

# PRODUCTS LIABILITY UPDATE

Welcome to the Summer 2003 issue of the Drinker Biddle *Products Liability Update*. Our continuing goal is to provide our readers with thoughtful and succinct comments on current developments and other subjects of interest to products liability defense practitioners—both inside and outside counsel.

Significant developments continue to ensue on both the judicial and legislative fronts. Our lead article discusses important aspects of the 2003 revisions to the class action rule, Fed. R. Civ. P. 23. We next discuss a successful challenge before the Eastern District of Louisiana to a plaintiffs’ theory created expressly for the litigation, followed by a discussion of the proposed Class Action Fairness Act and the ongoing Pennsylvania battle regarding joint and several liability. Finally, we note the recent Pennsylvania Superior Court decision that lowers the admissibility standard for experts testifying to novel theories and conclusions.

We would be pleased to receive any comments or suggestions concerning this Update. Your input could be forwarded to your regular Drinker Biddle products lia-

bility contact, one of the authors or any of the attorneys listed at the end of this issue.

## Changing Class: The New Rule 23

MaryCatherine Roper\*

After more than a decade of intensive study and debate, various proposals both modest and radical, and seemingly inexhaustible public commentary, the Advisory Committee on Civil Rules, the Standing Committee and the Supreme Court have approved the first substantive revisions to Fed. R. Civ. P. 23 since the modern version of the Rule was adopted in 1966.<sup>1</sup> The new class action Rule will take effect December 1, 2003 ... but how “new” is the new Rule 23?

### BIG CHANGES

While subsections (a) and (b)—which set forth the basic requirements for and structure of federal class actions—remain unchanged, the rest of Rule 23 has been substantially revamped. The most obvious changes are:

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1. The only previous change to Rule 23 was the addition, in 1998, of subsection (f), providing for immediate discretionary appellate review of decisions either granting or denying class certification. If the House version of the proposed Class Action Fairness Act, H.R. 1115 (passed by the House on June 12, 2003), becomes law, that discretionary review will be replaced by an appeal as of right from any decision granting or denying class certification, accompanied by a stay of discovery. The Class Action Fairness Act would also create a “Consumer Class Action Bill of Rights,” impose additional substantive and procedural requirements for class action settlements, and expand federal diversity jurisdiction to bring most multi-state class actions into federal court. See our third article in this issue of *Products Liability Update* for a further discussion of the proposed Class Action Fairness Act.

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- the revision of (c)(2), which now contains detailed notice requirements for classes certified under Fed. R. Civ. P. 23(b)(3) and a clarification that notice “may” be provided to classes certified under Fed. R. Civ. P. 23(b)(1) and (b)(2);
- the complete overhaul of subsection (e), which now sets forth detailed procedures and prerequisites for the settlement of certified class actions; and
- the addition of new subsections (g) and (h), which set forth requirements and procedures for the appointment of class counsel and the awarding of attorney fees.

### “BEST PRACTICES” AMENDMENTS TO RULE 23(C)(1)

The more subtle changes to subsection (c)(1) of the Rule, however, will have the greatest impact on whether a putative class action is certified and how class actions are managed in the federal courts up to the point of certification. One Advisory Committee member described these amendments as a codification of the current “best practices” of class action management, and suggested that they should not really alter the manner in which class certification is handled in the federal courts.<sup>2</sup> As many manufacturers can attest, however, even the uniform application of “best practices” would be a welcome—and profound—change in the treatment of class actions.

There are three amendments to subsection (c)(1) that will have particular impact in contested class certifications. First, the requirement under 23(c)(1) that class certification be addressed “as soon as practicable” has been replaced by an instruction, set forth at 23(c)(1)(A), to consider class certification at “an early practicable time.” Second, the reference to “conditional” class certification has been eliminated from the

Rule. Third, new subsection (c)(1)(B) requires that “[a]n order certifying a class action must define the class and the class claims, issues, or defenses, and must appoint class counsel under Rule 23(g).” Each of these changes is significant alone, as well as in combination with the others.

### TIMING OF THE CLASS CERTIFICATION DECISION

The clarification that a court need not rush to class certification and the Advisory Committee’s comments on new section (c)(1)(A) will finally put to rest the debate over whether a court should go beyond the pleadings and consider the factual record on class certification. The Advisory Committee note explains that there are often good reasons for delaying consideration of class certification, the primary ones being the need for discovery relevant to the class certification decision and for the development of a trial plan.<sup>3</sup> The clear purpose and effect of the “timing” amendment is to encourage discovery relevant to class certification, and the district court’s consideration of the information obtained in discovery during the battle over certification.

But the news is not all good. The Advisory Committee note expressly endorses a bifurcation of “class” discovery from all other discovery, while acknowledging that this distinction is not always apparent or easy to manage. The Committee also makes clear that the defendant will have to provide some discovery into the merits prior to class certification: “[I]t is appropriate to conduct controlled discovery into the ‘merits,’ limited to those aspects relevant to making the certification decision on an informed basis.” Thus, while new section (c)(1)(A) is good news overall for defendants battling the myth that the plaintiffs’ allegations are to be taken as true at the class certification stage, it will not help those who seek to preclude *any* pre-certification discovery “on the merits.” This may result in greater costs up front, along with the risks that accompany any

2 . Hon. David F. Levy, Sixth Annual ABA Institute on Class Actions, November 15, 2002, luncheon presentation.

3 . The Committee also mentioned as valid reasons for delaying the certification decision the pursuit by the defendant of a motion to dismiss or for summary judgment with respect to the named plaintiff’s claims, settlement discussions, and the need to “explore designation of [class] counsel under Rule 23(g).”

production of company documents, but it will also give defendants reason to demand that the plaintiffs articulate their theory as to why any discovery sought is relevant to the class certification issues.

The Advisory Committee's comments concerning trial plans are of particular interest to those who defend products liability actions, in which plaintiffs often propose a bifurcated trial at which "liability" is to be severed from "causation" and "damages" in some unexplained fashion. The best of these proposals seldom do more than detail the manner in which the first trial will permit plaintiffs to dwell on the perceived sins of the defendant, while referring only generally to the manner in which the "findings" of the first jury are to be used in the subsequent trials of the individual damage claims. Many plaintiffs have argued that they cannot provide any more specific roadmap at the class certification stage because of the lack of discovery, and that a specific trial plan is unnecessary because the court has the power to mold the class before trial and to adopt whatever case management techniques seem appropriate as the litigation develops.

The changes to Rule 23(c)(1)—notably the elimination of any reference to "conditional" class certification, discussed below—and the Advisory Committee's comments mandate a different approach. While 23(c)(1) and (c)(4) still grant the trial court the power to alter or amend the class certification order<sup>4</sup> and to provide for subclasses, the Advisory Committee has made clear that the new Rule rejects the idea that these powers obviate the need for the court to determine, before certifying a class, that the class can successfully be brought to trial: "A critical need is to determine how the case will be tried." The Advisory Committee, moreover, has identified a detailed trial plan (which an earlier draft of the Committee's note called "a desirable—and at times indispensable—practice"<sup>5</sup>) as the tool that will enable trial courts to make this "critical" determination:

An increasing number of courts require a party requesting class certification to present

a "trial plan" that describes the issues likely to be presented at trial and tests whether they are susceptible of class-wide proof.

These comments—offered as part of the Committee's discussion of the "information needed to make the class certification decision" and the matters that justify delay of the class motion—are an unequivocal endorsement of the oft-repeated mandate from the Fifth Circuit Court of Appeals that a trial court "consider how the plaintiffs' ... claims would be tried, individually or on a class basis" before certifying a class action. *Castano v. American Tobacco Co.*, 84 F.3d 734, 744 (5th Cir. 1996). They also provide strong support for the argument that nothing other than a detailed trial plan can provide a court with the means to accomplish that task.

## THE END OF "CONDITIONAL" CLASS CERTIFICATION

The second major revision of Rule 23(c)(1) is the elimination of the concept of "conditional" class certification. The Advisory Committee's note with respect to this amendment is unequivocal: "A court that is not satisfied that the requirements of Rule 23 have been met should refuse certification until they have been met." This change will end the practice followed by courts in the Diet Drug and other litigations of acknowledging potential manageability problems that have not been addressed sufficiently in the briefing—such as the difficulties posed by varying legal standards in multi-state class actions—but certifying the class "conditionally" while awaiting a trial plan or other submission in which the plaintiffs promise to satisfy all doubts on the open issue. This amendment is even more significant when read in conjunction with the change in the timing of the class certification decision, as the Advisory Committee's endorsement of pre-certification discovery may go a long way toward negating the reluctance of some judges to make difficult and potentially dispositive decisions early in the litigation.

4. Revised subdivision (c)(1)(C) clarifies that an order certifying a class may be altered or amended before final judgment (the current rule states "before decision on the merits"), which aligns the class certification decision with other pretrial decisions under Rule 54(b): "In the absence of such determination and direction [of the propriety of immediate entry of judgment], any order or other form of decision, however designated, which adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties ... is subject to revision at any time before the entry of judgment adjudicating all the claims and the rights and liabilities of all the parties." See also Advisory Committee note to Rule 23.

5. Redline version of Advisory Committee comments available at [www.uscourts.gov/rules/congress0303/CVRedline.pdf](http://www.uscourts.gov/rules/congress0303/CVRedline.pdf).

The new 23(c)(1) makes clear that the class certification decision is a time for hard choices, and that a court considering certification should take a long hard look at the proposed class and the way the litigation can be expected to play out.

## DEFINING THE CLASS ISSUES

Finally, the addition of subsection (c)(1)(B), requiring that any order certifying a class action “define the class and the class claims, issues or defenses, and ... appoint class counsel under Rule 23(g),” is a much-needed weapon against the failure of many courts to distinguish between different causes of action and their disparate suitability for certification. Standing alone, this provision would have only a moderate impact, but in combination with the elimination of “conditional” certification and the discretionary review afforded by subsection (f), the new requirement of specificity will compel a district court to be very thorough and certain of its certification decision, or risk reversal.

In particular, the requirement that a court specify whether it intends to certify entire “claims” or only certain “issues” will require a court contemplating certification to confront the issue of what, precisely, it expects a jury to determine in any trial of “common” issues and what will remain. This procedure will enable defendants to highlight any risk that subsequent juries will be forced to reexamine the issues considered and “decided” by the first jury, in violation of the Seventh Amendment.

This change in the Rule is more subtle than the others, and its import will likely not be immediately apparent to district judges who prefer to let the parties “work it out.” We expect to see some appellate decisions reversing class certification orders for lack of specificity shortly after the new Rule goes into effect, and expect those decisions to prompt greater precision and diligence on the part of judges considering class motions.

## BRAVE NEW WORLD

Only time—and the *Federal Reporter*—will tell whether these changes to Rule 23 result in stricter and more careful application of the federal class action procedure. In the meantime, the amendments and accompanying commentary from the Advisory Committee provide defendants with ample support for the argument that these new provisions have added teeth to the Supreme Court’s admonition that “[A]ctual, not presumed, conformance with [the] Rule ... remains indispensable.” *General Tel. Co. of Southwest v. Falcon*, 457 U.S. 147, 160-61 (1982) (citations omitted).

## Multi-District Litigation Plaintiffs’ Long-Term Damage Theory Found Inadmissible under *Daubert*

Susan M. Sharko and Theresa A. Lyons\*

The *Daubert* rule, as embodied in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), and its progeny, and the recently amended Federal Rule of Evidence 702, are among the most significant efforts in the last 20 years by the courts to level the playing field in jury trials where the plaintiff seeks to use the jury as the peer reviewer of a new theory. While at trial the defense naturally tends to focus on whether the product could (general causation) and did (specific causation) cause an injury to a plaintiff, the plaintiffs tend to move the discussion quickly past medical causation and instead focus the jury’s attention on unfortunately worded company documents and e-mails on which the plaintiffs shine a piercing and inflammatory light. Because the basic questions in any personal injury lawsuit remain—was the defendant negligent, did that negligence cause harm to the plaintiff, and if so, what amount will fairly compensate the plaintiff—early and intense *Daubert* review of the plaintiff’s general and specific causation theories is critical.

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A very recent example of this is seen in the multi-district litigation proceedings involving the prescription medication Propulsid®. In that litigation, the plaintiffs through their litigation experts, Dr. William Shell, Dr. Joel Morganroth, and Dr. Dwayne Eckberg, invented a theory that Propulsid® caused long-term or persistent damage after its use was discontinued. The defense challenged the theory under *Daubert*, and the United States District Court for the Eastern District of Louisiana granted defendants' motion in a detailed, yet sweeping opinion, which is likely to have a significant impact on other Propulsid® litigation cases which allege this claim. *In re Propulsid Prods. Liability Litig.*, \_\_\_ F.Supp. 2d \_\_\_, 2003 WL 21108338 (E.D. La. Apr. 29, 2003).

This *Daubert* challenge was successfully litigated by a team of lawyers from three of Drinker's offices. Plaintiffs' theory had been created expressly for the litigation. It was based on a "study" funded by the plaintiffs' lawyers, who even had a hand in selecting participants in the "study," all of whom were claimants or plaintiffs in the litigation. The Drinker team dismantled the plaintiffs' theory and exposed its lack of scientific basis. The team went on to marshal a study group of defense experts to demonstrate why the plaintiffs' theory simply was wrong and unreliable.

The plaintiffs had attempted to introduce a theory that Propulsid® caused long-term or persistent cardiac damage through some undefined impact on the autonomic nervous system which occurred at an unspecified time through an undefined mechanism. *Id.* at \*6-9. They attempted to moor that theory in a study of Propulsid® litigation claimants and plaintiffs which was funded by plaintiffs' counsel, extrapolations from the effects of other substances, and the notion of "biologic plausibility." *Id.* at \*6-11.

The Court noted at the outset that plaintiffs' theory had "developed over the course of the litigation," *id.* at \*5; and was at best an "untested hypothesis." *Id.* at \*11. Judge Eldon Fallon then went on to find that the theory was inadmissible under *Daubert*:

In this case, at best, Drs. Shell and Eckberg have discovered an event, but not a cause. They fail to identify the exact mechanism by which a person's QT interval can become permanently prolonged well after that person has ceased taking Propulsid. Dr. Shell, in his testimony and reports, has admitted as much. Moreover, as demonstrated above, Drs. Shell and Eckberg have been unable to show that such a condition exists with regularity and that it is caused by Propulsid. They have theories, but they have no proof to support those theories. Furthermore, their theories have not been tested or subjected to peer review and publication. They have no known or potential rate of error and there is presently no general acceptance of their methods in the scientific community. Under the prevailing logic of *Daubert* . . . , their testimony is unreliable.

\* \* \*

To properly show causation in this case, the experts must demonstrate that Brock did not suffer from a prolonged QT prior to taking Propulsid. They cannot do so. Furthermore, plaintiff's experts cannot explain why [the plaintiff] has none of the hallmarks of autonomic nervous system damage such as orthostatic hypotension, or light-headedness or fainting which is seen in people who have autonomic nervous system dysfunction. They also cannot rule out other explanations for the measurements that form the predicate of the QTc, the heart rate, or heart rate variability. They cannot even conclude that her QTc is abnormal for her because there are no pre-Propulsid measurements. Thus, their testimony is again unreliable and inadmissible since it fails to fit the facts of the case before this court.

*Id.* at \*13.

Judge Fallon also rejected the "study" performed by the plaintiffs' experts, noting:

[T]he very basis of [t]his study is flawed. He uses nine subjects hand-picked by attorneys involved in this litigation. Several of the subjects have questionable medical histories, making it difficult to determine that Propulsid was the cause of any QTc prolongation. The prolonged QTc interval itself is not evidence of a damaged autonomic nervous system. To succeed, Dr. Shell must establish damage to the autonomic nervous system; he has not done so. His testimony, therefore, is mere theory at this point and is unreliable in a court of law.

*Id.* at \*12.

In rejecting the plaintiffs' comparisons with other substances, the court held that "[s]ound scientific method does not support an extrapolation from one substance to another without some showing of identity or at least close similarity" and that the plaintiffs "fail[ed] to show that Propulsid is so similar in chemical structure to [other] drugs as to produce the same result." *Id.* at \*11.

Regarding biologic plausibility, the court found that the experts had left too great a gap in their theory and made it clear that speculation alone is not enough to pass through *Daubert's* gate: "The expert's mere assertion that he knows that Propulsid[']s . . . effects can be permanent simply cannot be reliable without some explanation of how or why it happens or proof that it has consistently happened." *Id.* at \*12.

The plaintiffs did not appeal the ruling.

## The Proposed Class Action Fairness Act

Gregg R. Melinson\*

Businesses across America will have their eyes trained on Capitol Hill this fall as Congress considers passage

of the Class Action Fairness Act, part of the Republican majority's plan to overhaul the tort system. The House passed its version of the bill (H.R. 1115) on June 12 by a vote of 253-170. The Senate Judiciary Committee reported its version (S. 274) on April 11, and the bill was placed on the Senate Calendar on June 2.

Both bills amend the Federal Judicial Code to prohibit a Federal District Court from approving a proposed class action settlement under which: (1) members would receive non-cash benefits or would be required to expend funds in order to obtain proposed benefits unless the court finds, after a hearing, that the settlement is fair, reasonable, and adequate; (2) any member is obligated to pay sums to class counsel that would result in a net loss to the member unless the court finds that non-monetary benefits to the member outweigh the monetary loss; (3) greater sums would be paid to some class members than to others solely on the basis of their closer geographic proximity to the court; or (4) a greater share would be paid to a class representative than to other class members (with an exception for any court-approved payment for reasonable time or costs for fulfilling representative obligations).

Perhaps more importantly, though, both bills make it much easier to remove class actions to federal court. Specifically, the bills grant Federal District Courts original jurisdiction over class actions where the matter in controversy exceeds \$5 million (exclusive of interest and costs) and any member of the putative class of plaintiffs is: (1) a citizen of a state different from that of any defendant; (2) a foreign state (or a citizen or subject of a foreign state), and any defendant is a citizen of a state; or (3) a citizen of a state, and any defendant is a foreign state or a citizen or subject of a foreign state.

There are, however, significant differences between the two bills. In addition to the provisions above, the House bill also includes a provision allowing immedi-

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ate appeal of certification rulings, as well as a provision which would apply the legislation to any pending case where a class has not yet been certified. The Senate bill does not include such provisions. Further, with regard to “private attorney general” suits, H.R. 1115 allows for the removal to federal court of private attorney general cases brought by a named plaintiff other than a state attorney general. The Senate bill, on the other hand, would not authorize removal, due in large part to the opposition of Sen. Feinstein (D-CA)<sup>6</sup>.

Likewise, the Senate version contains several provisions not found in the House version. Most notably, S. 274 includes language, agreed upon in a deal brokered by Sens. Specter (R-PA) and Feinstein on June 26, that would allow most mass torts involving 100 or more plaintiffs to be removed to federal court (except, for example, where all claims arise from a single, sudden accident—such as a building fire or a factory explosion—that occurred in the state in which the action was filed and that allegedly resulted in injuries in that state or in contiguous states). The House bill would permit all mass torts to be moved to federal court.

Prospects for passage of S. 274 in the Senate remain unclear. On July 1, Sen. Ben Nelson (D-NE) publicly announced his support for the bill. He is the seventh Democrat to do so. With Sen. Richard Shelby (R-AL) undecided, Senate supporters of the legislation are three votes short of the necessary 60 votes to end a potential filibuster on the bill. Floor consideration of the bill will most likely occur sometime in the fall. Assuming the Senate was to consider and pass S. 274, a conference between the House and Senate to hammer out the differences between the two bills would be necessary. For further information or a status update on the Class Action Fairness Act, please contact Gregg Melinson, Chair of Drinker’s Government Affairs Practice.

## The Pennsylvania Battle Continues Regarding Joint and Several Liability

*Michael O’S. Floyd\**

Our last issue discussed the ongoing Pennsylvania battle regarding joint and several liability. During June 2002 then-Governor Mark Schweiker signed legislation substantially limiting applicability of this doctrine. Under the new rule, each of several defendants will generally only be responsible for proportional damages equal to his or her proportion of the total liability. The new law also provides for several exceptions—where a defendant’s liability will be joint and several.

After passage of the legislation, two democratic leaders filed a petition for review in the Pennsylvania Commonwealth Court asserting that the amendment violated Pennsylvania’s Constitution and seeking an injunction. The tort law changes had been successfully added as an amendment to a Senate bill addressing DNA testing of sex offenders. According to the petition for review, the two purposes of this combined bill had no logical connection, and thus the legislation violated Article III, Section 3 of the Pennsylvania Constitution. Other constitutional issues were raised by the challengers. Respondent Secretary of the Commonwealth filed preliminary objections to the petition. Briefing and oral argument were completed in December 2002.

On May 13, 2003, a unanimous Commonwealth Court filed an opinion denying respondent’s preliminary objections to petitioners’ claim that the Act as passed unconstitutionally embraced two unrelated provisions. According to the opinion:

We cannot say that requiring DNA samples from incarcerated felony sex offenders bears a

6. California’s private attorney general statute permits an individual to bring an action against a company for the violation of consumer protection statutes. Because the law was intended to allow people to attack anticonsumer practices that the state’s attorney general had not addressed, the law allows suit to be brought without any demonstration that the plaintiff has actually suffered any harm. Companies, especially banks, believe the California statute has generated numerous frivolous claims amounting to what some consider a corporate “shake down.” Sen. Feinstein, who is vitally important to the passage of S. 274, remains committed to protecting the sanctity of California’s private attorney general law.

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“proper relation” to joint and several liability for acts of negligence. The claim that the two subjects relate to judicial procedure is a reach.... The germane standard is not a high one, but Act 57 does not satisfy it.

Opinion at Page 8.

A majority of the Court, however, did sustain preliminary objections striking a second constitutional challenge. Three judges would have overruled all the preliminary objections.

Following this decision, the Republican Speaker of the House of Representatives and President *pro tempore* of the Pennsylvania Senate were granted permission to intervene in support of the legislation. On June 30, 2003, intervenors filed with the Pennsylvania Supreme Court an application requesting that the Court assume extraordinary jurisdiction of this matter and set a briefing schedule concerning the Article III, Section 3 issue. The intervenors’ application argued in part that where—as in this instance—a codification of law is involved, “the single-subject and title restrictions of Article III, Section 3 do not apply....” Application for Extraordinary Relief at 9. In the meantime, there has been speculation that the petitioning democratic leaders might move for summary judgment in the Commonwealth Court. This battle continues unabated and is likely ultimately to end up before the Pennsylvania Supreme Court.

## Pennsylvania Superior Court (*En Banc*) Lowers the Admissibility Standard for Experts Testifying to Novel Theories and Conclusions

John F. Schultz\*

The Pennsylvania Superior Court has handed down its opinion in *Trach v. Fellin*, 2003 PA Super 53, which may have the effect of dramatically lowering the threshold for admitting “novel science” at trial. By a

7-2 majority, the *Trach* court rejected the “two bases” standard of admissibility for scientific evidence, which provides that scientific evidence is inadmissible whenever “either the methodology the scientist uses *or* the conclusion the scientist reaches is novel.” *Trach*, ¶ 21 (citing *Blum by Blum v. Merrell Dow Pharm., Inc.*, 705 A.2d 1314, 1322 (Pa. Super. 1997) (emphasis in original)). The Superior Court concluded that “*Frye* only applies to determine if the relevant scientific community has generally accepted the principles and methodology the scientist employs, *not* the conclusions the scientist reaches, before the court may allow the expert to testify.” *Id.*, ¶ 26 (emphasis in original). Based upon this relaxed standard of admissibility, the Superior Court admitted the novel conclusions of a medical expert that were not accepted in the scientific community or literature, but were based purely on “extrapolation” from accepted scientific theories.

In *Trach*, the plaintiff sued for injuries he sustained after Thrift Drug accidentally substituted Doxepin, a tricyclic antidepressant, for Amoxil, an antibiotic prescribed by Trach’s dentist. *Id.*, ¶ 3. The pharmacy’s error caused Trach, who followed the dosing instructions for Amoxil, to take a massive overdose of Doxepin. Trach claimed to have suffered unusually intense side effects as a result of ingesting large quantities of Doxepin, including visual problems, hallucinations, heartburn, confusion, and extreme difficulty concentrating. *Trach*, ¶ 5. While most of these problems subsided shortly after he stopped using Doxepin, Trach claimed to continue to experience cognitive difficulties, cluster headaches, and vision problems, and he was eventually diagnosed with open-angle glaucoma.

At trial, Trach presented the testimony of Dr. John J. Shane, a board-certified pathologist and toxicologist, to support his claim that the overdose of Doxepin caused his continuing cognitive and vision problems. *Trach*, ¶ 9. Dr. Shane testified that the symptoms Trach experienced immediately after ingesting Doxepin were consistent with the potential adverse reactions disclosed in the manufacturer’s package insert and in the

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Physicians' Desk Reference or PDR. Dr. Shane also testified that, to a reasonable degree of medical certainty, Trach's continuing problems, including his glaucoma, "[were] the direct result of the overdose of Doxepin." *Id.*, ¶ 11. Yet Dr. Shane did not ground his opinion in any studies, texts, or other materials, or otherwise suggest that his opinion was generally accepted. Instead, as the court noted, "Dr. Shane's opinions on these issues were based on his own reasoning from general toxicological principles." *Id.*, ¶ 29. "There [was] no evidence that any other members of the medical community share[d] his conclusions or concur[red] in his reasoning process." *Id.*

Compounding matters, the doctor testified that a massive overdose of Doxepin could cause certain long-term effects, although, as before, he failed to cite any studies, medical literature, or other data to support his conclusion. Rather, he based his opinion upon the "dose-response" principle and his "extrapolation" that a massive overdose of a drug could result in more intense or more permanent side effects than those known to occur with a therapeutic dose of the drug. *Trach*, ¶¶ 10 and 27.

At trial, the jury awarded Trach \$5 million in damages. Thrift Drug filed post-trial motions and the trial court granted a new trial, but only as to damages, ruling that Dr. Shane's testimony about the long-term effects of Doxepin did not meet the *Frye* standard for admissibility. *Id.*, ¶ 29.

On appeal, the Pennsylvania Superior Court, sitting *en banc*, reversed, finding that the Supreme Court had never adopted the "two bases" analysis and that no support for such a standard existed in the Supreme Court's *Frye* jurisprudence. *Id.*, ¶ 26. The Superior Court reached this decision despite the fact that it had previously followed the "two bases" analysis in *Blum by Blum v. Merrell Dow Pharm., Inc.*, 705 A.2d 1314 (Pa. Super. 1997), a decision affirmed by the Pennsylvania Supreme Court. *See* 564 Pa. 3 (2000). The Court then went on to hold that the scientific community has generally accepted the "Dose-

Response" principle employed by Dr. Shane. *Trach*, ¶ 27, 49.

As for the challenge to Dr. Shane's "extrapolation" theory, the Superior Court, ruling on an issue of first impression in Pennsylvania, held that extrapolation, "although not science," has gained general acceptance in the relevant scientific community under certain limited circumstances. *Trach*, ¶ 33, 49. The Court said that "as long as the basic methodology employed to reach ... a conclusion is sound ... the scientist may extrapolate from this sound scientific basis when it is either impossible or unethical to perform the sorts of clinical trials that would yield definitive results." *Id.*, ¶ 49. The Superior Court proceeded to find that a logical inference exists that a substance known to cause adverse side effects in its recommended dose is likely to cause a heightened level of the same or similar adverse effects when taken in a massive overdose. *Id.*, ¶ 44.

The result of the Superior Court's analysis was the admission of Dr. Shane's testimony concerning the long-term effects of Doxepin even though (1) Dr. Shane had not referred to "studies, texts, and other sources" to indicate general acceptance of his opinions regarding those effects; (2) Dr. Shane's opinions on these issues were based on nothing more than "his own reasoning from general toxicological principles"; and (3) there was no evidence presented "that any other member of the medical community shared [Dr. Shane's] conclusions or concurr[ed] in his reasoning process." *Trach*, ¶ 29.

*Trach* is quite clearly a troubling decision for defendants and, if allowed to stand (*allocatur* has been requested) may become the portal through which much "novel science" enters Pennsylvania courts. However, the good news is that the Pennsylvania Supreme Court may render *Trach* a nullity. The Supreme Court is currently deciding *Grady v. Frito-Lay, Inc.*, 2001 PA Super 382, *allocatur granted*, 569 Pa. 46 (2002), which raises the issue of whether Pennsylvania will abandon the *Frye* standard in favor of *Daubert*. Hopefully, we will have guidance from the Supreme Court on this issue soon.

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