

Preparing the Company Witness in a Drug or Medical Device Case

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An increased volume of litigation has recently been filed against pharmaceutical and medical device manufacturers. Adverse publicity about allegedly injured consumers, the large volume of direct to consumer advertising and the expansive volume of information about drugs/devices available on the internet, means a more educated jury panel might be selected to hear a company's defense to claims of defective products and/or false advertising. With the spotlight focusing intently on these trials and the media consultants debriefing the testimony of key witnesses for interested audiences, there is an even greater sense of anxiety and fear experienced by the corporate witness who will be called to "tell the company story" and be subjected to lengthy cross examination about innumerable documents, many not written by or even seen by the witness prior to litigation. All of the enhanced visibility reinforces the need for legal counsel to cover the fundamental principles of witness preparation. Initial considerations should also include whether the current defense counsel can prepare the witness, the scope of legal representation that can be provided, and which information and communications will be deemed privileged. Early recognition must also be given to the shroud of potential criminal liability for both the witness and defense

counsel under state and federal criminal statutes that deal with many of the marketing and costs attributes of the industry.

In the Beginning . . .

Before any meetings with the witness, counsel should familiarize herself with the industry and product. Great strides towards gaining the witness's confidence are made when the lawyer has done her homework, is acquainted with the issues and assures the witness he will not be starting from scratch to teach defense counsel the aspects of the case that he reasonably expects counsel should already know. Learn about the product through a review of its development documents and government agency communications. Analyze the annual reports and statements submitted, not only to the FDA, but also to the Federal Security Commission. Collect and read/watch the company's advertisements issued in print, on television and on the Internet. Take a look at the company's policies to get a sense of whether the policies convey an employee friendly environment. The preparatory education is akin to preparing to meet your prospective in-laws – know enough about them that you can converse with confidence and not embarrass yourself while allowing them to share the finer details of their lives.

Setting the Stage

Preparation of a corporate witness has often been plagued by the difficulty of getting the witness to devote sufficient time and attention to reviewing documents and meeting with lawyers and perhaps trial consultants. These time constraints may even be heightened with downsizing, restructuring or transactional proceedings that move at lightning speed and require immediate attention. If the witness is a research and development director or deals with the regulatory side of the company, find out what the witness is currently engaged in and whether critical deadlines or submissions are approaching. By providing advance notice and information about the amount of time expected for the witness's preparation, including clarity that this will not likely be a one session only event, you help create a working relationship built on respect for the witness's time and responsibilities. Ahead of meeting with the witness, define the role defense counsel will play while working with and advising the witness. Part of the answer to that question depends on the type of deposition or trial testimony that is requested. The focus of the preparation should be on the witness's participation and knowledge of the subject for which he is being called, and related subjects about which opposing counsel "thinks" he should have knowledge.

However, if the witness is responding to a FRCP 30(b)(6) deposition notice as the corporate representative, the scope of preparation is much broader and requires far more attention to the details. Under federal case law, a corporate representative is speaking on behalf of the company and unless counsel formally designates the areas of

testimony that will be provided by the witness ahead of the deposition, the scope of inquiry is broad and any answers of “I don’t know” or “I don’t remember” will be answers made on behalf of the company. If the witness, who is broadly designated as the responsive witness to a 30(b)(6) deposition, lacks knowledge of certain subject matters at the 30(b)(6) deposition, plaintiff may successfully move in limine to limit the scope of testimony about the company’s knowledge and restrict the deposition testimony to that offered at the time. Plaintiff’s counsel may also seek to exclude testimony from additional knowledgeable witnesses unless they also respond to the deposition notice. The watchword is to thoughtfully review the deposition notice and areas of inquiry and then select the witnesses most knowledgeable to respond. Witnesses must also be trained to testify that while they can be responsive to discrete areas of inquiry contained in the deposition notice, the company works on a team approach and other witnesses will respond to areas outside the expertise of the witness. Witnesses need to become comfortable with “staying in their box” of knowledge and expertise and practicing/thinking when it is appropriate to say “I don’t know” or “that question would be more appropriately directed to witness X.” As experienced counsel knows, the witness who can’t abide by this rule and guesses or speculates often sets the stage for disaster.

Executives are more comfortable with boardroom surroundings and conferring with directors than communicating with the members of the jury. In addition, many executives are used to being in control, rather than spending days in a room filled with attorneys, seemingly being subjected to the same questions over and over again. The

initial preparation needs to include a road map of what will be required, who the players are and the ground rules. Reminding the witness that the average juror has less than a 10th grade education, and has more likely been an employee, not a manager, will also help set the right stage and tone for his testimony. Some executives grasp the necessary communication style when asked to provide responses in a manner that their 10 year old daughter could understand, or in the same way they speak to a Sunday school class or a boy scout troop while explaining the steps to achieve the next merit badge.

Executive witness preparation requires a skillful conveyance of the extreme importance for being prepared, answering knowledgeably and presenting testimony accompanied by an attitude of interest, not arrogance. A common problem is facilitating the transfer of roles from being the executive who is used to “running the show” and making decisions to being the witness who must be responsive, rather than directing the deposition. Executives need only be reminded of the damaging videotape testimony presented by Bill Gates in the Microsoft trial during which he exuded arrogance, a lack of knowledge about many of the critical allegations and provided nonresponsive answers. One must wonder if that horse refused to be bridled or if the ranch hand lawyers failed to reinforce the need to communicate the legal defense to a “judicial”, not boardroom, audience.

Unlike an executive who may have developed a self image and comfort level with

presiding over transactions, board meetings and marketing adventures, the technical and research staff may possess a completely different skill set. Many of these incredibly bright scholars have never served as speakers or college faculty. Little professional time may have been spent preparing for speaking presentations. The comfort zone within which many technical witnesses exist revolves around the technical and medical jargon that the witness uses every day. Many of the scientific procedures/research that they deal with takes years to develop. Careful scientific analysis of many factors underlying research and development may have produced a mindset of being very reflective and contemplative. While being deposed, the jargon that will be interjected into the witness's world will be legal jargon...for example, the foundation for identifying a document or the multiple objections made to questions and sometimes heated colloquy among counsel. Don't forget that the witness needs assistance to first understand the venue of the deposition, the players and the "language" of the lawyers to minimize the witness's anxiety and maximize the deposition performance.

Technical witnesses should be advised that many of the attorneys are reasonably well versed in the development, approval, regulation and government oversight for drugs and medical devices. Caution should be encouraged so the witness does not become too comfortable with the attorney who appears to be "talking her language." At the outset, and repeatedly throughout the deposition preparation, the witness should be reminded of the three roles ascribed to deposition participants:

The examining lawyer has the duty to ask legally sufficient questions to elicit the information needed for her case.

The lawyer defending the deposition has the duty to object and make a record for the judge to review at a later date regarding the appropriateness of the questions and any privilege issues.

The witness has the duty to listen carefully, understand the question and then **ONLY** answer the question asked.

Technical witnesses, as well as executive witnesses, must appreciate the need to convert professional jargon into “jury speak”. The company’s defense is only as good as its witnesses’ abilities to explain what they do, why they do it, and why their actions were sufficient to meet the legal standards in ways that a jury will understand. Most juries are not comprised of a large number of individuals with advanced education. However, many jurors have worked in businesses or manufacturing plants where there is a team approach or overlapping departments that all perform a function that contributes to a safe product or delivery of service. Each witness must be able to explain the following in simple terms: his job duties, how his job fits in with others, the limitations of his job and how the company has checks and balances to make sure the

information/project he completes is reviewed or processed carefully by others who need to know and evaluate the product.

Videotaping the witness preparation is essential. Protection of the testimonial preparation materials is critical and each document, videotape, drawing, etc., must be noted as attorney client privileged and attorney work product. Plaintiffs' attorneys are more frequently asking witnesses to identify whom they have worked with and if a trial consultant was used. Obviously a misstep by the witness might lead to production of potentially damaging material. If the witness is required to acknowledge that he worked with a trial consultant, the witness should be instructed to respond and say, "Yes. Since being a witness is new to me, I appreciate the help of someone with expertise that I don't have." Witnesses need to watch the videotapes of the preparation sessions several times to observe their mannerisms and answers which were both favorable and unfavorable. Practicing responses to the "hot" areas of inquiry should also include discussing the witness's mannerisms that need to be changed to make him more credible and less anxious appearing.

Don't assume that witnesses who are still employed will be willing to invest the time and energy to present well at deposition or trial. Witnesses may have a company to run, a submission to make or a board of directors meeting to attend. Consideration should be given to multiple preparation sessions of discreet periods of time to address specific issues. The sessions should be held, to the extent possible, at a time/place of least distraction for the witness. Nonetheless, counsel must control the setting and the

preparation should be conducted away from the executive witness's office, without interference from pagers, cell phones, e-mail, etc. The company can survive without the executive's input for a few hours at a time, and may have a greater likelihood of heading off more litigation and legal expenses if time and energy are invested preparing for the deposition or trial. Likewise the technical/regulatory witness should be prepared in a setting where his attention is completely devoted to the deposition preparation.

There are numerous articles on the scope of witness preparation, particularly for a FRCP 30(b)(6) deposition, that are cited at the end of the article and won't be repeated. However, the recent large punitive damages verdicts and extensive press coverage of corporate financial misdealings, Senate hearings and the general distrust jurors hold towards corporations make the communication aspect of testimony the key to success. The executive must appear as if he cares about the corporate employees, not just the corporate profits. He must be familiar with the documents, and if he wasn't familiar with the documents at the time they were written, he must have a logical explanation that does not sound like corporate "passing of the buck". Jurors will accept an explanation about delegation of duties, if they are told why the executive selected other department managers to handle the employee's situation, why the manager was believed to be qualified to do the job and why the executive reasonably relied upon the person to handle the issue without the need to consult with the executive.

The technical/regulatory witness testimony needs to be artfully crafted to balance the

need for scientific explanations, with a clear message that the work being done is to ultimately improve consumer health, life style, longevity, etc. Most of the jurors will have been prescribed a medication and/or someone they know has used a medical device. Many jurors hold the belief that those who design and test drugs and devices are looking out for them, rather than have a motive just to make a profit. Conveying the human aspect of a drug and device manufacturing corporation can't be emphasized enough. If allowed and the reason is a convincing one, ask the witness why he pursued his additional degree or studies in the area and why he selected your client as the company he wanted to work for. As is often stated, putting a human face on the company and presenting a defense that is about the "people" and not the corporations can be successfully done when the process starts during witness preparation.

Handling the Witness Who Is No Longer with the Company

The reason for the witness's separation will determine whether the attorney-witness relationship will be prickly like cactus or smooth as silk. If the separation was amicable due to elective retirement, a better offer or other circumstances, the likelihood of participation for testimony will be greater. Don't be fooled that the amicably separated witness will give you all the time in the world. If the witness relocated to a different company with the same or greater responsibility, he may have the same time constraints of running the company or his department and not embrace this distraction from his duties. Even if loyal to the former employer and perhaps "grateful" for all of the experiences that were a springboard to his additional success, he is busy. Prior to the interview and witness preparation, determine the role he plays in the litigation, how long he has been separated from the company and the likelihood that he has been away from the company long enough to have become unfamiliar with the details of the company's procedures. Provide copies of all of these pertinent documents ahead of the preparation.

Play on any past loyalties to the company. Obviously if he is now more successful due to past opportunities at the defendant corporation, he may favorably provide testimony about the company. A common response from a former executive is that since he has so little time and no current relationship with the company to prompt him "studying" for the deposition, he will answer what he can and avoid what he can't answer by responding with "I don't know" rather than refreshing his memory. Asking the executive

how he would want one of his former employees to present at a deposition or trial helps personalize the need to be ready and do a good job, even if it is for your former employer. Advise the former executive that the trial is public and other colleagues affiliated with his former or current employer may evaluate his deposition and trial testimony. The adage of “you never know who will hear what you say” can go a long way. The executive will want to be able to stand tall at subsequent functions, professional meetings or conferences where he might have to engage with others who have heard or reviewed his testimony. Finally, as a current representative of a different but successful company, his peers and perhaps supervisors will be paying attention to his performance with an eye towards any future litigation in which he may have to be a witness for them.

One of the initial inquiries directed to the former executive witness is the reason for the separation or source of animosity towards the corporation. The reasons given by corporate counsel or other witnesses may not be the true source of the former executive’s contentious attitude. Some causes of ill will may still be corrected, thereby improving the witness’s attitude. Talking through the emotional overtones which cloud the prospective testimony will assist defense counsel in finding the “hot spots” that need to be reviewed with the witness several times, so the answer is factual, not emotional. Again, videotaping the sessions and having the witness watch the tapes may avail the witness of a first hand look at posture, speech and word selection that may be unprofessional and distracting. Ask the witness if he wants to be believed or just wants

the chance to air his grievance against the company. Finding the witness's goal will allow defense counsel to work more deliberately with the witness. Often professional pride can overcome a personal vendetta if the witness cares about his presentation at the deposition and in court.

A former witness who did not separate amicably, was wooed away by a competitor and/or has already "gone to the dark side" by aligning with the plaintiff and her counsel creates ethical and strategic dilemmas. Consideration must first be given to the existence, if any, of an attorney-client relationship with the former witness. In most circumstances the former witness, who was a speaking agent for the company during his employment, should be represented by legal counsel who is not associated with counsel representing the corporation to avoid conflicts of interest under the relevant state and federal rules of professional conduct and case law. (If the witness is also a party, the appearance of separate counsel does not create an atmosphere of adversity among defendants.) If he is not a named party, the suggestion of adversity by separate counsel is not a strong enough adverse factor not to retain separate counsel for the former witness.

On occasion, the former witness will refuse to participate in witness preparation at all and may be a total wild card at the deposition or trial. In those instances, defense counsel needs to be prepared to cross-examine the former witness as a hostile witness and, if necessary, discredit his testimony.

Should the former executive agree to prepare for the deposition or trial, care needs to be given to determine which documents, if any, will be produced that may be privileged, proprietary or contain trade secrets. If the separation did not go well, and/or a competitor employs the former witness, a protective order should be in place before any documents are produced, reviewed and discussed with the former witness to limit the improper use of the information.

Can the Testimony Give Rise to Criminal Liability?

President George W. Bush signed the Sarbanes-Oxley Act of 2002 on July 30, 2002. The Act was a legislative response to mandate the need for corporate compliance in light of the financial misdealings by Enron, Arthur Andersen, Global Crossings, etc. Relevant excerpts of sections 806 and 1107 that relate to employment decisions, are noted below:

[Section 806-PROTECTION FOR EMPLOYEES OF PUBLICLY TRADED COMPANIES WHO PROVIDE EVIDENCE OF FRAUD.

(a) IN GENERAL-Chapter 13 of title 18, United States Code, is amended by inserting after section 1514 the following: .SEC. 1107. RETALIATION AGAINST INFORMANTS.(a) IN Section 1513 of title 18, United States Code, is amended by adding at the end the following:

“Sec. 1514A. Civil action to protect against retaliation in fraud cases
“(a) WHISTLEBLOWER PROTECTION FOR EMPLOYEES OF PUBLICLY TRADED COMPANIES—No company with a class of securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 781), or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78o(d)), or any officer, employee, contractor, subcontractor, or agent of such company, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee—

“(1) to provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of section 1341, 1343, 1344 or 1348, any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders, when the information or assistance provided to or the investigation is conducted by—

“(A) a Federal regulatory or law enforcement agency;

“(B) any Member of Congress or any committee of Congress; or

“(C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate misconduct); or

“(2) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed or about to be filed (with any knowledge of the employer) relating to an alleged violation of section 1341, 1343, 1344, or 1248, any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders.

“(D) STATUTE OF LIMITATIONS—An action under paragraph (1) shall be commenced not later than 90 days after the date on which the violation occurs.

“(c) REMEDIES—

“(1) IN GENERAL—An employee prevailing in any action under subsection (b)(1) shall be entitled to all relief necessary to make the employee whole.

“(2) COMPENSATORY DAMAGES—Relief for any action under paragraph (1) shall include—

“(A) reinstatement with the same seniority status that the employee would have had, but for the discrimination;

“(B) the amount of back pay, with interest; and

“(C) compensation for any special damages sustained as a result of the discrimination, including litigation costs, expert witness fees, and reasonable attorneys fees.

“(d) RIGHTS RETAINED BY EMPLOYEE—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law, or under any collective bargaining agreement.”

(Emphasis added.)

Section 1107—RETALIATION AGAINST INFORMANTS.

(a) In General—Section 1513 of Title 18, United States Code, is amended by adding at the end the following:

“(e) Whoever knowingly, with the intent to retaliate, takes any action

harmful to any person, including interference with the lawful employment or livelihood of any person, for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense, shall be fined under this (sic) title or imprisoned not more than 10 years, or both.”

How do these statutes impact the testimony of a company witness? If an employee provides notice of financial mismanagement to a company representative and is later the victim of any retaliatory conduct because of such disclosure or participation in an investigation, relating to financial management or reporting, the company representative who retaliated against the employee may be subject to civil and criminal liability. Section 806. While the witness may not have all of the information necessary to make an employment decision, he may be the one signing off on an employment related decision, such as layoffs or reduction in force. The witness will be presumed to have knowledge, even if he didn't have actual knowledge.

The Act only applies to companies “with a class of securities registered under section 12 of the Securities Exchange Act of 1934 ... or that are required to file reports under section 15(d) of the Securities Exchange Act of 1934, or any officer, employee, contractor, subcontractor, or agent of such company.” The list of individuals who may be potentially liable for retaliatory conduct under the Act is expansive. In light of the breadth of potential defendants, defense counsel needs to assess whether the current or former executive engaged in any behavior that discriminated against the employee in the terms and conditions of employment because of reporting of a violative act or participating in the investigation of an alleged violation.

The casts of corporate employees who may be liable under the Act include “a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate misconduct).” Executive or management level employees with the authority to make employment decisions ranging from discipline, layoffs, termination, reduction in force, changes in work conditions, such as changing the employee’s supervisor, shifts, number of hours worked per pay period and work area assignments, may be covered. Should plaintiff believe that the acts taken by the executive fall within the Act and the employee either gives notice to Secretary within 90 days of the conduct or files suit within 180 days of notice to the department, the need for participation in an investigative interview, a deposition or a fact finding hearing may commence long before a civil lawsuit is underway. Executives may not appreciate the gravity of a phone or in person interview with a department employee and may not associate one legal avenue of investigation with the prospective suit, or appreciate the risk of civil and criminal penalties. Notice to all administrative staff, managerial staff and general employees should be given about the right to report, the right to be free of retaliation and the right to pursue remedies if a retaliatory conduct is perceived. Although nothing in the regulations suggests that an employer must give notice, a posting similar to that outlining the FMLA or ADA might be a prudent action for the employer to take.

Additional considerations during an executive witness preparation in light of the Acts

breadth include inquiring about any destruction, alteration or falsification of documents or records or tangible objects that may relate to an underlying claim by an employee that would simultaneously give rise to liability under the Act. If the allegations also include fraud or some other alleged misconduct that might give rise to criminal charges, consideration for the need for criminal defense counsel at the deposition preparation and deposition is essential to the protection of the witness's ability to defend himself at a later date.

On a Personal Note...

Remember first and foremost that the witness is a person, maybe a father, husband, coach, and parent. The witness may have things going on in his personal or professional life that overshadow his interest in preparing for a deposition. If the witness is going through a divorce, recently suffered the loss of a partner or is undergoing health care, consideration must be given to the impact of each of these on the witness. Each of these potential events are distracting and may require alternative venues for meeting with the witness, seeking a continuance of the deposition date or getting a protective order on the length of each deposition. Sensitivity must be demonstrated when inquiring about the witness's state of health or well being and how comfortable he is having information about his state of health, etc. included in a public pleading. In addition, witnesses who are distracted emotionally often have a more difficult time focusing and/or answering questions logically, rather than emotionally. Sometimes the recent loss of health or close friends/family place the witness on edge

and tears may flow easily or anger demonstrated with little provocation. Finally, many witnesses fear that a statement they make will either cause the company to lose the case, or that the witness will be fired from his job for failing to do a good enough job. Many witnesses express that they “don’t want to let the company down.” Counsel needs to educate the witness by providing a blueprint of the issues and which witnesses will be testifying about the many discrete aspects of the case. The witness can then learn that he is not the only person shouldering the company’s defense.

Finally – Maintain the Witness’s Ego-Not Yours!

While newlyweds hope they are a “match made in heaven”, reality demonstrates that many relationships don’t work. Candor and introspection are needed from defense counsel to make sure she is the best choice for preparing and defending the witness. Despite how bright, passionate or prepared counsel is, there may be a disconnect with the witness. If you don’t seem to be clicking with the witness, have another attorney from your office familiar with the case attend a meeting with you and the witness. Involve the attorney with the witness and see if there is better participation, less defensiveness or more candor. By way of illustration, as an associate attorney, I was a second chair defense counsel in a medical liability trial. I joined the senior lawyer in preparing the defendant physician the night before trial. The physician had done well during his deposition, but was doing very poorly the night before trial was to begin. Finally, we stopped for a break and senior counsel left the room. As it was my first meeting with him, I chatted with the physician. When I asked where he grew up, he

commented it was a very small town and I likely wouldn't know where it was. As it turned out, his hometown was about 100 miles from my hometown in Montana. While providing nothing more than a geographic "soul mate" for the moment, the witness felt more comfortable being able to express his concerns that he was not from a big city, didn't attend a major medical school, etc., and was worried that the jury would not view him as credible as the "experts". Once he aired his concerns and was reassured that his bedside manner would win the day, he returned to the articulate and caring witness he had been at his deposition. In that circumstance, it was merely fortuitous that the witness and the author had a connection. However, each witness and lawyer should make sure there is a connection that imbues trust and honesty. When one or the other can't agree that such a connection exists, its time to seek the assistance of another lawyer or trial consultant to help the witness do his best. Being a team player sometimes means "riding the pine" during certain witness preparation.

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