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A legal update from Dechert's Mass Torts and Product Liability Group

Keeping Adverse Event Reports Out of the Courtroom

A federal district court in Florida recently rejected personal injury plaintiffs' attempt to have Adverse Event Reports ("AERs"), which were collected and maintained by a defendant drug manufacturer, admitted as evidence of notice and medical causation. *In re Accutane Prods. Liab.*, 2007 WL 1288354 (M.D. Fla. May 2, 2007). This decision is important for drug manufacturers who elect, or are required, to gather and maintain AERs regarding the drugs they market to the public.

Plaintiffs in *Accutane* were former users of an FDA-approved drug for the treatment of severe acne. They alleged that their use of the drug resulted in inflammatory bowel disease, and in support of this allegation, sought to introduce evidence relating to AERs collected and maintained by the defendant. Plaintiffs attempted to show that this AER evidence was admissible in three different ways.

First, plaintiffs argued that the AERs constituted an admission of a party opponent under Federal Rule of Evidence ("FRE") 801. This claim was based in large part upon the testimony of defendant's Director of Drug Safety who, according to plaintiffs, testified that the AER database contained "fully investigated articulations of these adverse events." *Id.* at *3.

The court disagreed with plaintiffs' characterization, and found that "at no time did [the Director] testify or allude to the company's assessment of [a] 'yes' [database entry] being construed as the company's position that the reported events were actually caused by Accutane." *Id.* The court further found that "many of the 'yes' responses in this case reflect nothing more than an assessment of a *possible* relationship, not an actual relationship[.]" *Id.* (emphasis added).

The court also remarked that the AERs were based solely upon unverified statements by third parties who "may be a physician, patient, family member, or even a plaintiff's lawyer." *Id.* at *1. In fact, one of the AERs in question was actually reported by the lawyer for one of the plaintiffs in the underlying litigation. *Id.* at *3.

Plaintiffs next argued that the AERs could be relied upon and published to the jury through plaintiffs' expert witnesses under FRE 702 and 703. The court, however, rejected this argument and held that the AERs did not meet *Daubert*'s requirement for reliability and proper scientific method:

> The causality assessments in this case do not contain data which is reliable and upon which an expert opinion of causation can be based. The causality assessments reflect a synopsis of complaints from various reporters regarding their subjective beliefs as to the causes of their particular ailments. These reports are not presented in the form of a medical file, but rather are narratives from the reporter describing his or her opinion as to causality. They do not contain information regarding the patient's medical history, family medical history, or use of other medications or drugs.

Id. at *4. The court added that any conclusion derived from a review of the AER data "may serve as a basis for forming an hypothesis, but certainly does not support an opinion on causation." *Id.* Finally, the court noted that, at best, the AERs established a possible association between the drug and alleged injury, but that "an association is not equivalent to causation." *Id*.

Plaintiffs' third and final argument was that the AERs should be admitted under FRE 410 as evidence that could assist the jury in determining notice, i.e., when the defendant knew or should have known and should have warned of the alleged risk. The court, however, found that such evidence would confuse the average juror and that, under FRE 403, the prejudicial effect of such evidence therefore outweighed any probative value:

> [I]t is likely a lay juror would have difficulty distinguishing that the term 'causality assessment' as the term relates to safety surveillance, is not the same as 'causation'. . . . [I]t is highly probable that a juror would perceive the company's 'yes' response in the causality assessment field as an admission by Defendant's physicians that Accutane did in fact cause the adverse events reported.

Id. at *5. *See also Soldo v. Sandoz Pharm. Corp.,* 244 F. Supp. 2d 434, 546 (W.D. Pa. 2003) (holding that admitting AERs would be grossly misleading to a fact finder).

Accutane supports an enlarged safe harbor in personal injury lawsuits for drug manufacturers who perform elective and/or mandatory post-marketing research on new potential benefits and risks of the drugs they manufacture. If the *Accutane* analysis is widely adopted, drug manufacturers can continue to cast a wide net with their research, take adequate time to distill and analyze the results, and do so without fear that this work could later be unfairly used against them in front of a jury.

The court's analysis also demonstrates the importance of internal treatment and description of AERs; the court here found it significant that—unlike the interpretation offered by the plaintiffs counsel—the company never treated AERs as anything more than initial reports, derived from a wide array of reporters taken at their word, and collected in an effort to appropriately comply with federal law and to provide information as to even possible associations between drugs and alleged adverse events.

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