DRI The Voice of the Defense Bar

RX for the Defense
The Newsletter of the Drug and Medical Device Committee

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In RX for the Defense


Committee Chair
Scott W. Sayler
Shook Hardy & Bacon
(816) 474-6550
ssayler@shb.com


Committee Vice Chair
James F. Rogers
Nelson Mullins
(803) 255-6550
jim.rogersr@nelsonmullins.com


Newsletter Editor
Anne M. Talcott
Schwabe Williamson & Wyatt
(503) 796-2991
atalcott@schwabe.com

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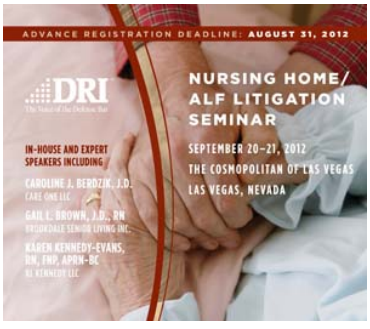

Leadership Notes

Letter from the Chair

by Scott Sayler

It was great to see so many of you at the 27th DRI Drug and Medical Device Annual Seminar, which took place May 10-11, 2012, in New Orleans. The Seminar was highlighted by excellent individual and panel presentations, a record number of Counsel Meetings, and some great receptions and parties. Please note on your calendar that next year's Drug and Medical Device Seminar is scheduled to be held May 16-17, 2013, at the Sheraton New York Hotel & Towers in New York City.

The just-completed Seminar was the result of hours of planning by a large group of people. The planning group included Jim Rogers (Committee Vice-chair), Carter Thompson (Program Chair), Sara Gourley (Program Vice-chair), Gail Rodgers (Marketing Chair), Sheila Boston (Marketing Vice-chair), and Mark Solheim (Law Institute Liaison). Others who contributed to the planning effort included Catherine Barrad, Tony Brazil, Ann Byrd, Mark Callendar, Cami Capodice, Joe Cohen, Alycia Degan, David Duke, Meade Hartfield, Jeni Heis, Kelly Jones, Steve Karg, Amanda Kitts, Sherry Knutson, Jeff Kruse, Catherine Levitt, Jeff Lilly, Barbara Litten, Skip McCowan, Gord McKee, Laurie Miller, Mike Miller, Leeanne Neri, Sarah Padgitt, Kai Peters, Rick Richardson, Anne Talcott, Melissa Tannery, Tracy Van Steenburgh, and Ray Williams. Finally, a sincere thank-you goes to the entire DRI staff who worked so hard to make the Seminar a success.

Many Committee members, especially newer members, are interested in how they can become more active and get more involved in Drug and Medical Device Committee activities. Here are a few possibilities:

--Provide a recommendation for a topic or topics to be included in future seminars. Our 2013 Program Chair, Carter Thompson (cthompson@bakerdonelson.com) would greatly appreciate any suggestions. In this regard, please note that the program for our May 2013 Seminar will largely be completed by the end of July 2012, so if you have suggestions please don't hesitate.

--Volunteer to assist in the marketing for next year's Drug and Medical Device Seminar. Our Marketing Chair, Gail Rodgers (gail.rodgers@dlapiper.com) would love to hear from any volunteers.

--Write an article to be published in an upcoming edition of *Rx For the Defense* or in the 2013 issue of *For the Defense* that focuses on drug and medical device topics. Please contact Anne Talcott (atalcott@schwabe.com) or Melissa Tannery (Melissa.tannery@troutmansanders.com) if you are interested.

--Attend or participate in a Drug and Medical Device Committee-sponsored webcast. The next upcoming webcast, scheduled to take place July 10, 2012, is entitled "FDA & Medical Products: Practices/Proposals for Internet & Social Media." The Drug and Device Committee is also preparing a Hot Topics Webcast for Fall 2012, which will include such topics as Recent Enforcement under the Foreign Corrupt Practices Act and What's Left After Mensing. Please contact Vivian Quinn (vquinn@nixonpeabody.com) or Mike Miller (mmiller@stronghanni.com) for further information.

Nursing Home/ ALF Litigation Seminar

September 20-21, 2012
Las Vegas, Nevada

DRI Publications

The Collateral Source Rule: A Compendium of State Law

Print to PDF

--Make plans to attend (or send one of your firm's young lawyers to attend) our traditional every-other-year presentation of a one-day Young Lawyers Drug and Medical Device Primer, scheduled to be held September 12, 2012, at Sidley Austin's offices in Chicago. Please contact Dave Geiger (dgeiger@foleyhoag.com) for further details.

--Make plans to attend the DRI Annual Meeting, October 24-28, 2012, in New Orleans. Archie Reeves (areeves@mcdowellknight.com) is serving as our Committee Liaison for the Annual Meeting. We will be holding a Committee business meeting at the Annual Meeting, which will include CLE presentations on several topics of interest. Our Committee is also co-sponsoring a Major Presentation at the Annual Meeting dealing with defense strategies in regulated industries.

If you have any questions, suggestions, or comments please do not hesitate to contact me or Committee Vice-chair Jim Rogers (jim.rogers@nelsonmullins.com). I hope you have a great summer and I look forward to seeing you at an upcoming DRI event.

Scott Sayler

Note from the Editor

by Anne M. Talcott

It was a pleasure to see so many of you in May in New Orleans at the Drug and Medical Device Seminar. I particularly enjoyed connecting face to face with those who have submitted articles to *Rx for the Defense* over the past two years. The ability for us to network in this way is such a great benefit of membership in the DRI Drug and Medical Device Committee.

This issue of our quarterly newsletter includes articles on an Oregon court's recent rejection of "innovator liability" and a discussion of whether the California Supreme Court's decision in the asbestos case *O'Neil v. Crane Co.* signals that *Conte* and innovator liability will soon be rejected in the state where that theory first emerged.

Another article discusses Medicare Advantage plans and the unique issues involved when settling a case with a plaintiff enrolled in such plans. Other articles provide valuable tips and pointers on interviewing and preparing former employees to testify and how to best use motions to preserve your trial record.

We are still accepting articles for our next issue, which will publish in September. The submission due date is August 17, 2012 (strategically calendared to allow full advantage of summer associate assistance). Please email me at atalcott@schwabe.com or my co-editor Melissa Tannery at melissa.tannery@troutmansanders.com if you have a topic in mind. We look forward to hearing from you.

Featured Articles

Another Jurisdiction Rejects Innovator Liability

by Nancy Erfle

A Circuit Court in the State of Oregon has confirmed that Innovator Liability does not exist under Oregon law. This is the latest in a long line of cases coming to a similar conclusion.

The case, *Suzanne M. Lukas-Werner, et al. vs. Novo Nordisk, A/S, et al.*, No. 1009-13177

(Multnomah Co, Cir Ct, Or, May 11, 2012), rejected *Conte vs. Wyeth, Inc.* (85 Cal Rptr 3d 299) and the concept of any brand-name liability in generic drug consumer cases based upon the "foreseeability" of injury to the plaintiff. In *Lukas-Werner*, the brand-name manufacturer of a hormone replacement medication moved to dismiss plaintiffs' so called "innovator liability" claims on the grounds that such claims are not legally cognizable under Oregon law. The generic manufacturer and seller had already been voluntarily dismissed.

The motion raised two questions for the court:

> (1) Under Oregon law, does a defendant owe a duty to a plaintiff with whom it has no relationship; and
>
> (2) If so, does Oregon law impose Innovator Liability on a brand-name manufacturer based upon a plaintiff's ingestion of a generic version of the brand name medication?

Defendants argued, in part, that a manufacturer/seller has no duty to a plaintiff with whom they have no relationship. Relying on the plain wording of the Oregon Product Liability statute, liability is imposed only upon one that has actually sold the injury-causing product. Case law in Oregon has consistently refused to impose a duty on any manufacturer or seller for an injury caused by a different entity's product.

Moreover, defendants argued that "foreseeability" does not expand the bounds of a product manufacturer's duty under Oregon law. Specifically, they argued that plaintiffs' "innovator liability" claims rely solely on *Conte* and most courts reject similar claims finding that "brand name drug manufacturers owe no duty to consumers of generic drugs." As defendants pointed out, even the California Supreme Court rejected the *Conte* foreseeability argument and thus argued that it should similarly be rejected in Oregon.

The *Lukas-Werner* counsel countered that the Product Liability statute was not the sole basis for a claim, and that a valid negligence claim did exist based on the concept of foreseeability. Plaintiffs argued that the brand-name manufacturer could be held liable under Oregon common law negligence for inadequate warnings if it violated any applicable standard of care. Specifically, plaintiffs contended that under Oregon case law, if the brand-name manufacturer provided defective and inadequate warnings on its branded drug, that defendants unreasonably created an entirely foreseeable risk of harm to those patients who consumed the generic equivalent carrying the same label. Relying on *Conte*, plaintiffs urged the Oregon court to follow its reasoning and find that a duty is imposed because it was foreseeable that users of the generic version would rely on the brand manufacturer's label.

The Circuit Court granted the Motion to Dismiss and in making its ruling stated:

> I think plaintiff's argument has a lot of appeal, but that's not my job here today. I am required to attempt to predict -- and I need a much bigger crystal ball than I am using -- what the Oregon Supreme Court would do with this theory. And my best prediction is that the Oregon Supreme Court would not recognize the innovator liability theory in these circumstances.
>
> And I do not think the Oregon Supreme Court would conclude that the innovator, the original manufacturer of a drug responsible for its labeling, has a duty arising out of the FDA regulations to the consumers or prescribers of all generic versions of its drug.
>
> And the plaintiffs acknowledge that foreseeability alone won't get them there. That really is kind of what it amounts to, because the regs don't permit the manufacturer or a generic that doesn't want to go through the labeling process to do anything other than use the innovator's labeling. That makes the harm foreseeable to the innovator.

> I don't think we can get there from here. So I'm granting the defendant's motion. I do it reluctantly, but I'm granting it.

Hearing Transcript, 25:2-26:21 (May 11, 2012).

The result is yet another jurisdiction rejecting *Conte* and the plaintiffs' continuing attempts to expand liability to the original drug creator when the generic manufacturer/seller is likely protected from any liability. This is a particularly encouraging result to this growing body of law given the opinion is in a state court that is known to be liberal and resistant to granting any type of dispositive motion.

Nancy M. Erfle *is a shareholder at Schwabe, Williamson & Wyatt where she is Chair of the firm's Product Liability and Business Litigation practice group. She is admitted to practice in Oregon, Washington, and Montana. She focuses her practice primarily on the defense of major manufacturers and complex business disputes.*

Record Preservation Through Trial and Post-Trial Motions

by Jennifer Y. Dukart and Shelby L. Myers

Introduction

Most trial lawyers know that a favorable judgment can and often will result from persuasive motions practice at the district court level. But regardless of whether a drug or device manufacturer seeks to affirm or reverse a judgment on appeal, effective motions practice is almost always the key to winning on appeal. This article provides a succinct primer of common trial and post-trial motions and also offers direction on less common motions that can constitute grounds for a successful appeal by pharmaceutical and medical device defendants.

I. Motion for Judgment as a Matter of Law – Rule 50(a)

The first major trial motion necessary for appellate record preservation is a motion for judgment as a matter of law under Federal Rule of Civil Procedure 50. A motion for judgment as a matter of law ("JMOL") under Rule 50(a) allows the judge to decide the case or an issue in the case in favor of the movant before it is submitted to the jury. The motion should be granted if the facts and inferences point so strongly in favor of one party that reasonable minds could not disagree. *See Reeves v. Sanderson Plumbing Prods., Inc*., 530 U.S. 133, 149 (2000). Even if a motion for JMOL is denied at the trial level, it may provide grounds for an appellate victory. *See Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 793-94 (6th Cir. 2005). The corollary to this rule is that failing to make a timely motion for JMOL can in and of itself preclude a party from winning on appeal, even if that party would otherwise have won. *See Maher v. City of Chicago*, 547 F.3d 817, 824 (7th Cir. 2008).

Rule 50(a) allows a party to move for JMOL at any point before the case is submitted to the jury, so long as the nonmoving party has been "fully heard" on the issue. Fed. R. Civ. P. 50(a)(1). Thus, a defendant can move for JMOL at the close of plaintiff's case-in-chief.

A motion for JMOL must be detailed and comprehensive. A good starting place to identify grounds for JMOL is a previously-filed summary judgment motion. Challenges to jury instructions and inclusion of general grounds as well as specific grounds can avoid waiving potential appellate arguments. *See* Scott Burnett Smith, *Ten Tips To Improve Your Case On Appeal*, 69 Ala. Law., 443 (Nov. 2008); Sylvia H. Walbolt and Susan L. Landy, *Pointers On Preserving The Record*, 25 Litig. 31 (Winter 1999). Although evidentiary issues are rarely grounds for appellate wins, sufficiency of the evidence arguments must be raised by a JMOL motion or they risk being waived. *See Maher v. City of Chicago*, 547 F.3d

817, 824 (7th Cir. 2008).

II. Renewed Motion for Judgment as a Matter of Law – Rule 50(b)

A 2006 amendment to the Federal Rules of Civil Procedure changed the requirements for a renewed Rule 50(a) motion at the close of all evidence. The current rules recommend, but do not require, a renewed Rule 50(a) motion at the close of all evidence. The best practice, however, is to make a Rule 50(a) motion at the close of all evidence where a Rule 50(a) motion has been made after plaintiff's case is submitted.

A renewed motion for JMOL under Federal Rule of Civil Procedure 50(b) permits the court to set aside the jury verdict and enter judgment for the movant. *See* Fed. R. Civ. P. 50(b); *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1316 (11th Cir. 2000). The renewed motion must specifically state the reasons the movant is entitled to JMOL, not simply provide a "renewal" of grounds previously raised. Legal arguments should be identified and supported. *See Ortiz v. Jordan*, 131 S. Ct. 884, 889 (2011) (noting that qualified immunity defense at issue on appeal did not present "neat abstract issues of law" and stating that appellant waived argument by failing to raise it in Rule 50(b) motion).

The relationship between the motion for JMOL under Rule 50(a) and the renewed motion under Rule 50(b) is important. The renewed motion for JMOL under Rule 50(b) can only be made if the moving party made a motion for JMOL under Rule 50(a) *before* the case was submitted to the jury. *See* Fed. R. Civ. P. 50. Failure to raise a sufficiency of the evidence challenge in a Rule 50(b) motion precludes appellate review of the issue even where a Rule 50(a) motion has been made. *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc*., 546 U.S. 394, 401 (2006). Moreover, appellate courts generally will only consider issues raised in a renewed motion for JMOL that were raised in the earlier motion for JMOL. *Arsement v. Spinnaker Exploration Co., LLC*, 400 F.3d 238, 247 (5th Cir. 2005).

II. Motion for New Trial

A successful motions practice often includes a motion for new trial under Federal Rule of Civil Procedure 59. The disadvantage of a motion for new trial is obvious: rather than an outright win the litigant has only won the right to a new trial. The advantage to a motion for a new trial, however, is that the standard for granting a new trial is less burdensome than the JMOL standard. *Winter v. Brenner Tank, Inc.*, 926 F.2d 468, 473 (5th Cir. 1991). A court may grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a).

The standard used by the district court to grant a motion for new trial depends on the grounds of the motion. A motion for new trial based on excessive damages may only be granted if the award is so excessive that it offends the conscience of the court. *See Mason v. Texaco, Inc.*, 948 F.2d 1546, 1561 (10th Cir. 1991); *Wyeth v. Rowatt*, 244 P.3d 765, 784 (Nev. 2010). A motion for new trial based on newly discovered evidence requires a showing that the evidence would probably produce a different verdict. *See Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 916 (Pa. Super. Ct. 2011). A motion for a new trial based on misconduct by opposing counsel is determined under a totality of the circumstances standard. *See Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 490 (1st Cir. 2010).

Rule 50(b) allows a movant to include a motion for new trial when the movant files a renewed motion for JMOL. The interplay between JMOL and motions for a new trial must be considered. If the renewed motion for JMOL is granted by the court, the court also must make a conditional ruling on the motion for new trial. Fed. R. Civ. P. 50(c)(1). It is the trial attorney's responsibility to make certain the judge rules both on the renewed motion for JMOL and the motion for new trial when the two motions are filed concurrently. If the lower court's ruling on JMOL is reversed on appeal, a litigant may lose a right to a new trial if the court failed to rule on the motion. *See, e.g*., *Johnstone v. American Oil Co.*, 7 F.3d 1217, 1224 (5th Cir. 1993).

III. Other Post-Trial Motions

In some circumstances, additional motions can be made to address error or unfairness in the proceeding that could not have been raised earlier.

A motion to alter or amend the judgment under Rule 59 asks the court to change the judgment in some way in the moving party's favor. *See* Fed. R. Civ. P. 59(e). This motion can be asserted due to an intervening change in controlling law, to account for new evidence not available at trial, and to correct a clear error or prevent manifest injustice. *See Servants of the Paraclete v. Does*, 204 F.3d 1005, 1012 (10th Cir. 2000).

A motion for relief from the judgment under Rule 60 allows a party to have the judgment altered, set aside, nullified or vacated in certain, limited circumstances. *See* Fed. R. Civ. P. 60(b)(1)-(6) (providing that an adverse judgment can be set aside for mistake, inadvertence, surprise, or excusable neglect; newly discovered evidence; misconduct of adverse party; void judgment; intervening events that justify vacating the judgment; or for "extraordinary circumstances"). The standard for granting a motion for relief from the judgment is a high one. Still, awareness of the motion is useful in the event that one of the limited circumstances for relief under Rule 60 is present. *See, e.g.*, *Graham ex rel. Graham v. Wyeth Labs.*, 906 F.2d 1399, 1417-19 (10th Cir. 1990).

Conclusion

Focused motions practice is the best way to preserve the record and to win on appeal. The lessons of this article are simple. Make your motions. Make them at the correct time. And make them specific and comprehensive.

Jennifer Y. Dukart *is a member of Faegre Baker Daniels' nationally-ranked products liability litigation group. She focuses on complex litigation and appellate work, with a particular emphasis on pharmaceutical and medical device product liability matters. Jennifer has experience in both procedural and practical aspects of complex litigation, including class actions and mass torts. Her appellate work contributes to her ability to craft and implement winning legal strategies in both trial and appellate courts.*

Shelby L. Myers *is a member of the litigation group in Faegre Baker Daniels' Denver office and focuses her practice on general product liability. She has been involved in multidistrict and complex product liability litigation involving pharmaceutical companies. Shelby has experience in preparation for discovery in a toxic tort case and she also has experience representing national banks in regional foreclosure litigation.*

Issues to Consider Before Meeting with Former Employees to Prepare for Deposition

by Greg G. Jackson

In defending drug and device companies, we routinely find that the individuals who possess the key knowledge or background information about the product at issue are no longer with the company. Further, it is not unusual for plaintiffs to seek depositions from former management and critical decision makers who were in place at the time of the events at issue, but are no longer employed by your client. Since the rules that apply to these former employees vary greatly from the rules for existing employees, and because former employees' testimony can have a significant impact on the outcome of the litigation, counsel need to be cautious in how to approach these depositions.

The list below highlights *some* of the key issues to consider before one meets with any former employees to prepare for a deposition.

1. Who are the former employees that are likely to be deposed?

At the earliest stage possible, work with your client to determine which former employees possess important knowledge and information relevant to the lawsuit. In the drug/device world, this often extends beyond former management, to include former scientists, engineers, sales representatives, and regulatory personnel. For large organizations, or those with high turnover rates, it may be challenging to identify these former employees. Moreover, when it comes to litigation, it is not unusual for both current and former employees to avoid taking ownership over certain responsibilities/business decisions.

Thus, you cannot simply rely on the memory of a few current employees. You need to analyze company documents, and speak with senior management, HR, outside consultants, and other former employees. Bear in mind that this is an ongoing process; you may learn of key former employees several months into your investigation, or as the litigation themes develop.

2. What background information on the former employees is available?

Before you contact any former employee, gather as much intel on that person as reasonably possible. Your client should have access to their personnel file and possibly the former employee's physical/electronic files. Without infringing on privacy rights, you should still be able to gather some critical background information on the former employee (*e.g.*, age, education, previous experience, positions with employer, disciplinary issues, performance reports, termination). Your client should be able to determine the former employee's role with the company, potential involvement with the underlying dispute that led to the litigation, and whether the employee has given prior testimony/affidavits/declarations on behalf of the corporation. Your client may know whether the former employee is articulate and polished, or short-fused and argumentative. Your client should also know whether the former employee is going to be friendly or hostile to the company.

You must understand why the employee is no longer with the company, and whether there are any factors associated with that separation that may impact the former employee's credibility, cooperation, or availability. Your client may also have information on the current whereabouts of the former employee. Find out about any recent communications or if any current employees maintain any relationships with the former employee. If the former employee works for a competitor, this may also impact your litigation strategy.

3. What law is going to apply to any interaction with a former employee?

The following scenario is not uncommon: The plaintiff resides in State A, the lawsuit was filed in State B, and the former employee resides in State C. Before you have any contact with the former employee, you need to understand what law applies to your communication with the former employee, as well as your conduct during their deposition. This is a case-specific inquiry. For example, some courts have applied the privilege law of the forum where the deposition takes place, whereas other courts may apply the privilege law from the employer's principal place of business/state of incorporation. *See, e.g.*, *Wright v. Jeep Corp.*, 547 F. Supp. 871, 875 (E.D. Mich. 1982); *McNulty v. Bully Park Place, Inc.*, 120 F.R.D. 27, 31 (E.D. Pa. 1988).

The applicable law will impact a number of substantive and procedural issues relating to former employees, including attorney-client privilege, ethical concerns, and permissible witness compensation. Thus, it is critical to know the applicable law before contacting any former employee.

4. What is the best way to initiate contact with a former employee?

While this depends on the circumstances surrounding each particular former employee, it is generally best to use an

intermediary (*e.g.*, the client or a colleague) to make the introduction. It is not unusual for former employees to be uncooperative or unresponsive to requests for their time, particularly when that requests involves litigation. Thus, when possible, use a familiar source to gain the former employee's confidence and trust.

Keep in mind that anything communicated to the former employee at this phase would not be protected by the attorney-client privilege. Also, many jurisdictions allow opposing counsel to conduct *ex parte* interviews of former employees, so it is possible that your former employee has already spoken with the plaintiff's counsel.

5. Whether to represent a former employee during the deposition.

Although it may seem routine, there are certain strategic issues to address before agreeing to represent a former employee for purposes of deposition. As an initial matter, you must assess whether there are any potential conflicts of interest that may exist (both currently and in the foreseeable future) between this former employee and either your client or your firm. Similarly, you should contemplate the possibility of having to cross-examine the former employee for impeachment purposes. You should also evaluate whether your client will want to distance itself from the former employee for reasons that extend beyond the subject matter of the litigation (*e.g.*, criminal conduct).

Ultimately, the decision may hinge on whether this employee is hostile to the company, and whether there are allegations against the former employee for conduct that falls outside the scope of his or her former employment.

6. Potential ethical concerns related to representing a former employee.

In addition to the conflict of interest issue referenced above, you must be careful how you enter into a representation of the former employee. If the former employee requests that you represent him, then such a representation would be appropriate. But if you "offer" to represent the former employee, that may be deemed an improper solicitation in violation of the rules of professional conduct. *See, e.g.*, Model Rule of Prof. Conduct 7.3 (prohibiting a lawyer from directly soliciting professional employment). Thus, it is best that your client (*i.e.*, not you) communicate to the former employee and offer to provide legal counsel if so desired.

7. Are communications during preparation protected by the attorney-client privilege?

There is no uniform rule governing whether communications with former employees in preparation of a deposition are privileged. In some jurisdictions, communications between counsel and former employees in preparation for deposition are privileged so long as those communications concern information within the scope of the employees' former employment. *In re Allen*, 106 F.3d 582, 606 (4th Cir. 1997) (extending privilege to prohibit discovery relating to interview between lawyer and former employee); *In re Coordinated Pretrial Proceedings in Petroleum Products Antitrust Litigation*, 658 F.2d 1355, 1361 n.7 (9th Cir. 1981) (prohibiting plaintiff's counsel from what transpired at a predeposition "orientation session" with former employees). In contrast, other jurisdictions have ruled that certain aspects of deposition preparation of a former employee are not privileged. *See, e.g.*, *Peralta v. Cendant Corp.*, 190 F.R.D. 38, 41-42 (D. Conn. 1999) (noting that "facts developed during the litigation, such as testimony of other witnesses, of which [the former employee] would not have had prior or independent personal knowledge" would not be privileged); *Infosystems, Inc. v. Ceridian Corp*., 197 F.R.D. 303, 306 (E.D. Mich. 2000) (counsel's communications with former employee of client corporation should be treated like communications with any other third-party fact witness).

Given the inconsistent application, you need to be cognizant of the governing law, and careful not to divulge anything that may later be deemed discoverable.

8. Can a former employee be compensated for time spent preparing for deposition?

Oftentimes, former employees will not agree to take time out of their day to prepare for a deposition without being compensated for their time and expenses. While it is usually appropriate to compensate fact witnesses for lost income and other expenses incurred while testifying, the law is less clear as to whether it is permissible to compensate those witnesses for time spent *preparing* for a deposition. The ABA and several state ethics commissions have taken the position that reasonable payments to former employees for time spent preparing for depositions are proper so long as the payment is not a pretext for an inducement to testify, or contingent upon a favorable outcome of the case. *See, e.g*., ABA Ethics Op. 96-402 (1996); Cal. Ethics Op. 1997-149 (1997); N.Y. Ethics Op. 668 (1994). In contrast, some courts have found that it is improper to compensate a witness for time spent preparing to testify within one's personal knowledge. *See, e.g.*, *Hamilton v. General Motors Corp*., 490 F.2d 223, 228 (7th Cir. 1973).

9. Whether to show a former employee documents in preparation for deposition.

Documents used to refresh the memory of the former employee during a preparation session are not protected by the attorney-client privilege or the work product doctrine. *See, e.g.*, *Heron Interact, Inc. v. Guidelines, Inc.*, 244 F.R.D. 75 (D. Mass. 2007). Arguably, the work product doctrine may protect certain aspects of predeposition conversations with former employees that would not otherwise fall under the attorney-client privilege, to the extent those discussions entail the attorney's mental impressions, conclusions, opinions, or theories of the case. However, the work-product doctrine only provides qualified protection, and will not preclude disclosure of otherwise nonprivileged documents.

There are many theories as to whether to show one's own witness documents before their deposition. The strategic decision of what documents to show the former employee will ultimately turn on the unique facts and issues of the particular case and witness. On one hand, the former employee may possess negative information that he or she may not recall unless their recollection is refreshed. The risk here would be that additional harmful information could come out if his or her memory is triggered. Ultimately, it is best to know before the deposition what the employee may testify to, and in that regard, likely best to review all pertinent documents.

10. What should be accomplished during the first meeting?

The primary goal for the first meeting is to gain confidence and trust. You should do your best to manage the former employees' expectations, by explaining up front what you intend to do to prepare for the deposition and how much time you anticipate using. Be conscious of the intrusion and burden you are imposing on the former employees, but make sure they understand that the deposition is not going away. Explain the case in general terms, and more importantly, why this particular former employee is being deposed.

Most people – even sophisticated business executives – have no idea what a deposition actually is, and how it can impact a case. Thus, describe a deposition, how it fits in to the case, and how a deposition transcript can be used, both in motions and at trial.

With a face-to-face meeting, you can begin to assess their general knowledge, comfort level, sophistication, and demeanor. Also, you may be able to assess issues with their mental and physical health that will need to be addressed before any deposition is taken (*e.g*., limitation on hours, location of deposition, physical impairment, hearing loss).

Gregory G. Jackson *is a Senior Associate with the San Diego office of Morris Polich & Purdy LLP (gjackson@mpplaw.com). His practice concentrates on products liability and commercial litigation, with particular emphasis on representing pharmaceutical and medical device companies.*

Conte Reeling in the Wake of California Supreme Court Decision

by Steven M. Thomas and Jennifer Stonecipher

A recent decision by the California Supreme Court may signal the end of so-called "innovator liability" under *Conte v. Wyeth*. The *Conte* decision arguably has spent three years on the ropes, with a long list of courts declining to hold brand-name manufacturers liable for injuries allegedly caused by generic-equivalent drugs. Nevertheless, undeterred litigants clinging to the California Court of Appeal's 2008 decision in *Conte* have continued to push for expanded tort-law duties in drug products litigation. The California Supreme Court's decision in *O'Neil v. Crane Co.*, 266 P.3d 987 (Cal. 2012), however, could be the blow that puts *Conte* on the canvas.

Conte's Expansive Duty of Care

In *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008), the plaintiff alleged injuries relating to her use of metoclopramide, a generic version of Reglan. She sued Wyeth, the brand-name manufacturer, as well as three generic manufacturers, and the trial court granted summary judgment in favor of all defendants. *Id.* at 304. The appellate court affirmed as to the generic manufacturers, agreeing that the plaintiff had failed to demonstrate that she or her physicians had relied on the generic labels. *Id.* However, the court allowed the plaintiff to go forward with her negligence claims against Wyeth. *Id.*

Because the claims sounded in negligence rather than strict liability, *Conte*'s reasoning turned on whether Wyeth owed a duty to consumers who received a generic drug. For the *Conte* court, foreseeability made all the difference. The court explained that a brand-name manufacturer's duty is not limited to consumers of its own product. Instead, the duty extends to "those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug." *Id.* at 304-05. Because the court found it foreseeable that a physician would prescribe a generic version in reliance on Wyeth's representations about Reglan, the court allowed the negligence claims against Wyeth. *Id.* at 313.

More than Foreseeability Under _O'Neil_

O'Neil involved allegations that the death of a Navy officer had been caused by exposure to asbestos fibers while working aboard a ship. The officer's family sued several companies that supplied products to the Navy, asserting claims based on strict liability and negligence. *O'Neil*, 266 P.3d at 993. Defendants Crane and Warren manufactured valves and pumps that were used in the ship. *Id.* at 991. While the defendants' valves and pumps did not contain asbestos, they often incorporated other vendors' asbestos-containing gaskets and packing materials into the parts that they supplied, as directed by the Navy's specifications. *Id.* at 992. The original asbestos-containing gaskets and packing materials were replaced many years before the decedent worked aboard the ship. *Id.* at 993.

The plaintiffs argued that, even if the decedent had not been exposed to asbestos from the defendants' products, they were nevertheless responsible for the injuries because their products originally included asbestos-containing components and because it was foreseeable that their products would be repaired with additional asbestos-containing components in the future. *Id.* The trial court dismissed all claims against Crane and Warren, but the Court of Appeal reversed. Notably, it found that the defendants could be strictly liable for the dangerous products with which its own products "will necessarily be used." *Id.* at 994.

The Supreme Court of California reversed, concluding that the defendants were not strictly liable for the decedent's injuries because any defect in the defendants' own products did not cause the alleged injury and they "had no duty to warn of risks arising from *other manufacturers'* products." *Id.* at 995.

In evaluating the negligence theories and whether the defendants owed a duty of care to prevent the injury, the court explained that "foreseeability alone is not sufficient to create an independent tort duty." *Id.* at 1006. Instead, the court followed the reasoning announced in *Rowland v. Christian*, 443 P.2d 561 (Cal. 1968), that foreseeability of harm is only one of several factors that a court must consider in deciding the existence and scope of duty. *Rowland* also instructs courts to consider the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty, and the availability, cost, and prevalence of insurance for the risk involved. *Rowland*, 443 P.2d at 582 (the "*Rowland* factors").

The *O'Neil* court concluded that the above-referenced factors did not support a duty of care. *O'Neil*, 266 P.3d at 1007. "[E]xpansion of the duty of care as urged here would impose an obligation to compensate on those whose products caused the plaintiffs no harm. To do so would exceed the boundaries established over decades of product liability law." *Id.* The court reversed and remanded the case for entry of judgment in favor of Crane and Warren.

O'Neil raises serious doubts as to whether *Conte* remains good law. First, *O'Neil* underscores the view that a manufacturer's liability under strict products liability is limited to defects in the products that it manufacturers or distributes. *Id.* at 995. Second, *Conte*'s reasoning under negligence theories is equally vulnerable. *Conte* focused almost exclusively on foreseeability and brushed aside the additional *Rowland* factors—citing a limited factual record. *Conte*, 85 Cal. Rptr. 3d at 314. But, in *O'Neil*, those factors tipped the scales against imposing a duty of care. *O'Neil* reemphasizes the multifaceted approach required in determining the limits of a manufacturer's duty and highlights the flaws in *Conte*'s elevation of foreseeability at the expense of important policy goals.

Post-*Mensing* Rejection of Innovator Liability

Despite the determined efforts of plaintiffs' attorneys, courts have routinely rejected the expansion of a brand-name manufacturer's duty of care announced in *Conte*, even characterizing the decision as "anomalous," *Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, at *3 (S.D. Tex. Oct. 29, 2009), and "the lone outlier against the overwhelming weight of authority." *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586 XXX MB, 2009 WL 4924722, at *5 (Fla. Cir. Ct. Dec. 21, 2009). While numerous courts have declined to impose liability on a brand-name manufacturer for injuries allegedly caused by another manufacturer's generic version, it appears that only one reported decision has embraced *Conte*-type liability. *Compare Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 696-97 (D. Vt. 2010) (agreeing with *Conte*), *with In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 716132, at *5 (E.D. Ky. Mar. 5, 2012) (noting that 55 decisions from across the country have rejected innovator liability).

While *Conte* may have seemed destined to fade into the background, the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), sparked renewed attempts to assign responsibility to brand-name manufacturers. If federal law preempted failure-to-warn claims against generic manufacturers, as the Court concluded in *Mensing*, who would be responsible for injuries when the consumer received a generic medication? The Court acknowledged the "unfortunate hand" that federal regulations had dealt to the *Mensing* plaintiffs—and possibly to the three-quarters of consumers whose prescriptions are filled with generics.

Mensing recognized that Congress or FDA could "change the law and regulations if they so desire," *id.* at 2581, but a

legislative or regulatory response may be easier said than done. In August 2011, Public Citizen filed a petition requesting that FDA implement regulatory changes to allow generic manufacturers to independently revise their labels. But as of April 2012, FDA had taken no action. In April, legislators in the House and Senate introduced the Patient Safety and Drug Labeling Improvement Act, a bill that would similarly allow revisions to generic labels. Despite the recent attention, legislators likely face an uphill battle in enacting such changes during an election year.

Following *Mensing*, courts have continued to reject the expansion of tort-law duties based on *Conte*. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Metz v. Wyeth LLC*, --- F. Supp. 2d ---, 2011 WL 5826005, at *2 (M.D. Fla. Nov. 18, 2011). The plaintiffs' bar may sense the weakness of innovator liability theories, as they have employed new strategies aimed at avoiding the preemptive effect of *Mensing* – for example, recasting failure-to-warn claims as breach of warranty claims or even as claims for failure to send "Dear Doctor" letters consistent with FDA-approved labeling. *See, e.g., In re Darvocet*, 2012 WL 718618, at *4 n.9, 5-6 (E.D. Ky. Mar. 5, 2012). Nevertheless, the issue of innovator liability persists. In fact, the Alabama Supreme Court is considering a similar issue in a certified question from the federal court in *Weeks v. Wyeth, Inc.*, No. 1:10-CV-602, 2011 WL 1216501 (M.D. Ala. Mar. 31, 2011), *certified by* No. 1101397 (Ala. Oct. 17, 2011) (certifying the question of whether a manufacturer can be liable for fraud or misrepresentation based on statements made in connection its brand-name drug when the plaintiff claims injury from another manufacturer's generic version).

Defending Against Innovator Liability After *O'Neil* and *Mensing*

In light of *O'Neil*, *Conte* does not seem to be a viable basis for holding a brand-name manufacturer liable for injuries allegedly caused by a generic-equivalent drug. Even so, with many courts faithfully applying *Mensing* and dismissing claims against generic manufacturers, brand-name manufacturers must be prepared to defend against claimed innovator liability.

In addressing such claims, counsel should note that *Conte* justified its quick disposal of the *Rowland* factors based on a limited factual record. Thus, developing a factual record to demonstrate the policy considerations weighing against an extension of duty, including the potential costs and insurance implications, may be persuasive in California and other jurisdictions. Public policy reasons, which were overlooked in *Conte*, provide additional strong support for rejection of innovator liability. The procedural history of *Mensing* could also be useful to counsel in showing that the Supreme Court's decision does not justify a departure from the overwhelming majority of authority rejecting innovator liability. Before it reached the Supreme Court, the Eighth Circuit affirmed the dismissal of the claims against the brand-name manufacturers, which was not at issue before the Supreme Court. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14 (8th Cir. 2009), *rev'd on other grounds*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Nothing in *Mensing* requires imposing a new duty on brand-name manufacturers.

Conclusion

Following *Mensing*, brand-name manufacturers may seem like attractive potential targets for creative opponents. But *O'Neil* may be a sign that *Conte*'s days are numbered. The decision provides strong support against innovator liability. Practitioners should be mindful of this and other emerging cases that reject the expansion of a manufacturer's duty.

Steven M. Thomas *is a partner in the Kansas City, Missouri, office of Shook, Hardy & Bacon L.L.P. Steve's practice focuses on complex, national product liability litigation, with an emphasis on representation of manufacturers of prescription drugs, biologics and medical devices. He has served as national and regional counsel for major pharmaceutical companies and has substantial experience with all aspects of personal injury and multidistrict litigation.* smthomas@shb.com

Jennifer Stonecipher Hill *is an associate in the Kansas City, Missouri, office of Shook, Hardy & Bacon L.L.P. She focuses her practice on the defense of pharmaceutical and medical device manufacturers engaged in product liability litigation. In addition, Jennifer advises clients on issues governed by the Food and Drug Administration, including product labeling, regulatory compliance and risk evaluation and management.*
jshill@shb.com

Medicare Advantage Plans and Medicare Secondary Payer (MSP) Recoveries

by David M. Melancon

Over the last few years, much has been written about Medicare's new reporting requirements and the resultant heightened focus on ensuring that Medicare is reimbursed for any conditional payments it has made. Less attention has been paid to the unique issues raised when settling a case with a Medicare beneficiary who is enrolled in a Medicare Advantage (MA) plan. This article discusses the recovery rights of MA plans and offers practical suggestions for compliance with the Medicare Secondary Payer Program when settling a case with a Medicare beneficiary who is enrolled in such a plan.

Medicare Secondary Payer Statute and MA Plans

In 1980, Congress enacted the Medicare Secondary Payer (MSP) statute in an effort to reign in the burgeoning costs of the Medicare program. Under the MSP statute, Medicare makes "conditional" payments, and Medicare has a right of reimbursement if it determines that a third-party primary payer bore responsibility for those payments. 42 U.S.C. § 1395y(b)(2)(B) (2006). The MSP also created a private cause of action to enforce the right to recover payments made by Medicare that are the responsibility of a primary plan. 42 U.S.C. § 1395y(b)(3)(A).

In 1997, Congress created Part C of the Medicare law, now known as the Medicare Advantage program, as an alternative to the traditional Medicare program under Parts A (hospital insurance) and B (medical insurance). MA plans are offered by private companies and provide all coverage provided by Medicare Part A and Part B and typically offer additional coverage, such as vision, hearing, dental, etc. MA plans are essentially Medicare HMOs operated by private insurers. The statute creating these plans contains an independent secondary payer provision, which references but does not fully adopt or incorporate the MSP statute. 42 U.S.C. § 1395w-22(a)(4).

Enacted in 2007, the Medicare, Medicaid, and State Child Health Insurance Program (SCHIP) Extension Act (MMSEA) expanded the ability of the federal government to recover sums owed under the MSP statute by imposing strict reporting requirements and penalties for noncompliance. 42 U.S.C. § 1395y(b)(7), (b)(8). Under MMSEA section 111, all insurers as well as self-insurers, collectively referred to as "responsible reporting entities" (RREs), must report information regarding payments made to Medicare beneficiaries and other data to ensure proper coordination of benefits with the Medicare program. 42 U.S.C. § 1395y(b)(7)(A); 42 U.S.C. § 1395y(b)(8)(A). This reporting requirement applies irrespective of whether the beneficiary is enrolled in traditional Medicare or in a MA plan.

Recovery Rights of MA Plans

While there is a general agreement that a MA plan has a contractual right to seek recovery of expenses paid to a Medicare beneficiary, the existence of a private right of action to enforce that claim in federal court under the MSP statute has been more controversial. MA plans contend that they have rights as a secondary payer under the MSP statute to

seek recovery of paid expenses. On the other hand, beneficiaries and primary payers argue that the MSP statute does not confer a private cause of action on MA plans. Recent federal district court cases lend support to the position that MA plans do not have a private right of action to enforce their reimbursement rights under the MSP statute, instead leaving MA plans to enforce their rights as secondary payers under state contract law. However, the more recent Third Circuit of Appeals opinion *In re: Avandia Marketing, Sales Practices and Products Liability Litigation*, 2012 WL 2433508 (6th Cir. 6/28/12) marks a departure from these decisions and will undoubtedly increase the uncertainty and debate surrounding the reimbursement rights of MA plans.

Federal Court Decisions

Most recently, a New York Federal District Court weighed in on the issue of the reimbursement rights of MA plans. In *Konig v. Yeshiva Imrei Chaim Viznitx of Boro Park Inc.*, 2012 WL 1078633 (E.D.N.Y. Mar 30. 2012), a Medicare beneficiary filed a premises liability action in state court for alleged damages arising out of an incident on the defendant's property. While the suit was pending, the MA plan asserted a claim against any funds that the beneficiary obtained in settlement. The beneficiary then sought and obtained in the state court proceeding an order to show cause why "any purported lien/claim and/or subrogation right" asserted by the MA plan should not be extinguished. *Id*. at *1. In response to this filing, the MA plan filed a notice of removal asserting that the federal court had federal-question jurisdiction based on the reimbursement rights found in the MSP statute. The federal court granted the beneficiary's motion to remand and found that the Medicare laws offer no private right of action – express or implied—to MA plans to enforce any claimed subrogation rights.

> Even if the Medicare laws could be read to create a right of subrogation for MAP providers [MA plans]—an interpretation rejected by many courts, who have instead held that the Medicare status simply authorizes MAP providers to contractually create subrogation rights . . . no provision expressly extends such providers a private right of action to sue upon their subrogation rights.

Id. at *2 (citations omitted).

Another example of a federal court decision that reiterates that MA plans cannot bring a cause of action in federal court to recover medical payments under the MSP provisions can be found in *Humana Medical Plan, Inc. v. Reale*, 2011 WL 335341 (S.D. Fla. Jan. 31, 2011), *order vacated* (Sep. 26, 2011). In *Humana*, a Medicare beneficiary filed suit to recover for injuries allegedly sustained in a slip and fall. Humana filed a separate lawsuit in federal court against the Medicare beneficiary alleging that under the MSP statute it was entitled to be reimbursed the benefits paid to the beneficiary. The beneficiary then filed a motion to dismiss on the ground that the MSP statute does not grant a MA plan a private cause of action and, thus, the court lacks subject-matter jurisdiction. The court granted the motion to dismiss and found:

> A Medicare Advantage organization, such as Humana, "will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations. However, under 42 U.S.C. 1395y(b)(2)(B)(i), the Secretary's authority is limited to making payments "conditioned on reimbursement to the appropriate Trust Fund." *Id*. The United States is vested with full authority to bring an action for reimbursement, not the Secretary. 42 U.S.C. 1395y(b)(2)(B)(iii). Therefore, because the Secretary does not have the authority to bring an action for reimbursement, Humana cannot claim such a right under 42 C.F.R. 422.108(f). Accordingly, Humana has failed to bring a claim arising under federal law.

Id. at *2 (footnotes omitted).

See also Parra v. PacifiCare of Ariz., No. 10 Civ. 8, 2011 WL 1119736 (D. Ariz., Mar. 28, 2011) (Statute enacting MA

program does not incorporate the provisions of the Medicare statute that created a private right of action to recover medical payments paid on behalf of Medicare beneficiaries and MA plan, therefore, cannot state a federal claim for relief); *Ferlazzo v. 18th Avenue Hardware, Inc.*, 33 Misc. 3d 421, 929 N.Y.S. 2d 690 (N.Y. Sup. Ct. 2011) (MA plan's right to reimbursement does not stem from the Medicare statute but rather from the private contract made with Medicare beneficiary).

Medicare Policy Memorandum

On December 5, 2011 two Directors at Medicare published a memorandum to MA plans and Prescription Drug Plans regarding their reimbursement rights, which challenges the recent federal district court decisions. The memorandum noted that court decisions "have challenged Federal regulations" governing collections by MA plans for payments made where Medicare is a secondary payer and that several MA plans "have not been able to take private action to collect for Medicare Secondary Payer (MSP) services under Federal law because they have been limited to seeking remedy in State court." The memorandum then summarizes Medicare's regulations regarding the right to collect expenses paid where Medicare is not the primary payer and concludes with the pronouncement that "[n]otwithstanding these recent court decisions, CMS maintains that the existing MSP regulations are legally valid and an integral part of the Medicare Part C [Medicare Advantage] and D [Prescription Drug Plan Sponsors] programs."

Third Circuit Opinion--In re: Avandia Marketing, Sales Practices and Products Liability Litigation

In *In re: Avandia Marketing, Sales Practices and Products Liability Litigation*, No. 11-2664, 2012 WL 2433508 (3rd Cir. 6/28/12), the Third Circuit Court of Appeals held that a MA plan has a private right of action under the MSP to recover payments it has made that are the responsibility of a primary plan. In doing so, the court reversed the district court, which had dismissed the claims of the involved MA plan on the basis that the MSP does not grant a MA plan a private right of action to enforce its rights as a secondary payer. The Third Circuit provided three distinct reasons for its holding.

First, the court found that the plain language of the private cause of action created by the MSP, 42 U.S.C. § 1395y(b)(3)(A), provides MA plans the right to bring suit. It noted that the language of this provision was broad and unambiguous and placed no limitations upon which private actors could bring suit when a primary plan fails to reimburse any secondary payer.

Second, the court concluded that the legislative history and policy rationales of the Medicare Advantage program supported a private right of action in favor of MA plans. It noted MA plans would be at a competitive disadvantage if they did not have the same recovery rights as traditional Medicare and added that allowing such recovery advanced Congress' stated goal of cost savings and providing competition for Medicare enrollees based on how efficiently MA plans could provide care to Medicare beneficiaries.

Finally, the court found that deference to relevant federal regulations and Medicare policy memorandum, which granted MA plans parity with traditional Medicare, supported the recovery rights of MA plans. As part of this analysis the court noted that 42 C.F.R. 422.108 states that an "MA organization will exercise the same rights to recovery from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations . . . . " Further, Medicare's December 5, 2011 memorandum, discussed above, clarified that Medicare itself understood this regulation to assign to MA plans the right to recover against primary payers using the same procedures available to traditional Medicare.

In sum, the Third Circuit found that MA plans have the same recovery rights as traditional Medicare based on a plain reading of the MSP statute, given the legislative history and policy goals of the Medicare Advantage program, and considering due deference owed to Medicare's interpretation of the MSP statute and related regulations.

Settlement with a MA Plan Participant

Irrespective of whether the plaintiff has received Medicare benefits through a MA plan or traditional Medicare, your client will need to report the settlement to comply with MMSEA section 111. This reporting obligation is separate and distinct from a MA plans recovery rights under the MSP statute. As a precautionary measure, you should also require that plaintiff's counsel provide written confirmation from Medicare that it has no interest in the settlement. The reason is that even though the plaintiff may be enrolled in a MA plan at the time of settlement, beneficiaries are allowed to switch back and forth between MA plans and traditional Medicare. This raises the possibility that at some point the plaintiff may have received benefits directly from Medicare and if so, you will need to ensure that Medicare is reimbursed. Finally, the settlement agreement should contain language expressly affirming that it is the obligation of the plaintiff and his attorneys to satisfy all claims or liens of any MA plan, outline the mechanism for payment of these claims or liens, and include related indemnity language.

Conclusion

While there undoubtedly will be ongoing discussion over the nature and extent of the recovery rights of MA plans, particularly outside of the Third Circuit, the recent *In re Avandia* decision increases the likelihood that MA plans nationwide will be more aggressive in their assertion that they have the same recovery rights as does Medicare under the MSP statute. Even assuming a MA plan has such a right, however, the manner in which a MA plan will apply the *In re Avandia* decision remains uncertain. For example, will MA plans generate conditional payment letters, allow primary payers an opportunity to negotiate the amount of the payments, issue a final demand letter, and follow other protocols Medicare already has in place? Until MA plans put in place the mechanism for enforcing their recovery rights and until there is additional guidance from the courts, defense practitioners should resolve potential reimbursement claims of MA plans by verifying the existence and amount of such claims and ensuring there is a mechanism in place for satisfying any interest that a MA plan may have in a settlement. Proactively addressing the claims of MA plans in this manner will relieve much of the uncertainty surrounding their reimbursement rights.

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