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In This Issue

dri™ Drug and Medical Device Seminar

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Boston

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From the Leadership

Chair's Corner

By Gail Rodgers

Happy Winter! Hopefully by the time you read this, it will be Happy Spring! And spring is time for the Drug and Medical Device Seminar! Come join us May 6–8 in a new and exciting venue in Boston. We are very much looking forward to excellent presentations on genomics, practical skills in dealing with expert witnesses, the impact of technology on patient care, perspectives on MDLs from MDL judges, TED-style talks and much more. We will again have our exclusive in-house counsel breakout, so invite your clients and remind them that they can attend for free. (Reach out to any of the committee leadership or check the DRI website for details.)

It would not be the Drug and Medical Device Seminar without networking and catching up with friends and colleagues. So there will be client counsel meetings, a Thursday morning indoor cycling class at SoulCycle Back Bay, lunch-arounds, dine-arounds, a Young Lawyers happy hour, a special Boston networking event, firm parties, and our community service project.

And of course we will hold our steering committee meeting and our committee business meeting so we get a jump start on planning and programs for the coming year.

You can find more information and register here.

See you in Boston!

Gail Rodgers is a partner in the New York office of DLA Piper. She focuses her practice on the national and regional defense of drug and medical device litigation and investigations and compliance. She is the new Chair of the Drug & Medical Device Committee of DRI.

From the Editor

By Heather Howard

If you are interested in writing an article for publication in *Rx for the Defense*, please contact Heather Howard at hhoward@kslaw.com to find out more information about the publication guidelines and the selection process.

Heather Howard is Counsel in the Atlanta office of King & Spalding LLP, where she is a member of the firm's Trial & Global Disputes practice. She focuses her practice on the defense of pharmaceutical and medical device manufacturers in product liability suits at the trial level and on appeal. She serves as the Newsletter Editor for the DRI Drug and Medical Device Committee.

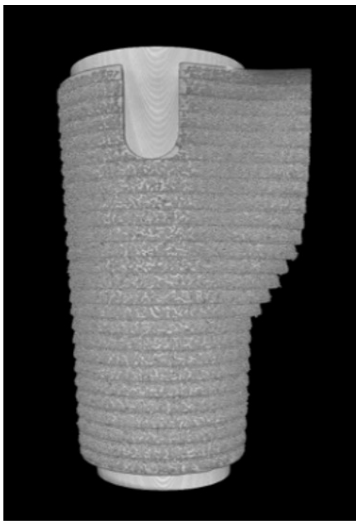
Feature Article

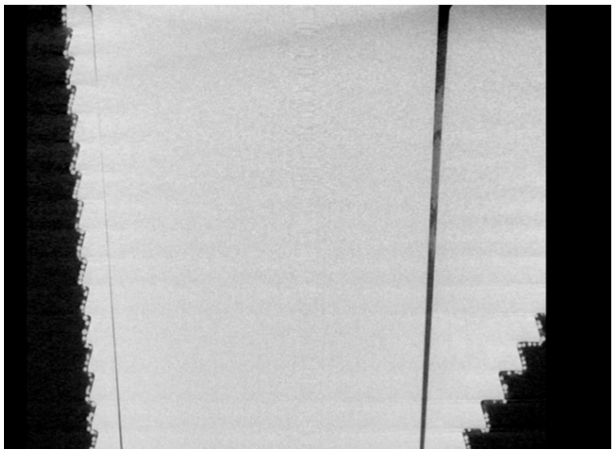
Expert Insights

A Picture Is Worth a Thousand Words—Using Imaging to Support Your Case

By Kevin Ong and Felicia L. Svedlund

As experts, we are often challenged with answering important questions regarding the medical device at issue in product liability and patent litigation matters. Owing to our natural penchant for visual media, a tool for addressing some of these questions is imaging. Just as pictures cannot replace words, words cannot fully describe a picture in terms of their ability to convey clear information. Hence, it is important to select the most appropriate approach and imaging technique to address the specific issue at hand. Imaging provides a means to capture the external and/or internal structures of an object. It can also be in stationary or video form.





A unique tool in the life sciences field is medical or clinical imaging, which is used to examine the condition of a device inside the human body. Forms of medical imaging include X-ray, fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI). X-rays involve the use of electromagnetic radiation that is either absorbed by or passes through the object and then forms an image on a detector (or film). The result is a two-dimensional image of the interior of an object. Dense materials, such as metals and bone, absorb a larger degree of the X-ray particles and thus appear brighter than less dense materials, such as soft tissue, in the developed film image. Fluoroscopy uses continuous X-ray imaging to gather real-time images of the internal structures of the body, as well as the internal components of a medical device. This technique is commonly used in angiography and orthopedic surgery to guide placement of devices and instruments inside the body. CT imaging uses numerous X-rays taken at different angles to generate a three-dimensional (3D) image set of the scanned object. This 3D volume can be viewed from different angles and be digitally adjusted. MRI uses a strong magnetic field and radio waves to create detailed images of organs and tissues within the body. Patients will sometimes receive an injection of intravenous contrast agent to improve the visibility of a particular tissue of interest.

Figure 1. A total hip replacement device with a modular sleeve (top left) was scanned using microCT and the region of interest was reconstructed into a 3D volume for examination (top right). An image slice through the reconstructed microCT volume revealed a contaminant (later determined to be bone) in the interface between the modular sleeve and the femoral stem of the device (bottom center).

While medical imaging is commonly used to visualize a device inside the body, it can also be used for examination of a device outside of the human body. For example, high resolution CT, called microCT (Figure 1), can provide both external and internal visualization of a device with voxel (3D pixel) resolutions on the order of micrometers (one-thousandth of a millimeter). There are also non-medical imaging techniques that are designed to view the internal and external surfaces of an object outside of the human body. Optical microscopy is a technique allowing magnification of a surface using lenses and visible light. Scanning electron microscopy (SEM) uses a high-energy beam of electrons to capture a highly magnified image of the surface of an object (Figure 2) with resolutions of less than 1 nanometer (one-millionth of a millimeter). While the above imaging methods are predominantly non-destructive in nature, there are others that are destructive. Focused ion beam (FIB) tomography is almost identical to a SEM, but uses a beam of ions rather than electrons. The focused ion beam can directly cut or "mill" the specimen surface with nanometer precision (about 10 nanometers). By careful control of the energy and intensity of the ion beam, very precise nano-machining can produce minute components or remove unwanted material to allow visualization of a cross-section of the device.

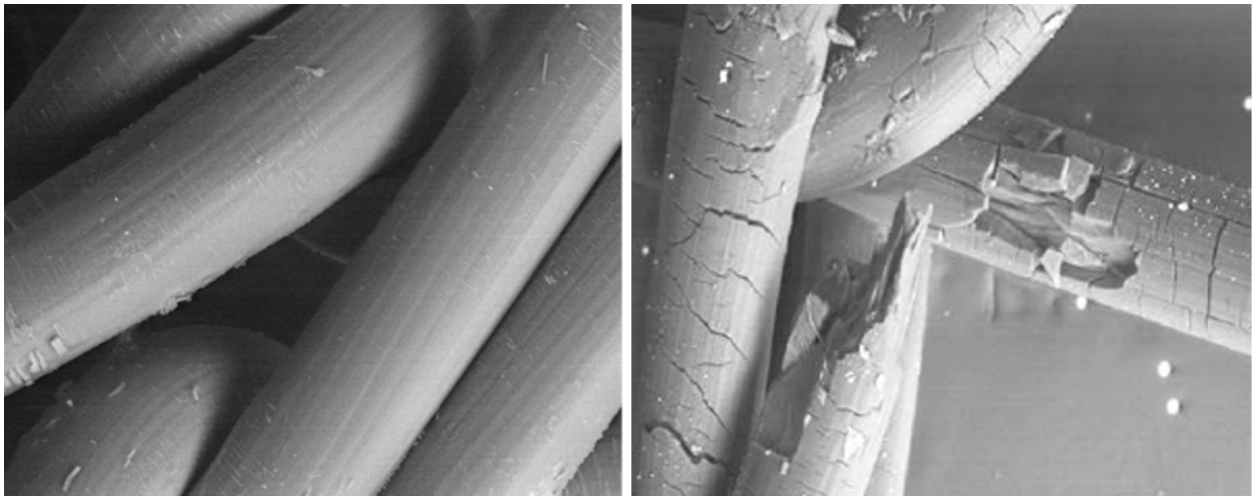


Figure 2. Scanning electron microscope image of an explanted pelvic mesh after removal of the outer biological layer (left) in contrast with an intentionally oxidized un-implanted mesh (right), demonstrating the difference in appearance and characteristics. The explanted mesh had non-degraded fibers, while the fibers in the un-implanted mesh had deep cracks and brittle damage.

Has a Component of the Device Failed? What Was the Mode of Failure?

In many product liability cases, there is an alleged failure of the device that must be investigated through inspection of the device. Different imaging technologies can provide non-destructive means for assessing whether failure has occurred, and if so, the method (mode) of the failure. Techniques, such as optical microscopy and SEM, can be used to examine the outer surface for cracks or breaks. Additionally, examination of the fracture surface at high magnification allows for the visualization of small, characteristic features to determine the mode of failure, such as whether a fracture was brittle or ductile in nature, whether corrosion or other forms of environmental degradation played a role, and what type of stresses a component was subjected to prior to failure. However, not all failures are evident on the outer surfaces of a device, thus imaging techniques such as X-ray imaging and microCT can be employed to non-destructively examine the interior features for cracks, fractures, and other failures. These techniques also allow one to identify the presence of inclusions or contaminants in the components and wear of the components.

What Was the Condition of the Device While in the Patient?

Many times it is of interest to investigate the condition of a device while it was in use in the patient's body, including how the components of the device were interacting with one another. Some questions regarding the condition of the device *in vivo* include: Did it move or migrate? Did it break or fracture? Did any of the components disengage or separate? How is it interacting with other biological

structures (*e.g.*, clots, tissue) or other devices/components? How is it sized relative to the anatomy? How well is it attaching to the body? This is where medical imaging can play an important role by helping to decipher these questions and providing evidence to support or refute medical and engineering opinions about how a device may have failed. For example, the position or condition of an inferior vena cava filter can be examined using a cavagram (X-ray imaging of the inferior vena cava). X-rays are frequently used to evaluate orthopaedic devices, while MRI imaging may be useful for examining polymeric (plastic) devices, such as surgical meshes. Likewise, medical imaging can also be used to illustrate the condition of the patient's anatomy or health condition prior to surgical treatment, to demonstrate comorbidities, complex anatomy, or how the use of the medical device helped to improve the patient's health condition.

How Do the Components of the Device Interface with One Another?

It is often crucial in both intellectual property and product liability cases to have a thorough understanding of the different components that make up a device and how each of those components interface with one another. In patent litigation, this is important in evaluating whether a specific claim limitation is present in the accused product, while in product liability cases, an understanding of how the components interface with one another allows for an assessment of the structural and functional integrity of the overall device. Utilizing optical microscopy and SEM imaging allows small components and fine details to be examined at high magnifications to gain a thorough understanding of how the components fit together. However, because these imaging methods only allow examination of the outer surfaces of a device, the device may need to be cut open or partially disassembled to image the components of interest. X-ray imaging and microCT are powerful tools for imaging the internal structures of a device without any disassembly, while FIB may be used to cut through the device which can then be imaged with SEM.

Was the Device Properly Manufactured?

In product liability cases, there is often a manufacturing defect claim that must be investigated through inspection of the subject device. Compositional information provided by SEM, X-ray imaging, and microCT can be used to determine if the material composition is generally consistent with the manufacturer's specification and to identify or rule out the presence of foreign materials and contaminants. Based on the general compositional information acquired via these imaging techniques, it can be determined if further, more advanced chemical analysis is merited. Additionally, imaging techniques allow for precise measurements of dimensions and features of a given device, allowing for comparison to manufacturer's specifications and engineering drawings to determine if the device and its components are consistent with the specifications. However, it is important to keep in mind that the use conditions of a medical device, such as wear on the bearing surfaces of orthopaedic implants, can impact the dimensions. Therefore, in cases where the dimensions of the subject device do not exactly match the manufacturer's specifications, it cannot automatically be assumed that there is a manufacturing defect present.

How Can the Evidence Be Presented in a Compelling Manner?

The adage "a picture is worth a thousand words" holds true in product liability and patent litigation cases where evidence and complex scientific concepts need to be portrayed in a compelling manner to jurors and judges. Images obtained from the various imaging techniques can provide key visual aids and demonstratives for conveying information, such as how a device functions and its internal structures, the state of an explanted device, and the failure mode of a device. In addition to two-dimensional images, data from imaging techniques, such as microCT, can be used to generate three-dimensional models of a device so as to create three-dimensional animations and schematics. These models can also be scaled up, if desired for small devices and components, and then 3D printed to create physical demonstratives for use during trial.

How Can You Determine Which Imaging Technique(s) to Use in a Given Case?

Each of the different imaging techniques discussed above offers distinct advantages, as well as disadvantages, such as allowing only imaging of the external surfaces of the device, potential image artifacts (distortion), size limitations in regard to how large of a device can fit in the given instrument, and compatibility with the materials in a given device. Depending on the objective of the imaging and what is being imaged, some techniques will work better than others. Generally, to conduct a thorough investigation of a medical device, a combination of multiple imaging techniques will be needed. Scientific and engineering experts can assist in recommending specific imaging

techniques to utilize in each unique case. After all, seeing is believing.

Kevin Ong, Ph.D., P.E., is a Principal Engineer in the Biomedical Engineering Practice at Exponent, Philadelphia, PA. He provides engineering consulting services related to product liability and intellectual property litigation matters, as well as product design consulting services to the medical device industry. His background is in failure analysis of medical devices/equipment, with a focus on how patient, surgical, and device factors influence performance.

Felicia Svedlund, Ph.D., is a Managing Scientist in the Biomedical Engineering Practice at Exponent, Menlo Park, CA. Dr. Svedlund applies her background in biomaterials, materials characterization, and failure analysis to provide scientific and engineering consulting services to medical device companies, as well as product liability and intellectual property litigation. She utilizes her experience in materials characterization and imaging, including microCT, to inspect and analyze explanted medical devices in order to understand use conditions, performance, and/or failure modes.

Litigation Update

Taylor v. Mentor Worldwide, LLC: "Evolved" Expert Opinion or Ambush Trial Tactics?

By David J. Walz and Caycee D. Hampton


The Eleventh Circuit recently reached a controversial conclusion involving pretrial disclosure requirements, the duty to supplement expert reports, and adequate penalties for failure to comply with the rules. In *Taylor v. Mentor Worldwide, LLC*, 940 F.3d 582 (11th Cir. 2019), one of more than 800 cases previously consolidated in the multidistrict proceeding known as *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, the court tolerated a significant inconsistency between the Rule 26 report and trial testimony of the plaintiff's causation expert.

In his written report, the plaintiff's expert concluded that the plaintiff "suffered pain and chronic inflammation that was primarily attributable to ObTape's faulty design," a conclusion that he reached "largely through a process of elimination." *Id.* at 588. At his deposition, however, the expert "expressed less confidence in the opinions" stated in his report. *Id.* The expert "conceded that none of Taylor's medical records showed an erosion of her ObTape," conceded that there could be other causes of the plaintiff's injury, and "stated that he could not say 'to a reasonable degree of medical probability'" that the plaintiff's ObTape caused her injury. *Id.* at 589. Furthermore, the expert "expressed skepticism" about plaintiff's other expert's "degradation theory." *Id.*

At trial, plaintiff's expert had yet another change of heart. This time, the expert opined that "ObTape caused a thinning of Taylor's urethral tissue, [or] an 'erosion' of the urethra," despite the fact that he "had not opined on Taylor's urethral thinning in his report or deposition . . . ." *Id.* The expert "conceded that his opinions had 'evolved and changed' in this respect as a result of having gone over Taylor's medical records 'with a fine-tooth comb' and answering some of the questions Taylor's attorneys had posed to him after his deposition." *Id.*

At the conclusion of his direct examination, Mentor moved to strike the expert's testimony under Rule 37, arguing that the expert's trial opinions "were not disclosed in his Rule 26 report" and "differed from his deposition testimony." *Id.* Rule 37 provides, in relevant part:

> If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the court, on motion and after giving an opportunity to be heard:
>
> (A) may order payment of the reasonable expenses, including attorney's fees, caused by the failure;
>
> (B) may inform the jury of the party's failure; and
>
> (C) may impose other appropriate sanctions . . . .

Fed. R. Civ. P. 37(c)(1).

The district court denied Mentor's motion to strike, "but granted the alternative relief it requested: the opportunity to prepare overnight for [the expert's] cross-examination." 940 F.3d at 589. Upon conclusion of the cross-examination, Mentor renewed its motion to strike the expert's testimony, "arguing that the opportunity to prepare for cross overnight had failed to alleviate the prejudice resulting from [the expert's] previously undisclosed opinions." *Id.* at 590. Again, the district court denied Mentor's motion, "concluding that Mentor had done 'a fine job in that cross-examination' such that it was 'clear . . . there was no prejudice.'" *Id.*

The Eleventh Circuit acknowledged that the "urethral erosion" issue constituted a "true inconsistency between [the expert's] Rule 26 report and his trial testimony[,]" but found no abuse of discretion in the trial court's denial of the motion to strike. *Id.* at 592. The court reasoned:

> [W]e have no doubt that [the expert's] Rule 26 report should have been supplemented prior to trial to flesh out his "evolved" opinion on that issue. We do not condone Taylor's conduct in failing to make that required disclosure. But striking [the expert's] testimony was not the only viable response under the circumstances.
>
> Rule 37 gives a trial court discretion to decide how best to respond to a litigant's failure to make a required disclosure under Rule 26. *See* Fed. R. Civ. P. 37(c)(1) . . . . The district court's decision to allow Mentor additional time to prepare for [the expert's] cross-examination, rather than striking his testimony entirely, was not an abuse of that discretion.

Id. at 592–93.

The dissenting opinion enthusiastically rejected the majority's determination that the plaintiff's Rule 26 violation was harmless, reasoning that "[t]his was no mere 'evolution' in [the expert's] opinion. This was a complete about-face." *Id.* at 610 (Tjoflat, J., dissenting). As a result, the expert "was not the [same] expert Mentor encountered at the pretrial deposition. He was a new expert, one whose identity [the plaintiff] deliberately withheld." *Id.* As explained in the dissenting opinion, the plaintiff's tactics represent exactly "the procedural abuse that [Rule 37] is meant to discourage," and "now that this behavior has received the majority's seal of approval, I fear that this is not the last we'll see of this trick." *Id.* at 613–14.

For now, the *Taylor* opinion is an outlier compared to existing Rule 37 authority in the Eleventh Circuit and elsewhere. Most courts interpret Rule 37 to require strict adherence to the disclosure requirements of Rule 26; namely, that an expert's report "must contain . . . *a complete statement of all opinions the witness will express and the basis and reasons for them*[.]" Fed. R. Civ. P. 26(a)(2)(B)(i) (emphasis added). *See, e.g.*, *Mitchell v. Ford Motor Co.*, 318 F. App'x 821, 825 (11th Cir. 2009) (affirming district court's order granting motion to strike expert testimony where plaintiff "did not properly disclose the necessary scientific basis" for the expert's opinion "in a timely fashion pursuant to Rule 26," which "left [the defendant] unable to depose fully [the expert] or question what he relied on to form his opinions"); *see also Dynamic Concepts, Inc. v. Tri-State Surgical Supply & Equip., Ltd.*, 716 F. App'x 5, 12 (2d Cir. 2017) (affirming order precluding expert testimony where plaintiffs failed to timely disclose witnesses as experts); *Poulis-Minott v. Smith*, 388 F.3d 354, 358 (1st Cir. 2004) ("'[T]he required sanction in the ordinary case [of a failure to disclose information required by Rule 26] is mandatory preclusion."); *Brumley v. Pfizer, Inc.*, 200 F.R.D 596, 603–04 (S.D. Tex. 2001) (striking untimely opinions of expert on causation and adequacy of warnings that went beyond those disclosed in his original expert report).

If any silver lining exists in *Taylor*, it may be that subsequent courts recognize the importance of Rule 37 and treat *Taylor* as a narrow holding limited to its specific facts. *See Pringle v. Johnson & Johnson*, No. 13-81022-CIV, 2019 WL 6723822, at *5 (S.D. Fla. Dec. 11, 2019) ("Plaintiff's belated attempt to bring a new expert opinion into the case is not justified. Nor is it harmless, since discovery has been closed . . . and the summary judgment briefing [is] completed . . . ."). The dissenting opinion in *Taylor*, however, raises a realistic concern that the majority opinion may signal an unwanted flexibility by the court that worsens the risk of trial-by-ambush.

The plain purpose behind the disclosure rules is to prevent the unfair tactical advantage gained by failing to unveil an expert or his opinions. A party must be able to rely upon an expert report in crafting a motion for summary judgment or preparing for trial without the "gotcha" factor of the opposing party lying in wait and offering evidence at the last moment reflecting opinions not timely disclosed. The *Taylor* opinion undermines established principles of discovery procedure aimed at eliminating surprise. Ideally, this Eleventh Circuit opinion will remain an aberration among decisions assessing critical expert issues.

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Caycee D. Hampton is a litigation associate in the Tampa office of Carlton Fields, P.A. Caycee concentrates on the national and local defense of complex litigation for pharmaceutical, medical device, and cosmetic manufacturers in federal and state courts. Her practice includes general products liability, mass tort, premises liability, and medical malpractice cases.

Practice Pointers

Preparing for and Defending Pharmaceutical Sales Representatives Depositions: Three Tips

By Joseph J. Stroble and Alicia Netterville


Plaintiffs' counsel in pharmaceutical product liability cases continue to pursue depositions of company sales representatives and seek to elicit testimony supporting their common theme that pharmaceutical companies disregard the health and safety of their consumers in the dogged, single-minded pursuit of sales and profits. In a recent pharmaceutical product liability multi-district litigation, core discovery consisted of depositions of the plaintiff, the prescribing physician, one treating physician, and a sales representative selected by the plaintiff. Based on our experience in that litigation we offer below three targeted practice pointers for preparing for and defending pharmaceutical sales representative depositions.

Be the Expert on Plaintiffs' Litigation Themes and Supporting Proof and the Sales Representative Specific Facts

Sales representative depositions are typically taken after significant discovery has been conducted addressing product research and development, clinical trials, regulatory activity and communications with FDA, drug labeling, pharmacovigilance, and general marketing. As such, plaintiffs' litigation themes will have been well-formed by the time your sales representative is in the witness chair.

Plaintiffs' counsel will likely not favor a "discovery"-type deposition where counsel generally inquires as to the nature of the representative's background, training, and responsibilities. Rather, plaintiffs' counsel will look to conduct a targeted cross-examination hoping the witness will provide sound bites (that can later be played for the jury) in support of plaintiffs' already established themes. You'll want to be an expert on all of plaintiffs' themes and supporting proof so you can best prepare your witness for those lines of examination.

Expect that a number of plaintiffs' litigation themes will not touch on representatives' areas of responsibility. For example, plaintiffs may contend that the Company refused to conduct a clinical trial that plaintiffs maintain should have been conducted. Plaintiffs may argue that the medication's label failed to include a necessary warning or safety information/data.

Even though representatives have no involvement in the conduct of clinical trials or the content of a medication's label, plaintiffs' counsel in the above-referenced litigation were not deterred from cross-examining the representative on those areas. Plaintiffs' counsel will try repeatedly to push the representative to speculate and provide damaging testimony on matters outside her/his areas of involvement/responsibility.

As an expert on plaintiffs' litigation themes, you can appropriately familiarize your witness with those themes and alleged supporting proof, as well as the company's counter positions. This will decrease the chances at deposition that your witness will feel surprised or sense there is something she/he should know but doesn't. Rather, your witness will remain composed in the pressure of the moment, and armed with "safe harbors," refuse to speculate as to matters outside her/his areas of involvement/responsibility.

Typically, representatives are deposed after the depositions of the plaintiff and the prescribing and treating physicians. Ahead of your witness prep sessions you'll want to know the case specific deposition testimony so you can

appropriately address any testimony that could impact your witness.

Expect plaintiffs' counsel when examining your witness to take liberties with the testimony of the prescribing and treating physicians. For example, "Are you aware that (prescribing physician) testified that if the clinical trial data were just as I have now shown you it to be, that (prescribing physician) testified that she would have wanted to have that information, and that if she had had that information, she would have prescribed a different medication to plaintiff?"

Make your witness aware of this tactic. The representative should not accept as true plaintiffs' counsel's characterization of witness testimony. If your witness has not read the depositions given by plaintiff and the prescribing and/or treating physicians, she/he is not placed in a position of having to comment upon or vouch for such deposition testimony (unless shown the actual testimony at deposition).

Spend Sufficient Time with Your Witness So You Build Rapport and Understand Their Concerns About Both the Deposition Process and Substantive Matters

Spend enough time with your witness so you build rapport with her/him. The importance of this cannot be overstated. Most witnesses dread the prospect of cross-examination. A witness' unfamiliarity with the process can cause apprehension. There may be specific substantive areas of examination that a witness fears or hopes to avoid. It takes time to understand any process and/or substantive concerns and the reasons for them so that you can then properly address them.

Securing adequate time with a witness can be a challenge. Representatives are busy, often on the road, and have numerous obligations. Time spent in deposition prep is disruptive and time away from the representative's real job. Your witness may feel that spending ample time in prep is not necessary, that she/he is "good to go" already. A witness may be in a sort of denial and keep putting things off. From the company standpoint, witness prep is expensive. Despite these challenges, we've never had a witness post-deposition complain about being too prepared or spending too much time in prep. Rather, each witness has expressed appreciation for the time spent with her/him.

In terms of a suggested structure for the prep sessions, consider an initial meeting with your witness where you provide an overview of the litigation and the deposition process. The witness can discuss her/his educational and employment history, experience with the company, and what a typical work day is like for the representative. At a second session you should consider a substantive discussion of plaintiffs' themes and tactics, witness responses and safe harbors, an extensive discussion of your witness' detailing of the product, and deposition best practices.

After this work has been done, we strongly recommend conducting mock cross-examinations. In our experience mock cross-examinations are the most helpful component of witness prep. It is best that someone unfamiliar to the witness be brought in to conduct mock cross-examinations.

In this way you create some discomfort for the witness and give the witness a sense for what it will be like on deposition day. We believe it's best for the mock-examiner to err on the side of being too aggressive with the witness, without being over-the-top. We like when witnesses tell us post-deposition that the mock examinations were more difficult than the actual deposition. Consider mock examination modules that last for 30 minutes to an hour, then break so you can debrief your witness and provide constructive criticism and comments.

Your witness is likely to feel most deflated after the mock cross-examination, as this comprises the "tearing down" phase. After the mock cross-examination(s), the focus should be on building the witness back up and restoring confidence. We do not recommend any mock cross-examination the day before the deposition; rather, consider a two-hour prep session where you and the witness go over the high points of themes, safe harbors, and best practices, and have the witness leave refreshed for the next day.

Prepare the Witness for the Shaming Tactic Employed by Plaintiffs' Counsel

Plaintiffs' counsel employ a sort of "shaming technique" in an effort to make the representative uncomfortable and increase the chances the witness will provide damaging testimony. Plaintiffs' counsel will try to make a sales representative feel defensive about the nature of her/his job and any success achieved. In addition, plaintiffs' counsel will try to make the representative feel that her/his knowledge of the product and its label is inadequate.

This tactic involves plaintiffs' counsel mischaracterizing the nature of the representative's position and her/his responsibilities. It's important to prepare your witness for this tactic so that she/he doesn't become defensive and susceptible to offering speculative testimony. An effective

way to counter the shaming technique is to emphasize in witness prep what the representative does in the real world and her/his responsibilities, and contrast that with plaintiffs' counsel's mischaracterizations of those matters.

Plaintiffs' counsel will try to make your witness feel like she/he is interested only in securing prescriptions, arguing that the more the product is prescribed, the more money the representative makes. Plaintiffs' counsel will have reviewed your witness' resume and LinkedIn page and will address in pejorative fashion any incentives earned. (Some witnesses feel the need prior to their deposition to edit their resumes or LinkedIn pages to remove any references to pre-pharma sales positions, sales rankings, earned incentives, etc. Inform your witness that such is not necessary or advisable and will only lead to more questions in the deposition.)

There is of course a marketing component to the representative position, but that isn't something the witness should be ashamed of or deny. The objective is to give the jury an accurate understanding of the position and its responsibilities.

A representative is a resource to health care professionals. The representative provides information to prescribers, but the prescribing decision is of course left to the prescriber. The company provides the representative with the information presented to health care professionals. In order for a representative to earn an incentive, her/his detailing of the product must comply with company/legal guidelines. If your witness can focus on these fundamentals of the position, she/he will be better positioned to counter plaintiffs' counsel's characterization of the position.

Plaintiffs' counsel will look to shame your witness as to her/his command of the content of the label. The label is the foundation of the representative's discussion of the product, and representatives take pride in their knowledge of the label. Plaintiffs' counsel may take issue with language contained in the label or argue that based on clinical data the company failed to include appropriate language in the label. This can lead to a rather detailed cross-examination of your witness regarding clinical trials, and what is/is not in the label and the reasons therefor, matters outside the representative's purview.

Plaintiffs' counsel will present the examination as anchored to the label, but again most of the examination involves matters outside the label. If the text at issue does appear in the label, it is often cherry picked by plaintiffs' counsel for lawsuit purposes and has not been raised by healthcare professionals to representatives in the conduct of their business.

When faced with this line of examination the witness may feel she/he should know something she/he doesn't and feel compelled to speculate. Here again it is best in prep to emphasize the realities of the representative's position. A representative can only discuss what is in the label. The representative has no involvement in what language does and does not appear in the label. A representative is not provided with clinical trial data absent what appears in the label. A representative has no involvement in the conduct of clinical trials.

Key Takeaways

1. Plaintiffs' counsel seek to use deposition testimony of sales representatives to support their contention that pharmaceutical companies disregard the health and safety of consumers in favor of the single-minded pursuit of sales and profits.
2. You can best prepare your witness for deposition when you are an expert on plaintiffs' litigation themes and supporting proof and the representative specific facts.
3. Spend the time it takes to develop a rapport with your witness and understand and address her/his concerns about the deposition process and any substantive matters.
4. Counter the shaming technique employed by plaintiffs' counsel by having the representative focus on the realities and responsibilities of her/his position.

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Dealing with Pro Se Product Liability Plaintiffs: Constructive Engagement, De-escalation, and Ethical Confrontation

By Gregory E. Ostfeld

Pro se plaintiffs represent a modest and often overlooked subset of the typical product liability defense portfolio, yet the ability to manage such cases effectively can return dividends in reduced cost, effort, and pain. Approximately two percent of plaintiffs in product liability suits are pro se litigants. *See* Mitchell Levy, Comment, *Empirical Patterns of Pro Se Litigation in Federal District Courts*, 85 U. Chi. L. Rev. 1819, 1840 (2018) (analyzing empirical data on federal lawsuits from 1998 to 2017). Of these, about five percent end in a judgment for the plaintiff, well under half the rate of represented plaintiffs. *Id.* at 1842–43.

Notwithstanding their comparatively low filing and success rates, pro se product liability cases present a host of challenges differentiating them from represented party lawsuits. Pro se plaintiffs often have a deep emotional investment in their cases, are mistrustful of defendants and their counsel, can be angry or unreasonable, can misapprehend scientific, medical, and technical issues, and are less familiar with procedure and law. They may also occupy disproportionate time and attention with frequent communications, frivolous or disorganized filings, inappropriate requests for guidance, or unreasonable settlement demands. These challenges compete with client expectations that pro se actions should be inexpensive to defend and quickly dismissed.

These opposing currents can collide in a lose-lose scenario for defense counsel despite the low risk of an actual adverse judgment—where the client expects a near-immediate favorable resolution, the opponent consumes disproportionate time, effort, and emotional energy, and the court indulges impenetrable pleadings and filings in the interest of fairmindedness. Yet long experience with pro se litigants, coupled with a review of the legal, empirical, and psychological literature, indicates these cases need not degenerate in this way. The following five principles, consistently applied, can steer the course of a pro se case to a faster and more satisfactory outcome for all involved.

Respect. The guidepost for all interactions with pro se litigants should be respect for them as persons, as litigants, and as adversaries. This is easy to say but can be difficult to achieve. Psychological literature indicates that pro se status has a profound signaling effect on lawyers, generating negative stereotypes about the claimant and large downward effects on settlement offers. *See* Victor D. Quintanilla, Rachel A. Allen, and Edward R. Hirt, *The Signaling Effect of Pro se Status*, 42 Law & Soc. Inquiry 1091 (2017). Put simply, attorneys are more likely to view pro se plaintiffs as unimportant and unsophisticated adversaries with frivolous claims and bad (or incomprehensible) arguments. These perceptions, justified or not, can become a self-fulfilling prophecy as disregard of the pro se litigant causes early resolution opportunities to be missed, generates anger and insecurity on the part of the plaintiff, and spirals into a cycle of miscommunication, mistrust, and prolonged conflict. Setting aside biases and adopting a respectful approach and tone interrupts this cycle, defuses plaintiff anger or intimidation, and creates opportunities for constructive engagement, early resolution, and interactions that are more productive and less emotionally charged for both sides.

Clarity. The ethical framework for dealing with unrepresented parties is set forth in Model Rule 4.3 of the ABA Model Rules of Professional Guidance and Section 103 of the Restatement of the Law Governing Lawyers. Rule 4.3 states that a lawyer dealing with an unrepresented person

"shall not state or imply that the lawyer is disinterested," shall make "reasonable efforts" to correct misunderstandings of the lawyer's role, and "shall not give legal advice" other than to secure counsel. Section 103 of the Restatement prohibits a lawyer from misleading a nonclient concerning the identity and interests of the person the lawyer represents, and requires reasonable efforts to correct misunderstandings. These specific and targeted obligations speak to a larger guiding principle in dealing with unrepresented plaintiffs—the importance of clarity. Pro se plaintiffs may not understand their relationship with opposing counsel. They may at one extreme try to use defense counsel as a substitute for their own counsel, asking legal or procedural advice and seeking help to achieve their goals, or at the other extreme view defense counsel as a mortal enemy to be abused, blockaded, and opposed at every step. To avoid these extremes, it is helpful to set clear expectations at the outset of the case, communicating (1) defense counsel is an adversary and represents the interests of the party the plaintiff is suing, (2) defense counsel will treat the plaintiff with courtesy and professionalism and will seek the same in return, and (3) defense counsel will work with the plaintiff to move the case forward and (if the client seeks early resolution) to resolve it, but cannot provide legal advice or guidance.

Early Outreach and Resolution. The first contact and character of early interactions between the plaintiff and defense counsel take on magnified importance in pro se cases, as these initial exchanges set the tone for the parties' relationship. Pro se litigants are more likely than represented parties to misunderstand an initial filing as hostile, aggressive, or exploitative. A "file first" strategy is thus not well-suited to pro se cases. Before filing a dispositive motion, responsive pleading, or even an appearance, defense counsel should consider an initial round of communication to introduce himself or herself to the plaintiff, to inquire into the factual details of the claim, to ask what the plaintiff is seeking from the litigation, and to state what defense counsel will do next and why. This communication establishes the themes of respect and clarity from the earliest stages of the case and is more likely to result in open and constructive exchanges throughout the case. Early engagement can also create opportunities for early resolution. Though pro se plaintiffs at times come to cases with unrealistic expectations of the value of their claims, early engagement and a serious, respectful conversation about the plaintiff's alleged injuries, out-of-pocket expenses, and goals can lead to reasonable demands and valuations much earlier in the litigation cycle than is common in represented party cases. Not every pro se case is suited to early settlement, but early opportunities for a quick and amicable resolution should not be overlooked.

Investigation and Discovery. Before filing a product liability suit, many pro se plaintiffs will first attempt to make their complaints and resolve their claims directly with the defendant. Initial investigation should therefore include inquiry into whom is responsible for handling such complaints on behalf of the client (*e.g.* medical safety), together with collection of all pre-suit communications, medical records, and other documents given to the client and all investigative files and event reports prepared by the client. The plaintiff's pre-suit communications and the records he or she discloses can offer valuable insight for purposes of evaluating whether to pursue early case resolution. Informal or formal discovery also affords an opportunity to learn the details of the plaintiff's case that may be lacking from pro se pleadings and court filings. Though long lists of numbered interrogatories and document requests with multiple sub-parts are unlikely to yield much in the way of productive responses, an early request for initial disclosures and copies of the plaintiff's medical and other records, coupled with a request for signed authorizations, is simple and likely to lead to a more meaningful response. Other discovery requests should similarly be short, simple, direct, and easy to answer, with the goal being to gather enough information to take the plaintiff's and treaters' depositions and learn the remaining details of the case. Requests to admit can be a tempting tactic to secure valuable admissions from a non-responding plaintiff, but keep in mind they are likely to be viewed skeptically by the court and, if used, should be limited to those facts the defense has a reasonable, good faith basis to believe are genuinely true and merit admission.

Dispositive Motions. Many pro se cases will conclude with dispositive motion practice, either at the dismissal or summary judgment stages. None of the preceding principles are meant to discourage such practice. The primary obstacle to meritorious dispositive motions in pro se cases is resistance from judges inclined in the interest of fairness to give the pro se litigant every opportunity to state a viable claim. This understandable tolerance can be addressed through a combination of tone, engagement, and education. The tone of pleading papers should be polite, respectful, sympathetic to injury, and constructive in presenting the plaintiff's claims fairly and accurately rather than appearing to exploit the pro se litigant's lack of sophistication. Counsel should use available opportunities at court appearances to make clear to the court that defense counsel has engaged constructively with the plaintiff, that an attempt has been made to investigate

and understand plaintiff's claims, and that the dispositive motion is the outcome of this process and not an attempt to avoid such engagement. In the same vein, counsel should use follow-up motions to dismiss (where leave to amend is granted) or summary judgment motions to educate the court on the valid grounds for disposition and to alleviate fears the court may be prematurely terminating a potentially meritorious claim. Judges are concerned with providing both a just outcome for pro se litigants and a fair process en route to that outcome. By partnering with the court in supplying a fair process and persuading the court the outcome sought is the right result, defense counsel can secure the final dismissal or judgment sought.

None of this is to suggest that every pro se case can be addressed quickly, easily, or formulaically. Pro se cases are as different from one another factually and legally as any other case, and pro se plaintiffs run the full gamut of personalities from quiet and easygoing to temperamental and mistrustful to abusive and even unbalanced. But understanding the different psychological, legal, ethical, and factual makeup of pro se cases as compared to represented party litigation helps lay a framework for more efficient, more satisfactory, and more successful outcomes for the client, defense counsel, and even the pro se litigants themselves.

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