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PRACTICE TIP

FDA Issues Draft Guidance for REMS

Part Two of a Two-Part Article

By Alan Minsk

The first part of this article discussed the background of REMS (Risk Evaluation and Mitigation Strategies) and provided a summary of the Draft Guidance, including the content and format of a proposed REMS submission. The conclusion of the article herein explains the second part of the procedure, including proposed modifications and communicating with the FDA.

Part Two: REMS Supporting Documentation

The REMS supporting documents should include a detailed explanation of the rationale for the proposed REMS, including how and when each REMS element will be implemented and the basis for the timeline, in addition to all supporting information for the REMS. The REMS Guidance notes that a template for the REMS supporting document is available on the FDA's Web site at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm. The FDA notes the documents should include the following sections listed as well as a table of contents:

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When Attorneys Ghostwrite Experts' Reports

By Michael Hoenig

How much attorney involvement in the drafting of experts' reports is permissible? Must the entire work product be that of the expert? Or, at the other extreme, would it be acceptable for an attorney to draft the entire expert's report with the expert "adopting" it? And, if at least some lawyer input is tolerable, then what is the boundary line between permission and perdition?

These questions are perhaps better targeted at practice in federal courts where Federal Rule of Civil Procedure 26(a)(2)(B) calls for disclosure of experts retained or specially employed to provide expert testimony and which "must be accompanied by a written report prepared and signed by the witness." The words "prepared and signed by the witness" arguably could signal that an expert's report which was primarily ghost-written by a litigant's attorney is taboo. Were the report to be so tainted, the disclosure required by Rule 26(a)(2) might fail and the expert could be barred. Or so the argument could go.

State Courts

In New York state courts, for example, expert disclosure proceeds differently so that the questions posed at the outset arguably may not raise front-burner issues. CPLR § 3101(d)(1) requires "each party" to identify each expert expected to be called as a witness and "shall disclose in reasonable detail the subject matter on which each expert is expected to testify, the substance of the facts and opinions on which each expert is expected to testify, the qualifications … and a summary of the grounds for each expert's opinion." Unlike the expert's report in federal practice, which calls for the expert's preparation and signature, the CPLR calls for a mere statement by the party. Thus, many attorneys forego sending opposing counsel a formal letter or report signed by the expert. Since what is disclosed is a statement by the party, it seems normal for the attorney to have significant input in the draftsmanship.

Despite the absence of expert-signature formalities in state disclosure practice, the question of attorney ghostwriting of experts' opinions is not totally eliminated,

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however. Explicit in the obligation to disclose experts' opinions is the need for the opinion actually to be that of the expert. For example, CPLR 3101(d)(1)(i) refers to producing a summary of the grounds "for each expert's opinion." The quoted language clearly contemplates that it be the expert's opinion.

Further, even without such explicit reference to the expert's opinion, one would implicitly expect from the context of the provision that it must be the expert's opinion, not the lawyer's, that is to be disclosed.

'Adopted' Opinions

If the opinions actually were ghost-written by the lawyer, arguably, they might not truly be the expert's opinion. If an opinion is articulated by the lawyer and "adopted" by the expert as his or her own, some sticky questions might ensue, depending on the circumstances. For example, under state practice, an expert may rely upon professionally reliable hearsay in forming his or her opinion. But an attorney-drafted opinion or conclusion regarding a scientific matter in which the attorney has no expertise would hardly amount to professionally reliable hearsay. Thus, technically, were an expert to rely on the attorney's formulation for expressing an opinion, that methodology may be inadequate. The expert's mere "adoption" of the attorney's opinion as his or her own without some independent exercise of professional judgment or expertise or some personal professionally based intellectual grappling with the problem, would simply camouflage the lawyer as the "expert" and render the expert as a mere "conduit" for the lawyer's wishful conclusions. New York decisions have held that an expert's opinion that amounts only to "conduit hearsay" is highly problematic.

Nevertheless, it is possible that some experts will simply adopt the lawyer's draftsmanship of an opinion and its underlying reasoning. The litigation field is, in many respects, an industry in which experts must perform well and satisfy retaining attorneys. To do this, an expert must deliver reports and conclusions that keep the case alive, hold up well during depositions, and testify effectively at trial. As in any service profession, the expert aims to please his or her client and seeks repeat business and enthusiastic referrals.

'*Supervening Domination*'

This motivational chemistry could yield rather hasty approvals of lawyer-crafted opinions by some experts. One federal court, speaking about lawyer-inserted changes to an expert's draft report, emphasized that lawyers do not "have license to change the opinions and reports of expert witnesses. Any changes in the preparation of a report must be what the expert himself has freely authorized and adopted as his own and not merely for appeasement or because of intimidation or some undue influence by the party or counsel who retained him." *Marek v. Moore*, 171 F.R.D. 298, 302 (D. Kan. 1997) (finding nothing to suggest "supervening domination" by the attorney over expert). Thus, the potential for the lawyer's "supervening domination" exists.

Still, these ruminations may seem theoretical to some since few experts are likely to admit that all they did was "adopt" and parrot the attorney's opinion. Minimally, an expert incorporating a lawyer's formulation of an opinion will likely assert that the conclusion was his or her own after due consideration of the facts, grounds and bases. So, the mechanism of CPLR 3101(d) disclosure may not pose the same tensions that attorney ghost-writing does under Federal Civil Procedure Rule 26(a)(2).

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Michael Hoenig, a member of this newsletter's Board of Editors, is a member of Herzfeld & Rubin. This article originally appeared in the *New York Law Journal*, an ALM affiliate of this newsletter.

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'Failure to Warn' Claims Against Generic Manufacturers Not Preempted By Federal Law

By David M. Gossett, Henninger S. Bullock and Daniel L. Ring

The U.S. Court of Appeals for the Eighth Circuit recently held that "failure to warn" claims brought against generic manufacturers of Reglan® (a prescription drug used to treat certain gastric disorders) were not preempted by federal law and could, therefore, proceed to discovery. The Eighth Circuit's decision in *Mensing v. Wyeth, Inc.* (http://druganddevicelaw.net/Opinions%20in%20blog/Mensing.pdf) rejected the generic manufacturers' argument that the Food, Drug and Cosmetic Act (FDCA) impliedly preempted state law tort claims relating to the labeling of the drug.

Background

After four years of ingesting generic metoclopramide, the plaintiff in *Mensing* allegedly developed a neurological condition known as tardive dyskinesia. The plaintiff's suit asserted various tort claims against both the manufacturers of the generic metoclopramide she had ingested, and the manufacturers of brand-name Reglan. At their core, all of the plaintiff's claims were premised on a failure-to-warn theory. The plaintiff contended that patients who took metoclopramide were at greater risk of developing tardive dyskinesia than was indicated by the language on the drug's labeling.

The district court granted the generic manufacturers' motion to dismiss. (In the same ruling, the district court also granted the brand name manufacturers' motions for summary judgment, a decision later affirmed by the Eighth Circuit. For more information about that aspect of the case, see Mayer Brown's Client Alert, "Eighth Circuit Rejects Innovator Liability Theory in *Mensing v. Wyeth, Inc.*" (http://www.mayerbrown.com/productliability/article.asp?id=8194&nid=12487)) The generic manufacturers argued that the plaintiff's failure-to-warn claims conflicted with, and, therefore, were impliedly preempted by, federal law because the claims would require generic manufacturers to deviate from the drug label prescribed for name brand Reglan. The district court agreed, and the plaintiff's appeal to the Eighth Circuit followed.

The Ruling

The Eighth Circuit reversed the judgment and held that the plaintiff's claims were not preempted. The court concluded that generic metoclopramide manufacturers could, in fact, simultaneously comply with both federal and state law and, moreover, that enforcement of state tort law in this context would not present an obstacle to the purposes of federal law.

Following the Supreme Court's lead in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), the Eighth Circuit began its implied preemption analysis by applying "a presumption against preemption." In the Eighth Circuit's view, *Levine's* holding that failure-to-warn claims against name brand manufacturers were not preempted by the FDCA "carrie[d] significant implications" for the generic manufacturers' preemption arguments because *Levine* clarified that the responsibility for ensuring the adequacy of drug warnings typically rested with manufacturers in the first instance.

According to the court, it was possible for the generic manufacturers to comply with their state law tort duties and with the FDCA's labeling requirements. The generic manufacturers argued that they were prohibited by federal law from modifying their labels to include the additional warnings that the plaintiff asserted should have been added because the FDCA required labels for generic drugs to be substantively identical to the label for the corresponding brand name equivalent. The Eighth Circuit rejected this argument, stating that the generic manufacturers could at least have "proposed a label change" to the brand-name drug label that the FDA could then have imposed uniformly on all manufacturers of metoclopramide, brand name and generic. True, it was not clear what the FDA would have done if such a change had been proposed. But under *Wyeth*, the Eighth Circuit held, uncertainty about the FDA's response weighed against a finding of preemption. Because the generic manufacturers did not present "clear evidence" that the FDA would have not acted, preemption was inappropriate.

The court also rejected the generic manufacturers' alternative argument that failure-to-warn claims would obstruct the objectives and purposes of federal law. The generic manufacturers asserted that they could not have proposed any label change without first conducting expensive clinical studies — thereby thwarting the goal of the Hatch-Waxman Amendments to bring generic drugs to market quickly — because all requests for a label change had to be scientifically substantiated. The Eighth Circuit was not persuaded. The court reasoned that generic manufacturers were already required by federal law to collect and report adverse drug experiences. By presenting this information to the FDA, the generic manufacturers could in principle have substantiated a request to change the label without the need to conduct expensive studies.

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'Failure to Warn'

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In sum, the Eighth Circuit concluded that the plaintiff's state law claims were not impliedly preempted. Federal law did not prevent generic manufacturers of metoclopramide from taking further steps to warn (or at least to seek permission to warn) customers of the risks of developing tardive dyskinesia.

CONCLUSION

Mensing is the first appellate decision addressing preemption for generic drug manufacturers since the Supreme Court's decision in the *Levine* case. Other courts will be addressing the issue soon, however. Furthermore,there are a number of pending appellate cases addressing the circumstances in which a name brand drug manufacturer may succeed on a preemption defense after *Levine*.

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Nevertheless, the questions posed above arguably might apply frontally to ghost-written expert affidavits offered in support of or opposition to motions for summary judgment. State practice regarding such expert submissions would seem to be implicated, since the expert would be signing the affidavit with the force and formality of an oath and representing that the statements and conclusions are his or her own. Would an entirely ghost-written affidavit offering opinions formulated by the attorney truly pass muster? There may be some room for inquiry as the ensuing discussion suggests.

FEDERAL CASE LAW

Case law on the federal side of the issue is not plentiful, but it has evolved into a respectable body of precedent that offers some guidelines. Spearheading our discussion here is *Hoskins v. Gunn Trucking*, 2009 U.S. Dist. LEXIS 83630 (N.D. Ind. Sept. 14, 2009). The case involved a plaintiff's claim for personal injuries in an automobile accident.

One of the issues was causation and permanency of the injuries alleged, since the plaintiff also had been injured in two prior accidents. The plaintiff's medical expert was Dr. K, but the physician had no prior experience in testifying as an expert. In preparing an amended Rule 26 disclosure, the plaintiff's counsel drafted a report, provided it to Dr. K, and wrote: "Thank you for agreeing to provide a revised report … . In hopes of saving you time, we drafted the attached report for you to consider for formatting purposes. Please make as many changes, corrections or additions to the report that you see appropriate for accuracy and completeness … Let me know once you've completed your report … ."

Lawyer's Input

The plaintiff's counsel admitted to drafting the report, but explained that the opinions originated with Dr. K during an in-person conference before any work on the report began. Even though the lawyer did "pen" the report, he asserted that it reflected Dr. K's analysis and that Dr. K thereafter "reviewed, corrected and added" to the report before signing it. A line-by-line comparison revealed that the report drafted by counsel was substantially similar to Dr. K's signed report.

A number of the differences were merely stylistic and grammatical — inserting commas and replacing common language with medical terminology — but did not alter the substance of the report. However, the final report did include a substantive addition regarding a surgery the plaintiff underwent at an earlier time and her recovery, a medical situation at issue in the lawsuit. The substance of Dr. K's opinions and conclusions, as well as their underlying basis and reasons "remain essentially the same in the final version of the report as in the first."

The district court framed the issue: Did Dr. K's expert report, drafted by counsel, comply with the disclosure requirements of Federal Rule 26? Since the written report must be "prepared and signed by the witness," the defendant contended that Dr. K's report was noncompliant having, in effect, been ghost-written by plaintiff's counsel. The plaintiff countered that the report reflected Dr. K's opinions and analysis. The plaintiff also asserted that any error was harmless because the plaintiff did not object to defendant's deposing Dr. K, even though discovery was closed.

Reviewing precedents, the court noted some guidelines. Compliance of the report with Rule 26 "is not based on who actually penned an expert report but, rather, whose opinions and analysis the report contains." While attorney involvement in the preparation of an expert report is permissible, the expert "must substantially participate in the preparation of the report." Citing *Manning v. Crockett*, 1999 U.S. Dist. LEXIS 7966, 1999 WL 342715 (N.D. Ill., May 18, 1999), the court further observed that "preparing the expert's opinion from whole cloth and then asking the expert to sign it if he or she wishes to adopt it, conflicts with Rule 26(a)(2)(B)'s requirement that the expert prepare the report."

"Preparation" implies involvement other than "perusing a report drafted by someone else and signing one's name at the bottom to signify agreement." In other words, the assistance of counsel contemplated by Rule 26(a)(2)(B) "is not synonymous with ghost-writing." Thus, in *Bekaert Corp. v. City of Dyersburg*, 256 F.R.D. 573, 579 (W.D. Tenn. 2009), the expert's testimony was excluded where the report was wholly prepared by counsel, the expert could not actually identify any portion of the testimony that was his, and the expert's participation amounted to signing the document after reviewing it.

In *In re Jackson Nat'l Life Ins. Co. Premium Litigation*, 2000 U.S. Dist. LEXIS 1318, 2000 WL 33654070 (W.D. Mich. Feb. 8, 2000), the court found Rule 26 was violated where

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substantial similarities were found in reports provided by different experts in unrelated cases, yet drafted by the same counsel, and it was clear that the language of the report and formulation of the opinions was provided to the experts by counsel. In the *Hoskins* case, however, Dr. K had never before testified or been deposed. She needed assistance to meet Rule 26's requirements and plaintiff's counsel "was entitled to, if not obligated to, provide that assistance."

Dr. K seems to have reviewed the attorney's draft report carefully, for, as mentioned above, she made grammatical corrections, as well as some substantive changes. The final report was not "identical" to counsel's work. Citing a 2008 decision by the U.S. Court of Appeals for the Sixth Circuit in *United States v. Kalymon*, 541 F.3d 624, 637-38 (6th Cir. 2008), the district court observed that "a party's attorney can reduce an expert's oral opinion to writing so long as the report reflects the actual views of the expert." Thus, Dr. K's in-person conference with plaintiff's counsel, in which she shared her opinions to be reflected in the report written by the attorney, combined with her review and revision of the report, complied with the type of "preparation" required in Rule 26(a)(2)(B).

Deposition Ordered

The court next regarded the question whether, even if the report were noncompliant, the failure was harmless: 1) Here there was no prejudice or surprise to defendant. The identity of Dr. K was timely disclosed, and the report was substantively adequate, except for counsel's drafting. The report fulfilled its purpose of informing defendant of the substance of Dr. K's expected testimony and the reasons for it. There was no evidence of bad faith on the part of the attorney, especially in light of Dr. K's inexperience as an expert testifier; 2) The trial, yet to be scheduled, would not be disrupted; and 3) Further, the party had the ability to "cure the prejudice" and thus offered Dr. K for deposition. The court accepted this alternative suggesting that it would "ensure the goal of Rule 26 is achieved … ." Accordingly, defendant would be allowed to depose Dr. K "regarding the report's contents and creation."

The notion that merely allowing the expert to be deposed can cure violations of Rule 26 disclosure is not without potential criticism. Thus, in *Ciomber v. Coop. Plus Inc.*, 527 F.3d 635, 642 (7th Cir. 2008), the Seventh U.S. Circuit Court of Appeals observed that the purpose of Rule 26 would be completely undermined if parties were allowed to cure deficient reports with later deposition testimony. There, however, the plaintiff had only identified the expert but failed to provide a complete and detailed report of the expert's opinions, conclusions and the basis and reasons for them. In Hoskins, however, the ordered deposition of Dr. K was not meant to avoid ambush at trial. Rather, deposing Dr. K would allow defendant to "fully explore whether or not [Dr. K] held the opinions set forth in her disclosures." Quoting from a federal decision, the district court noted that "[e]xperts participate in a case because, ultimately, the trier of fact will be assisted by their opinions … . They do not participate as the alter ego of the attorney who will be trying the case … "

In ordering Dr. K's deposition, the district court observed: "Should it later prove at deposition that the collaborative process described herein did not result in the report's containing the opinions of [Dr. K], but that of plaintiff's counsel, then Defendants shall be entitled to refile their Motion to Bar." The court concluded that the "spirit of Rule 26" was not violated; that, to the extent counsel's drafting of the report failed to comport with the expert reporting requirements, the failure was "harmless"; and, thus, sanctions would not be imposed. But, the denial of the defendant's motion to bar Dr. K's testimony was declared to be "without prejudice."

A Related Issue

An interesting related issue may be presented from the language of Rule 26(a)(2)(B). The rule describes what the expert's report "shall contain." One item requiring a "complete statement" is "the data or other information considered by the witness in forming the opinions." One might well ask: When the attorney ghostwrites a draft report or crafts substantial portions of the expert's report, which the expert can later add to, modify or correct, is not the attorney's draft itself "data or other information considered by the witness in forming the opinions"? And, if so, must the attorney's draft or the attorney-created portions of it be disclosed in accordance with Rule 26? The ramifications could be considerable.

Conclusion

Clearly, mere assistance by counsel to the expert in drafting the disclosure report is permissible. Indeed, the Advisory Committee Notes to Rule 26 (1993 amendments) state: "Rule 26(a)(2)(B) does not preclude counsel from providing assistance to experts in preparing the reports … ." This is especially true when inexperienced experts are involved. They need guidance on how to meet the requirements of the disclosure rule and the rudiments of a reliable expert opinion and report. But, as the Sixth Circuit said in *Kalymon*, 541 F.3d at 638, a party's attorney "can reduce an expert's oral opinion to writing so long as the report reflects the actual views of the expert." Mere agreement of the expert with a report drafted by someone else and signing one's name at the bottom is not the "preparation" contemplated in Rule 26. As stated by the district court in Manning, 1999 U.S. Dist. LEXIS 7966 at 8-9 (N.D. Ill., May 18, 1999), the assistance of counsel "is not synonymous with ghost-writing."

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Background

This section should provide a concise summary explaining the necessity of the proposed REMS and how the plan will verify that the benefits of the product outweigh the risks. In addition, the FDA provides that:

- An initial REMS for a previously approved product should describe the new safety information suggesting the need for the REMS;
- Detailed information about the risk to be minimized should be provided, and the following factors, which the FDA must consider in determining whether a REMS is necessary, should be addressed: the estimated size of the patient population; the seriousness of the disease or condition treated; the expected benefit of the product to the disease or condition; the duration of treatment; the risks and benefits of alternative therapies; and whether the drug is a new molecular entity; and
- Discussion of historical information about any successes and failures related to mitigating the risks for the specified product or similar products may be provided, as well as any information on relevant past experiences that would help in the development of the proposed REMS.

Goals

A summary of the rationale for the proposed goals of the REMS, describing how the elements will individually and collectively contribute, should be provided.

Supporting Information About Proposed REMS Elements

Describe why each element or tool was chosen for the proposed REMS and indicate how each tool contributes to the goals of the REMS. The FDA notes:

> Each method used to monitor and evaluate the implementation system should be discussed along with any plans to improve implementation.
>
> The rationale and supporting information for the proposed timetable should be provided, addressing each interval that each assessment will cover as well as the planned date for submission to the FDA.
>
> The applicant should give a thorough description of the available evidence, indicate whether any input was obtained from patient or health care interests, and discuss any feedback that was received regarding the feasibility of the proposed REMS.

Supporting Information with Elements to Assure Safe Use (ETASUs)

Proposed REMS that include ETASUs should include: 1) An explanation of how the ETASUs correspond to the specific serious risks listed in the labeling; 2) An explanation of how the ETASUs mitigate the observed serious risk; 3) Verification that the elements proposed are not unduly burdensome on patient access for patients with serious or life-threatening diseases or difficulty with access to health care; and 4) A description of how the ETASUs will minimize the burden on the health care delivery system, including discussion of any other drugs that pose similar risks to provide further information about the compatibility of proposed ETASUs with established health care delivery systems.

REMS Assessment Plan

REMS Assessments measure whether the goals are being met, and the proposed plan to assess the REMS should be fully explained in this section. Information should include the proposed evaluation methods, targeted values and time frames for each measure, the type of data collected and timing for data collection, and any applicable plans to assess unintended or unfavorable consequences. Plans to obtain information on the effectiveness of REMS elements to meet the stated goals or the need to modify the goals or the REMS elements should be included. The FDA requires that specific assessment instruments and methodology should be identified, and such information, once it is available, should be submitted to the FDA to update the REMS supporting documents at least 90 days before the assessments are conducted. In general, each assessment should contain sufficient detail to identify any need for changes to the REMS. In addition:

- For REMS that include an ETASU, the assessment must consider the extent to which the ETASUs are meeting the goal.
- For REMS with a MedGuide, the assessment should include a survey of the patients' understanding of the risks of the product, a report on periodic assessments of the distribution of the MedGuide, and a report on any failures as well as corrective actions to address non-compliance.

Required Postapproval Studies Or Clinical Trials

The status of any post-approval study required or otherwise undertaken to investigate a safety issue must be included in the assessment. Specifically, the assessment must include the status of each clinical trial, the number of participants enrolled, the expected completion date, any difficulties encountered with completing the trial, and the clinical

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CASE NOTES

Philadelphia Jury Awards $9.45 Million in Damages Over Prempro Drug

Another Philadelphia jury has decided that drugmaker Wyeth should be punished with punitive damages for the warnings provided to a plaintiff and her doctor over the risk of breast cancer from Wyeth's hormonal drug Prempro.

The jury awarded $6 million in punitive damages and $3.45 million in compensatory damages on Feb. 22 in *Singleton v. Wyeth*. According to plaintiffs' counsel Zoe Littlepage of Littlepage Booth in Houston, this case is the first in the country involving a plaintiff diagnosed with breast cancer well after the July 2002 release of the Women's Health Initiative (WHI), a randomized, controlled trial of the risks and benefits of hormone replacement. The WHI received national notoriety because the study was discontinued early due to its finding that HRT correlated to an increased risk of invasive breast cancer and other health problems.

Littlepage said the jury's verdict was significant because plaintiff Audrey Singleton was prescribed Prempro during a period in which the label had changed following the WHI, and the jury verdict showed the jury found that Wyeth failed to react appropriately to the WHI.

The verdict in *Singleton* has continued the run of jury verdicts in favor of plaintiffs in Philadelphia hormone replacement therapy cases. There are 1,500 HRT mass tort cases pending in Philadelphia Common Pleas Court. Last fall, a jury awarded $75 million in punitive damages and $3.7 million in compensatory damages to the plaintiffs in *Barton v. Wyeth*. The total *Barton* award now stands at $10.6 million after a judicial remittitur. Also last fall, a jury awarded $28 million in punitive damages and $6 million in compensatory damages against Wyeth and Pharmacia & Upjohn in *Kendall v. Wyeth*.

Three other Philadelphia verdicts in favor of plaintiffs in the HRT litigation were overturned by trial judges and now are on appeal. In a statement, Wyeth expressed disappointment in the verdict. Wyeth also said in its statement that it has won in 24 of 29 HRT cases set for trial through a combination of rulings by judges, verdicts by juries and dismissals by plaintiffs to avoid going to trial.

— **Amaris Elliott-Engel**, *The Legal Intelligencer*

Trial Court Abused Its Discretion

A trial court abused its discretion by prohibiting a manufacturer from introducing evidence of a car seat's compliance with the safety standards. *Malcolm v. Evenflo Co.*, 352 Mont. 325; 217 P.3d 514 (Mont. 2009). --

The parents sued the manufacturer of a baby's car seat after their four-month-old son suffered fatal brain injuries in a rollover car accident. A jury awarded the parents $6.697 million in compensatory damages. The jury awarded them $3.7 million in punitive damages. On appeal, the court held that the trial court did not abuse its discretion when it excluded the manufacturer's evidence that the car seat complied with safety standards for the purpose of compensatory damages. The safety standards addressed only minimum levels of performance in frontal impacts. The dynamic forces unleashed in a high-speed rollover collision were very different from those present in a frontal crash. The trial court did not abuse its discretion under Mont. Code Ann. § 27-1-719(2) by admitting evidence regarding the recall and test failures of an earlier car seat model. The trial court did, however, abuse its discretion when it did not allow the manufacturer to introduce evidence of the car seat's compliance with the safety standards for the purpose of considering the appropriateness of punitive damages under Mont. Code Ann. § 27-1-221(2). The court affirmed the award of compensatory damages, but reversed the punitive damage award and remanded the case for a new hearing on the issue of punitive damages.

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MOVERS & SHAKERS

Wildman, Harrold, Allen & Dixon LLP announced that partner **Sarah "Sally" L. Olson**, a member of this newsletter's Board of Editors, has been elected to the board of the Product Liability Advisory Counsel (PLAC). Her three-year term began Jan. 1, 2010. The PLAC seeks to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. It has more than 100 corporate members representing a broad cross-section of American and international product manufacturers.

Sedgwick Detert Moran & Arnold LLP recently added **Gregg Dulik** and **Tanya Lawson** to the firm's partnership. They are based in the firm's San Francisco and Fort Lauderdale, FL, offices respectively and represent the firm's Construction, Product Liability and Insurance Practice Groups.

Baker & Daniels LLP has announced the addition of **Abigail M. Butler**, resident in the firm's Fort Wayne, IN, office, to partnership. Ms. Butler concentrates her practice in product liability.

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trial's registration information. A reference to the relevant information in the applicant's most recent annual report, with any updates since the report was prepared, may suffice to satisfy the requirement for information on the status of the post-approval study or clinical trial.

Other Relevant Information

This section should include information on positions within the applicant's company responsible for REMS policy, management, and implementation, with organizational charts, and any other information that is relevant to the proposed REMS.

REMS Assessment and Proposed Modifications Of REMS

As noted above, REMS assessments must be submitted in accordance with the timetable included in the proposed REMS. Applicants may voluntarily submit assessments, and the FDA may also require additional REMS assessments. For example, the FDA may require an assessment when a supplemental application is submitted for a new indication for use or where the Agency determines that new safety or effectiveness information suggests that the assessment timetable requires modification or that a cause for withdrawal or suspension of the approved REMS exists.

After approval of the REMS, applicants may request proposed modifications to enhance or reduce the REMS requirements, including potential changes to any materials included as part of the REMS. Applicants may also ask for changes to the assessment timetable, including the elimination of any assessments after the three-year submission.

Proposed modifications should be submitted to the FDA using a new prior-approval supplemental application and may not be implemented until the FDA gives approval. Each proposed modification should include the new proposed REMS with the previous approved REMS, with all proposed modifications highlighted, along with an update to the REMS supporting document for the rationale and the impact of the changes on other REMS elements. The FDA intends to provide more detailed guidance on assessments and modifications to approved REMS in the future.

REMS assessments must be submitted in accordance with the timetable included in the proposed REMS.

Communicating with the FDA About REMS

A proposed REMS may be submitted in the product's original drug application, a supplemental application, or as an amendment to an original or supplemental marketing application. The FDA specifically provides that:

- All supplemental applications that include a proposed REMS or for proposed modifications to an approved REMS should be submitted as prior-approval supplements;
- A proposed REMS submitted after approval, which is not associated with an existing supplemental application, should be filed as a new supplemental application;
- Although a REMS assessment alone, without a proposed modification, is not considered a supplemental application, REMS assessments with a proposed modification to the approved REMS may be submitted as either a new supplemental application or a related supplemental application, at the time of admission or as an amendment; and
- With few exceptions for those drugs not subject to Section 503(b) of the FDCA (*e.g.*, nonprescription drugs) where the REMS includes only the timetable for the submission of assessments, a supplemental application for a new indication for use for a product with an approved REMS must include a REMS assessment and may propose modifications to the REMS.

A template for submissions of proposed REMS and proposed modifications of approved REMS is available on FDA's Web site at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm. The Agency requests that applicants also include electronic versions of the documents to facilitate processing. In addition, the REMS Guidance emphasizes that each submission, whether a proposed REMS application or REMS assessment, should provide identifying information to allow for tracking and provides detailed instructions for the labeling of each type of submission. The FDA notes that applicants may contact the regulatory project manager in the division assigned to the drug for questions, while the Director of the Division of Labeling and Program Support in the Office of Generic Drugs will be the primary contact for ANDA applicants.

Conclusion

For obvious commercial reasons, companies would prefer not to have to adopt a REMS program. However, if the FDA mandates such a program as a condition of approval or continued marketing, the FDA's draft guidance offers an outline for companies seeking to prepare a robust and quality system, which should help minimize product liability risk.

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