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### Product Liability

## Excluding Adverse Event Reports in Drug and Medical Device Cases



BY JEFF SINDELAR

**P**laintiffs in prescription drug and medical device personal injury cases often seek to introduce evidence of other incidents where the same product allegedly caused a similar injury. The plaintiffs' bar points to this "other incident evidence" because it relieves them of the burden of actually proving their case and invites the jury to speculate that if a product caused injuries to other people, it likely caused injury in the case at bar. This evidence is often presented through adverse event reports (AERs) to the United States Food and Drug Administration (FDA).<sup>1</sup> While causation arguments based on AERs have surface appeal to those not versed in FDA's Adverse Event Reporting System (FAERS), those knowledgeable about adverse event reporting understand that AERs are inherently anecdotal and prone to inaccuracy and untrustworthiness. Because of juror susceptibility to arguments based on AERs, it is important to strategize early in the litigation

<sup>1</sup> Other incident evidence takes many forms, including AERs (such as FDA MedWatch reports), medical case reports, and legal complaints and demand letters. Because plaintiffs in drug and device cases most often focus on AERs presented to FDA, this article focuses on AERs.

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about how you will frame your motion in limine to exclude such evidence. In order to successfully challenge other incident evidence, you must familiarize the court with the issues surrounding adverse event reporting, the inherent weaknesses of information garnered from AERs, and why courts across the country have excluded this evidence.

### I. AERs Are Subject to Multiple Evidentiary Challenges

In order to maximize your chance of success on a motion in limine to exclude AERs, employ a multi-pronged approach that addresses the numerous problems with information gleaned from these reports. As a threshold matter, under Federal Rule of Evidence 402 and analogous state evidence rules, other incident evidence is only relevant (and thus admissible) if the plaintiff can establish that the other incidents are substantially similar to the facts of your case. This is often an insurmountable burden because AERs do not contain enough information to make a useful comparison to the facts in your case.

Even if the court is inclined to admit certain AERs as substantially similar, there are multiple additional arguments for exclusion. First, AERs have been excluded as irrelevant because they are not the type of competent scientific evidence required to prove causation in complex medical cases. Second, AERs are prone to exclusion under Evidence Rule 403 because they have particularly low probative value balanced against their

high potential to create undue prejudice, mislead the jury, and waste time. Third, AERs are often barred as inadmissible hearsay.

## II. AERs Are Not Relevant Evidence of Causation in Drug and Device Cases

**A. The Substantial Similarity Test.** A party seeking to introduce AERs at trial must prove that the events underlying those reports are “substantially similar” to the facts at issue before the court. Both state and federal courts have held that substantial similarity is required to establish relevance under Evidence Rules 401 and 402.<sup>2</sup> See *Dunn v. Nexgrill Indus., Inc.*, 636 F.3d 1049, 1055-57 (8th Cir. 2011) (excluding experimental evidence because conditions not substantially similar to those in case at bar); *Fusco v. Gen. Motors Corp.*, 11 F.3d 259, 263-64 (1st Cir. 1993) (same); *Renfro v. Black*, 52 Ohio St. 3d 27, 31, 556 N.E.2d 150, 154 (1990) (proponent of evidence regarding prior accidents must show circumstances substantially similar); *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-837, 2012 BL 81816, at \*2-3 (S.D.W. Va. Mar. 30, 2012); *Ballweg v. City of Springfield*, 114 Ill. 2d 107, 114, 499 N.E.2d 1373 (1986). Substantial similarity is required “because the probative force of evidence of other accidents decreases as the circumstances and conditions of the other accidents become less similar to the accident under consideration.” *Chlopek v. Federal Insurance Co.*, 499 F.3d 692, 699 (7th Cir. 2007) (internal quotation marks omitted). Generally, establishing substantial similarity requires proving:

- (1) the products are similar;
- (2) the alleged defect is similar;
- (3) causation related to the defect in the other incidents; and
- (4) exclusion of all reasonable secondary explanations for the cause of the other incidents.

*Hershberger*, 2012 BL 81816, at \*2.

In drug and medical device cases, courts routinely find substantial similarity lacking because each patient’s medical history and course of treatment present unique factors. In *Chlopek*, which involved a medical cooling therapy device, the Seventh Circuit upheld exclusion of numerous AERs that did not specify injury type, involved different types of injuries, or involved injuries to different body parts. 499 F.3d at 699. In *Hershberger*, which involved surgical staplers, the court excluded forty-five AERs that involved similar devices, allegations of similar defects, and similar causation attributions by medical professionals because the AERs did not rule out reasonable alternative explanations for injury, such as surgical team error. 2012 BL 81816, at \*2-3. Because alternative explanations were not ad-

ressed, the reported injuries did not clearly result from a defective medical device, and substantial similarity was lacking. *Id.*

In framing your motion in limine, it is important to draw out the facts in your case that are significant to the causation analysis. Because AERs are not intended to provide a definitive causation analysis, they rarely contain enough information to provide a basis for comparison on key causation factors.

**B. AERs Are Not Scientifically Valid Causation Evidence.** In addition to challenging the relevance of AERs on substantial similarity grounds, AERs are not the type of rigorous scientific evidence required to prove causation in cases involving complex medical issues. See generally *In re Trasylol Prods. Liab. Litig.*, MDL No. 1928, 2013 BL 181889, at \*3 (S.D. Fla. July 3, 2013) (“Expert medical opinion evidence is usually required to show the cause of an injury or disease because the medical effect on the human system of the infliction of injuries is generally not within the sphere of the ‘common knowledge of the lay person.’”). Third-party reports of adverse events do not meet this burden.

In order to explain why AERs are inadequate to establish causation—or even serve as evidence thereof—it is important to familiarize the court with FDA’s Adverse Event Reporting System (FAERS). As part of its drug safety monitoring (or “pharmacovigilance”) efforts, FDA collects adverse drug experience information from drug manufacturers, healthcare providers, and consumers. An “adverse drug experience” is “[a]ny adverse event associated with the use of a drug in humans, **whether or not considered drug related.**” 21 CFR § 314.80(a) (emphasis added). Drug manufacturers are required to report adverse drug experience information they receive “from any source,” whereas consumers and healthcare providers may voluntarily report such information.<sup>3</sup> FDA regulations are explicit that submission of an AER does not constitute an admission that either the reporter or FDA has concluded a drug caused an adverse event. 21 CFR § 314.80(k).

Because AERs are anecdotal and often contain incomplete information, FDA acknowledges their limitations. Indeed, there is no guarantee that a reported event actually happened, let alone was caused by a given product. See FAERS Website (full cite at n.3) (“FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event.”). Because of these limitations, FAERS is not used to assess whether a drug actually caused an adverse event; rather FDA uses AERs to identify potential new safety concerns, known as “safety signals.” See *id.* A safety signal merely calls for further evaluation, such as conducting additional studies. FAERS Website (full reference at n.3); see also FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacovigilance Assessment, at 4 (Mar. 2005) (hereinafter “FDA Guidance on GPP”).

Against this backdrop, courts throughout the country have held that AERs are not competent to prove causation. See *Cosgrove v. Merrell Dow Pharms.*, 117 Idaho 470, 475 (holding AERs are anecdotal in nature and

<sup>2</sup> Both state and federal courts applying the substantial similarity test attribute it to the relevance, prejudice, confusion, and waste-of-time considerations embodied in Evidence Rules 401–403. See *Downey v. Bob’s Discount Furniture Holdings, Inc.*, 633 F.3d 1, 8 (1st Cir. 2011); *Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 297 (6th Cir. 2007); *Lorenz v. Pledge*, 2014 IL App (3d) 130137, ¶ 17, as modified on denial of reh’g (June 24, 2014).

<sup>3</sup> 21 CFR § 314.80(b)-(c); FAERS Website, available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm> (last visited Nov. 16, 2015).

cannot form the basis of any conclusions, expert or otherwise). As another court explained, “Adverse event information, whether in the form of MedWatch forms or the underlying data used to create the reports, does not constitute valid scientific proof of medical causation and therefore, has little relevance in a product liability case.” *Freeman v. Hoffman-LaRoche, Inc.*, No. 964469, 2004 WL 5382304 (Neb. Dist. Ct. Mar. 18, 2004) (non-paginated opinion) (citing *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003) (rejecting causality assessments and adverse event reports as valid proof of causation); *Brumbaugh v. Sandoz Pharms. Corp.*, 77 F. Supp. 2d 1153 (D. Mont. 1999); *Haggerty v. UpJohn Co.*, 950 F. Supp. 1160 (S.D. Fla. 1996) *aff’d*, 158 F.3d 588 (11th Cir. 1998)).

It is also useful to highlight the distinction between FDA’s use of AERs in drug safety monitoring and the much higher standard of causation required in a products liability suit. As mentioned above, FDA itself recognizes the inherent limitations of AERs and uses them only to detect safety signals. FDA’s 2005 Guidance for Industry on Pharmacovigilance explains that a safety signal indicates only the need for further investigation, “which may or may not lead to the conclusion that the product caused the event.” FDA Guidance on GPP, at 4; see also *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1247 (11th Cir. 2005) (“Data from spontaneous reports usually provide only preliminary evidence of risk and not proof of risk.” (quoting G. Alexander Fleming, *The FDA, Regulation, and the Risk of Stroke*, 343 NEW ENG. J. MED. 1886–87 (2000))); *id.* at 1254 (“case reports raise questions; they do not answer them”); *Pauley v. Bayer Corp.*, 2729 March Term 2002, 2006 WL 463866, at \*2 n.1 (Pa. Ct. Com. Pl. Jan. 26, 2006) (“[R]eceipt of a number of similar [AERs] may raise a red flag to a drug-maker to go back and re-examine clinical data, but the reports are not a substitute for the data itself.”). FDA also recognizes that “voluntary adverse event reporting systems . . . are subject to a variety of reporting biases,” such as those caused by concomitant treatment, underlying disease, co-morbidities, unrecorded confounders, incomplete or duplicate reports, or reporting stimulated by publicity or litigation. FDA Guidance on GPP, at 9. And because FDA encourages doctors to report even **suspected** drug reactions, there is no certainty the drug caused the reported reaction. *Pauley*, 2006 WL 463866, at \*2 (citing FDA Adverse Event Reporting System—Brief Description (10/18/99) (“The event may have been related to the underlying disease for which the drug was given, to concurrent drugs being taken, or may have occurred by chance at the same time the suspected drug was taken.”)); see also FAERS Website (full cite at n.3) (acknowledging “there is no certainty that the reported event . . . was actually due to the product,” as no “causal relationship between a product and event [need] be proven.”). AERs lack medical controls or scientific assessment, do not prove causation, and are “one of the least reliable sources to justify opinions about both general and individual causation.” *McClain*, 401 F.3d at 1250. The bottom line is that admitting AERs at trial allows a plaintiff to prove causation through a “federal agency risk analysis approach, rather than a courtroom causation analysis.” *Id.* at 1250.

### III. Excluding AERs Under Evidence Rule 403

In addition to relevance challenges, AER evidence is subject to challenge under Evidence Rule 403.<sup>4</sup> AERs have inherently low probative value and a high potential to confuse the issues, mislead the jury, waste time, and create undue prejudice. For example, *Hershberger v. Ethicon Endo-Surgery*, barred AERs even for the purpose of establishing notice<sup>5</sup> because the defendant’s knowledge of other reported incidents was of minor probative value and there was “significant danger” the jury would consider AERs to be direct evidence of negligence. No. 2:10-cv-837, 2012 BL 81816, at \*4 (S.D.W. Va. Mar. 30, 2012); see also *In re Norplant Contraceptive Prods. Liab. Litig.*, MDL No. 1038, 1997 WL 80527, at \*1 (E.D. Tex. Feb. 19, 1997) (AERs are only marginally probative because submission is required regardless of proven causal connection between drug and injury and introduction of AERs may confuse the jury and waste time).

Similarly, *Goldstein v. Centocor* excluded FDA MedWatch reports under Rule 403 because AERs contain “uncontrolled anecdotal information” and are not a reliable source on which to base general or specific causation opinions. No. 05-21515, 2007 BL 217022, at \*3 (S.D. Fla. May 14, 2007) (citing cases). Their probative value is “questionable, at best,” even if considered with other causation evidence. *Id.* Further, the very limited relevance of AERs is outweighed by the risk of prejudice resulting from jurors speculating that AERs show causation in the underlying incidents and “then applying that speculation to the cause of Plaintiff’s” injuries. *Id.*

Additionally, a plaintiff’s attempt to introduce AERs at trial wastes time by necessitating mini-trials on the collateral issue of substantial similarity. See *Bachman v. Gen. Motors Corp.*, 332 Ill. App. 3d 760, 787; 776 N.E.2d 262 (Ill. 4th Dist. 2002) (not abuse of discretion to exclude similar occurrence testimony that would result in a trial within a trial); *Ficken v. Alton & S. Ry.*, 291 Ill. App. 3d 635, 647–48, 685 N.E.2d 1 (5th Dist. 1996) (not error to exclude evidence that would confuse issues and require trial of collateral issue).

Presenting FDA MedWatch forms to the jury also creates a substantial risk that the jury will give undue weight to the official-looking government agency documents, not appreciating that the forms contain unsubstantiated allegations from private parties. See *Johnson v. Ford Motor Co.*, 988 F.2d 573, 580 (5th Cir. 1993) (excluding National Highway Transportation Safety Administration letters because “the ‘official’ nature of the inquiries could have misled the jury”).

Given the high risk of prejudice, confusion, and waste of time, courts have excluded other incident evidence even after finding the evidence had some probative value. See, e.g., *Buford v. Howe*, 10 F.3d 1184,

<sup>4</sup> Federal Rule of Evidence 403 provides: “The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”

<sup>5</sup> One of the few permissible uses for AERs at trial is for a plaintiff to establish a defendant drug manufacturer was aware of a potential safety issue.

1188–89 (5th Cir. 1994) (upholding exclusion of evidence of other surgeries as irrelevant and prejudicial); *Figueroa v. Boston Scientific Corp.*, 2003 WL 21488012, at \*4 (S.D.N.Y. June 27, 2003) (granting defendant’s motion to preclude evidence of other lawsuits because “probative value of the fact that approximately 720 plaintiffs have brought suit is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and considerations of undue delay and waste of time”); *Norplant*, 1997 WL 80527, at \*1 (introduction of AERs may confuse jury, which must also consider patients’ medical histories, and waste time because defendants would require opportunity to rebut the significance of AERs).

#### **IV. Other Incident Evidence Is Inadmissible Hearsay**

An additional reason to exclude AERs is that they are classic hearsay—out of court statements offered to prove the truth of the matter asserted. Moreover, AERs often contain multiple layers of hearsay. For example, a consumer may report an adverse experience to a family member, doctor, or lawyer, who in turn may report to the drug manufacturer, who would then be required to report to FDA.

Several of the cases discussed above cite the hearsay rule as an additional reason to bar AER evidence. In

*Goldstein*, the court excluded AERs because they “are inadmissible hearsay, and even if admissible, should be excluded from consideration by the Court and the jury under Fed. R. Evid. 403.” 2007 WL 7428597, at \*1. *Goldstein* also refused to admit AERs under the hearsay rule exceptions for business records and admissions against interest. *Id.* at \*1–3. And the Idaho Supreme Court has held that AERs are unreliable hearsay that cannot be used to prove the truth of their contents. *Cosgrove v. Merrell Dow Pharms.*, 117 Idaho 470, 475–76, 788 P.2d 129 (1989).

#### **V. Conclusion**

The biggest challenge in framing a motion to exclude AERs is often familiarizing the court with the nature and purpose of AERs. By framing the issues before the court in a well-thought-out brief, you increase the likelihood that your judge will approach your challenge with a full understanding of the issues. Even if the court is disinclined to grant your motion outright, a well-crafted brief can set the stage for later rulings barring or severely curtailing the use of AERs. As you chip away at plaintiffs’ ability to present AERs to the jury, you force them to prove their case based on the actual facts and increase the odds of a favorable outcome for your client.