similar to the tire at issue in the case. *Ronald Hall v. Ford Motor Company,* Continental General Tire, Inc., et al., Civil Action File No. 99VS-152700C.

been injured. *Id.* The Supreme Court found the claim impliedly preempted, concluding the claim conflicted with the MDA, which authorized the FDA to pursue a variety of remedies to punish and deter the submission of false or misleading information, and that these remedial options provided the FDA with the flexibility needed to balance the FDCA's objectives. This balance, the Court held, would be thrown awry by permitting state common law claims of fraud-on-the-FDA. The Court explained that "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court[, thereby creating] an incentive to submit a deluge of information that the Administration neither wants nor needs." *Id.* at 351. Moreover, the Court noted that "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants — burdens not contemplated by Congress in enacting the FDCA and the MDA." *Id.* at 350.

Since the Court's decision in *Buckman*, lower courts have grappled with whether preemption under *Buckman* applies in the context of pharmaceutical products, whether it extends to failure-to-warn and other negligence claims, and, to a lesser extent, what evidence of alleged non-disclosure to the FDA may be admissible. For example, plaintiffs have attempted to steer clear of *Buckman* by arguing that it is limited to medical devices by virtue of an express preemption provision Congress included in the MDA, and that its holding has no effect on claims alleging that the manufacturer was negligent in disclosing purported risks to the FDA or to prescribing physicians. On the other hand, manufacturers have been striving to strip away this post-*Buckman* re-labeling of claims, pointing out to courts that the facts alleged are simply a reiteration of the now-preempted fraud claim. The efforts of both have met with mixed results.

### Application Beyond the MDA

In *Buckman*'s wake, courts have been willing to apply its preemption analysis to the FDA's regulation of pharmaceutical products under the FDCA as well as its regulation of medical devices under the MDA. See *Flynn v. American Home Products Corp.*, 627 N.W.2d 342, 347-49 (Minn. Ct. App. 2001) (*Buckman* preemption principles apply equally to the FDA's regulation of drugs); accord *McCall v. Pacificare of California*, Inc., 25 Cal. 4th 412, 425 n.9 (Cal. 2001) (suggesting *Buckman* preemption extends to disclosures made by a health care provider to the Health Care Financing Administration).

Courts have been right to apply preemption to FDA regulation of pharmaceutical products. First, after the Supreme Court's recent preemption decision in Geier, the fact that the MDA contains an express preemption clause and the FDCA does not should be of no consequence. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 870-74 (2000) (holding that the ordinary working of conflict preemption principles is not affected by the presence or absence of an express preemption provision). Second, with both medical devices and pharmaceuticals, the FDA's approval, oversight, and policing powers are similarly extensive. Compare *Buckman*, 531 U.S. at 1017, with Flynn, 627 N.W.2d at 349. In fact, at issue in *Buckman* was arguably the lowest level of scrutiny the FDA exerts — approval as a "substantially equivalent" device under § 510(k), which does not involve the safety and efficacy inquiries required by the FDCA for non-generic or "pioneer" pharmaceuticals.

### Artful Pleading Versus Putting Substance Over Form

More controversial and less predictable, however, has been lower courts' treatment of claims that are not denominated as "fraud-on-the-FDA," but that nonetheless implicate the quality and sufficiency of information provided by a manufacturer to the FDA. These claims may be couched within a variety of different legal theories, but most often may appear as claims for negligent failure to disclose to the FDA, fraud against the prescribing and consuming public, or failure to warn the plaintiff's prescribing physician. In any event, these claims — to some degree — call into question the accuracy and adequacy of a manufacturer's disclosures to the FDA. Courts have not been in agreement, however, on whether these claims are preempted under *Buckman*.

On the one hand, a number of courts have rejected manufacturers' arguments that claims of fraud or misrepresentation against the public, or failure to warn, are preempted based upon the FDA's role in approving drugs and medical devices as safe and efficacious, approving the labeling for those products, and policing any wrongdoing committed during those approval processes. See, e.g., *Eve v. Sandoz Pharm. Corp.*, 2002 WL 181972 (S.D. Ind. Jan. 28, 2002) (negligent testing and warning claims not preempted); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp.2d 1018 (S.D. Ill. 2001) (claims that drug warnings were inadequate not preempted); *Dawson v. Ciba-Geigy Corp.*, 145 F. Supp.2d 565 (D.N.J. 2001) (no "complete preemption" removal of claims that defendants failed to provide the public with adequate information about the hazards of Ritalin).

Still other courts, however, have declined to read *Buckman* so narrowly, instead holding that where a claim includes within it the allegation that the defendant was somehow deficient in apprising the FDA of risks allegedly associated with the product, that claim is preempted. See, e.g., Flynn, 627 N.W.2d 342 (negligent and fraudulent misrepresentation and statutory consumer fraud

claims arising out of defendant's alleged failure to advise the FDA and, as a result, physicians, of risks associated with fenfluramine were preempted); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 234-36 and n.14 (6th Cir. 2000) (decided pre-*Buckman* on express preemption grounds, but holding that claims based on alleged misrepresentations to consumers and medical community and failure to warn were preempted because the latter was premised on the adequacy of the warnings reviewed and approved by the FDA, and in order to prove in the former that the representations made about the safety and efficacy of the medical device were false, plaintiffs had to show that the product "was falsely represented to be safe and effective — the very determination made by the FDA," which necessarily implied that fraud had been committed on the FDA). See also *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002) (holding that claim for intentional interference with prospective economic advantage was impliedly preempted under FIFRA because the state law claim "hinge[d] upon [the] contention that DowElanco committed fraud against the EPA").

### The Open Evidentiary Question

With some lower courts narrowly interpreting the scope of preemption under *Buckman*, one thing is certain: *Buckman* has not yet, but certainly will, spawn many disputes over the extent to which evidence of alleged shortcomings in the information a manufacturer has provided to the FDA will be admissible in product liability actions asserting claims of negligence and failure to warn. Plaintiffs inevitably will attempt to present evidence and argument that what the manufacturer provided to the FDA was insufficient or did not tell the whole story, in an effort to incline the jury toward an award of punitive damages. Manufacturers will contend that, under the rationale of *Buckman*, this evidence should not be allowed. Since claims resting on the existence of the manufacturer's disclosure duty to the FDA are out of bounds, so, too, should be evidence of an alleged breach of that duty. See *Buckman*, 531 U.S. at 353.