Litigation Lessons From
The Vioxx Verdicts

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In the pharmaceutical products case,
the defendant has to do more than meet its burden.
It has to show that it did no wrong.

WHEN THE VERDICT in the Ernst v. Merck
case became public, newspapers and media
outlets across the globe spread the news far and
wide. After a trial that played out over six
weeks and jury deliberations lasting a day and
a half, the jury of seven men and five women
voted 10-2 to find that Merck’s negligence, as
well as marketing and design defects in Vioxx,
led to Robert C. Ernst’s death. Actual damages
of $24.4 million were awarded to his widow, in
addition to $229 million in punitive damages.
Although the punitive damages award will be
reduced dramatically in accordance with Texas
law, for Merck, the public relations effect of the
award was dramatic.

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In the days and weeks that followed the verdict, there was a lot of discussion about the inferences to be drawn from the outcome—the possible long-term implications for Merck, the pharmaceutical industry as a whole, and for patients in need of life-saving medications. The plaintiffs' supporters touted the verdict as an indication of significant problems with Merck's defense; others waited to see whether the *Ernst* verdict would establish a pattern for future cases or just be seen as an anomaly. A few months later, a defense verdict was rendered in the *Hummeston v. Merck* case, which was tried in Atlantic City, New Jersey. Jurors in New Jersey deliberated for nine hours over three days before finding for Merck on all counts. The trial, which generated some heated courtroom debates outside the presence of the jury, resulted in jury deliberations that were reported to have been conducted without any hostility among the jurors.

Although resulting in very different outcomes, these two trials serve as a reminder of the communication challenges inherent in defending a case involving personal injury and allegations of corporate greed and wrongdoing. Our experience conducting research with mock and actual jurors in cases like *Ernst* and *Hummeston* has taught us that there are common communication problems that can be avoided with the benefit of well-designed pretrial research to establish how jurors are likely to react to a specific fact pattern. In particular, our research has identified key questions that must be answered for jurors before a pharmaceutical company can convince them that it should not be held liable for an injury alleged to have been caused by one of its products. This article discusses the most important of those questions.

**WHAT ARE THE INDUSTRY NORMS?** • A typical jury selection process yields a jury made up of individuals who have little or no expertise in the subject that they will be asked to evaluate. In complex cases, the jury's lack of experience with the subject matter necessitates that trial counsel do a significant amount of teaching through the opening statements and questioning of witnesses. In a pharmaceutical products liability case, this means that jurors need to know and understand the roles, rules, and responsibilities (the three Rs) of the relevant parties, namely the pharmaceutical company, the FDA, and the prescribing physician.

A successful defense will give the jurors a foundation to understand:
- What the FDA requires for approval of a prescription medication;
- What a risk/benefit analysis is and why it is important;
- How and when warnings are included in a package insert provided with a prescription medication;
- Who those warnings are developed to inform; and
- When, how, why, and by whom the decision is made to strengthen a drug's warning label or remove a medication from the market.

**“What’s Normal”**

By educating the jurors about the industry and regulatory norms related to the approval of prescription medications and the FDA-approved marketing of those drugs, jurors will have a framework in which to evaluate the specific activities that occurred in the case they are being asked to decide. Without first knowing “what’s normal,” jurors cannot decide if the case-specific conduct was appropriate.

**A Helpful Voice**

Additionally, how the information is conveyed to the jury is often as important as what information is presented. Teaching jurors about the normal activities involved in the drug ap-
proval and marketing process without preaching to the jurors is critical. Jurors in the Ernst case reportedly felt that the defense had talked down to them. The defense must appear to be striving to be helpful to the jurors by providing them with useful background information that will aid the jury in its ability to reach a just verdict, but the defense must be careful not to appear to be telling them how to decide the case.

WHAT IS THE CASE-SPECIFIC CONTEXT?

• In any complex case involving thousands of pages of documents (particularly now that email is a regular element of business communication), there will always be documents (or phrases within documents) that have to be explained to a jury. Providing the proper context for the words in question is crucial, so you need to explain:
  • What was the objective or the intent of the person who wrote the words?
  • Is the document really relevant to the case or is it being taken out of context in an attempt to distort the truth?

In describing the evidence presented in the Ernst case, it has been widely reported that the marketing team at Merck developed a sales training program with the unfortunate name of “Dodgeball.” The apparent objective of the program was to demonstrate how sales representatives might choose to respond to questions from doctors concerning possible cardiac risks associated with Vioxx. Although it is easy to see in hindsight that this is not a message that Merck wants to convey to the public, what was the intent of the people who put those materials together? Were they really trying to hide information from physicians or the public? Is overzealous marketing a common practice for Merck or was this an isolated incidence of bad judgment? Perhaps most importantly, did the marketing of Vioxx have anything to do with why Mr. Ernst’s physician prescribed the drug for him and was his physician fully informed of all known risks?

What Did Internal Risk Assessments Really Mean?

Were internal conversations about the possible risks evidence of withholding important information about actual risks, or did these discussions reflect the honest diligence of the company’s scientists in determining whether a risk truly existed or not? Jurors need to understand that a responsible pharmaceutical company wants to be able to encourage open and honest scientific dialogue and debate. Such conversations may not be evidence of anything sinister at all. But, without the context for these conversations, it may be easy for jurors to conclude that the pharmaceutical company knew more than it was telling the public.

Was The Company Completely Candid About The Risks?

Did the defendant try to hide information about the risks of its drug? This is a fundamental question that the pharmaceutical company defendant must be prepared to answer to convince a jury that the defendant acted appropriately when it sought FDA approval and in marketing the drug once it was approved. This means that the defense team must convey the impression that the company was completely forthcoming about the pros and the cons associated with its product. The jurors will need to learn about the process that is followed and the context in which scientific evidence is evaluated. For example, the jury will need to understand the important distinction between association and causation. As scientists strive to determine whether a drug causes a certain side effect, they will evaluate evidence of association with that side effect to determine if it is scientifically reliable. If a defendant is to be successful in convincing jurors that an association
does not automatically equal causation, its witnesses will be prepared to answer questions about evidence of association in an open and non-defensive manner. Pre-trial preparation that helps defense witnesses to see the evidence from the plaintiff’s perspective (and possibly the jurors’ perspective) will give those witnesses the tools to persuasively explain why that perspective may be incorrect.

**Trial Conduct**

Additionally, throughout the trial process, the pharmaceutical company must remember that even the appearance of impropriety on its part will be enough for some jurors to conclude that the company acted inappropriately. During the trial, this includes the presentation and discussion of evidence, as well as counsel’s conduct in the courtroom. The defense team needs to find ways to explicitly and implicitly demonstrate openness and the fact that they and their client have nothing to hide. For example, discussing some of the weakness of the defense case and even admitting some product weaknesses can help to build credibility.

**The Danger Of Objections**

The use of objections in the courtroom can also influence the jurors’ perception of whether the defendant is trying to hide something. If defense counsel chooses to object repeatedly during the testimony of an adverse witness, it creates the impression that this witness has information that the defendant does not want the jury to hear. Although there may be good legal reasons for those objections, the impression left with the jury can be quite negative.

**Nonverbal Behavior**

Even nonverbal demeanor in court can play a role in shaping jurors’ opinions about the defendant. Do defense counsel seem to converse secretly with their mouths covered and backs to the jury, or do they talk openly with one another, apparently with nothing to hide? These nonverbal cues can convey an openness that makes the defense team seem less mysterious and less intimidating to a juror.

**WHAT IS THE ALTERNATIVE CAUSE OF DEATH OR INJURY?**

• Although the legal burden is on the plaintiff to prove that the product caused the injury, human nature often causes jurors to expect the defense to prove that something other than the drug harmed the plaintiff. It is not enough for a defendant to say that there is no evidence that the drug caused the injury to the plaintiff; a successful defendant will be able to illustrate what did cause the injury or death and why the accused product was not involved.

**The Bigger Medical Picture**

This is particularly true in cases in which the plaintiff was an otherwise healthy individual. When a plaintiff’s medical picture is complex, it can suggest numerous contributing factors, thereby decreasing the likelihood that the medication harmed the plaintiff. For example, in the *Hummeston* case, a member of the jury noted that she was convinced that the plaintiff’s heart attack was likely caused by stress and anxiety, not Vioxx. She also noted that she thought that “Mr. Hummeston had way too many health issues to pinpoint the cause of his heart attack to Vioxx.” By contrast, in the *Ernst* case, Mr. Ernst was said to be an avid runner who was generally in excellent physical health. In cases like *Ernst*, it can be very difficult for a jury to believe that a man in his condition drops dead without some intervening cause. Technical distinctions about the type of cardiac event experienced by the deceased will be difficult for some jurors to accept (and difficult to understand), unless the jury is already convinced that the pharmaceutical company acted...
appropriately. Conversely, if there is no strong alternative cause, it is much easier for a juror to believe that the pharmaceutical company must have done something wrong.

This is the point of tension around which most jurors determine the verdict in a pharmaceutical products liability case. Defense counsel must create a balance between showcasing the evidence of an alternative cause of injury and providing jurors with an adequate level of comfort that the defendant company did the right thing regarding its product.

WHY ARE DRUGS PUT ON THE MARKET EVEN WHEN SERIOUS RISKS EXIST? • In this country, most people have become accustomed to having a relatively safe medicine available to treat whatever ails them. Adverse events are usually perceived as few and relatively inconsequential. Low probabilities of risk leave most individuals believing, “It won’t happen to me.” As a result, most people do not focus on the risks, instead they think only about the promised benefits of a medication. When a serious adverse event does occur, most people are taken by surprise and wonder, “How could this have happened?”

All Drugs Have Risks
Because most jurors do not focus on the risks associated with a medication that they or their loved ones take, this perspective creates a hurdle for a defendant pharmaceutical company to deal with in defending its product. Jurors need to be reminded or educated that all drugs have risks, and often those risks can be potentially serious. Jurors must be shown that there are people responsible to evaluate the risks and that it often makes sense for patients to accept some degree of risk. That is why important medicines are approved for use in this country, even with the possibility that serious adverse events may occur. In this case, the FDA and the prescribing physician are the ones whose job it is to worry about the risk on behalf of patients.

Explaining The FDA’s Role
The FDA’s role is to undertake a nationwide risk/benefit analysis before approving a drug for manufacture and sale in this country, whereas the prescribing physician must do a similar analysis on a patient-by-patient basis. First the FDA, and then the treating doctor, must decide:
• Is the condition being treated sufficiently serious or debilitating to justify the potential risks associated with this medication?
• Are there alternatives available to treat this condition with fewer risks?

To prevent a drug from being made available to the public, or to pull the drug off the market without reliable scientific evidence that a drug carries excessive or unnecessary risks, is to deprive patients with chronic or life-threatening conditions from being able to have access to treatments that may be of great benefit to them. Jurors often respond positively to the suggestion that the drug approval process should ensure that physicians in this country have every option available to them to treat serious illnesses and this assertion can be a powerful defense theme. It is a particularly compelling theme when the lawsuit concerns an illness that is life-threatening or particularly debilitating, that is, so long as the jurors are also comfortable concluding that the defendant company did not hide information about the risks associated with the drug.

Helping jurors to see that the FDA approval process and the practice of medicine are a mix of art and science will help them to understand that there is professional judgment that must be applied to the decisions to approve and to prescribe a particular medication. Even the most commonly used medicines like acetaminophen or penicillin can cause fatal reactions, but that
does not mean that these important treatment options should be taken off the market.

**WHY AREN’T THE RISKS OF PRESCRIPTION DRUGS PUBLICIZED FULLY TO CONSUMERS?** • Direct to Consumer (“DTC”) advertising has generated a lot of sales for the pharmaceutical industry, but it has also created a lot of headaches for companies faced with litigation. Jurors believe, based in large part on the DTC advertising they see on television or in magazines, that warnings on prescription medications are directed to the patient.

**The Learned Intermediary**

As a result, jurors need to be educated about the concept of a “learned intermediary” and become comfortable with the fact that prescription drugs are controlled for a reason—so that a physician can weigh the risks and control access to medications which have potentially serious risks of adverse events. Consumer advertising may have been used by the pharmaceutical companies to generate interest in a medication (although it looks like we will see much less of DTC advertising in the future), but ultimately it is the doctor’s decision whether or not a medication is right for a particular patient.

That is why the information provided along with a prescription medicine is written in complex medical language and is often difficult for a patient to comprehend. The physician is supposed to serve as an intermediary by making the decision to prescribe the medicine and by counseling the patient about the risks. Explaining the role of the learned intermediary and demonstrating that the prescribing physician made an informed choice for his patient based on what was known at the time will help jurors to accept that the pharmaceutical company acted properly.

**WHY WOULDN’T THE DEFENDANT PUT PROFITS AHEAD OF SAFETY?** • Perceptions of corporate greed are a powerful psychological filter for many jurors and an extremely difficult hurdle for a defendant corporation accused of any type of wrongdoing, but particularly when a personal injury is involved. Most jury-eligible citizens in this country (although a smaller majority than several years ago) are cynical about corporate conduct, and many believe that it is typical for large companies to be willing to do anything to make money. This perception, combined with frustration about the costs of health care and prescription medicines, turns even the slightest appearance of impropriety into damning evidence in a case alleging harm from a prescription medication.

**Overcoming Anti-Corporate Bias**

Given that many jurors will be predisposed to believe that corporate greed plays a role in business decision-making, this is a theme of the plaintiff’s case that will be plausible to jurors and difficult for a defendant to discredit. Jurors’ pre-existing bias on this issue increases the importance for the defendant to demonstrate full disclosure—the appearance that the company has nothing to hide and in fact was forthcoming about the strengths and weaknesses of its product. Illustrating the defendant’s full cooperation and compliance with FDA regulations concerning all areas of safety is critical to the successful defense of a large pharmaceutical company.

As described above, this is why teaching jurors about the norms involving prescription medicines and providing the proper context for them to evaluate the case-specific conduct is critical to a successful defense. Jurors must feel comfortable that the defendant company did not cut corners and was not motivated by greed. Only then can a defendant successfully point out that, although it strives to earn a profit, it would not serve a company well to inten-
tionally sell a drug knowing that it had unreasonable risks associated with it. It is not that the company is altruistic; it simply would not be in its best economic interest to do so.

**WHY DOESN'T THIS CORPORATION DESERVE TO BE PUNISHED?** • As in any litigation, the best punitive damages defense is to demonstrate first and foremost that the defendant is a company that did the right thing. If the facts demonstrate that an error was made, jurors must be convinced that the error was not made with malice. Although it may be important to educate the jurors about the long-term implications of the punishment they choose, it cannot be done effectively without first being able to demonstrate that the company strove to do the right thing.

In cases in which the jury decides that punishment is warranted, it is not unusual to see a jury rely on internal revenue or profit estimates as a benchmark for punitive damages, just as the jury in the *Ernst* case is reported to have done. In *Ernst*, the $229 million punitive damages award was reported to be linked to a Merck estimate made in 2001 of the additional profit the company might earn if it could postpone adding a warning of cardiac risks to the Vioxx label. With that context, it is easy to see how the jurors could conclude that the punitive damages award, which has been described as excessive, seemed appropriate. In assessing punitive damages, jurors often strive to take away the benefit that they perceived the company gained, or expected to gain, from its malicious conduct.

Given the possibility that a jury will rely on internal valuations as a benchmark for punitive damages, it may be necessary to take the time to place seemingly tangential or irrelevant documents in their proper context to minimize the influence these valuations could have on the jury’s punitive damages determination.

**CONCLUSION** • Although hearing about the *Ernst* and *Hummeston* cases reminds us of some of the communications challenges facing a defendant in a pharmaceutical products liability case, it also reminds us that a sample of two verdicts is not a reliable trend. However, as subsequent Vioxx trials take place in courtrooms around the country, we will learn which outcome is the more reliable indicator of how future juries will view plaintiff’s Vioxx claims and whether it will be possible for Merck to successfully answer the questions described above for jurors on a consistent basis.
PRACTICE CHECKLIST FOR
Litigation Lessons From The Vioxx Verdicts

Were the verdicts in the Ernst and Hummeston cases anomalies or a harbingers of things to come? Regardless of whether they begin a trend or not, the lessons for defense counsel in pharmaceutical products cases are clear—and a big one is that you have to answer questions for the jurors that don’t arise in other cases.

• The first question to answer is, “What are the industry norms?” Few jurors will know much about how the pharmaceutical industry works, so at the very least, you have to give the jury a foundation to understand:

  _ What the FDA requires for approval of a prescription medication;
  _ What a risk/benefit analysis is and why it is important;
  _ How and when warnings are included in a package insert provided with a prescription medication;
  _ Who those warnings are developed to inform; and
  _ When, how, why, and by whom the decision is made to strengthen a drug’s warning label or remove a medication from the market.

• Next you have to answer, “What is the case-specific context?” In any complex case involving thousands of pages of documents you have to provide the proper context for the words at the center of the controversy and explain:

  _ What was the objective or the intent of the person who wrote the words?
  _ Is the document really relevant to the case, or is it being taken out of context in an attempt to distort the truth?

• Next, you need to answer, “Was the company completely candid about the risks?” This is a fundamental question that the pharmaceutical company defendant must be prepared to answer, so:

  _ The jury will need to understand the important distinction between association and causation. Scientists strive to determine whether evidence of association with a adverse event has a causal link. The jurors need to understand that association is not causation, and the defendant’s witnesses must be prepared to answer questions about evidence of association in an open and non-defensive manner;

  _ Additionally, throughout the trial process, the pharmaceutical company must remember that even the appearance of impropriety on its part will be enough for some jurors to conclude that the company acted inappropriately.

• The jury will also want to know, “What is the alternative cause of death or injury?” It is not enough for a defendant to say that there is no evidence that the drug caused the injury to the plaintiff; a successful defendant will be able to illustrate what did cause the injury or death and why the accused product was not involved:
Establish the bigger medical picture. This is the point of tension around which most jurors determine the verdict in a pharmaceutical products liability case. You need to create a balance between showcasing the evidence of an alternative cause of injury while providing jurors with an adequate level of comfort that the defendant company did the right thing regarding its product.

- Jurors often want to know, “Why are drugs put on the market even when serious risks exist?” Most jurors are accustomed to how easy it is to obtain effective and safe medication, so they do not focus on the risks associated with a medication; as a result they need to be reminded or educated that all drugs have risks and often those risks can be potentially serious:

  - Explain that the FDA’s role is to undertake a nationwide risk/benefit analysis before approving a drug for manufacture and sale in this country, whereas the prescribing physician must do a similar analysis on a patient-by-patient basis.

  - “So why,” jurors will want to know, “aren’t the risks of prescription drugs publicized fully to consumers?” Jurors must be educated about the concept of a “learned intermediary”:

  - Jurors need to know that risks are described in scientific language for a reason—it is the physician’s job to assess how a particular medication will work for a particular patient. Explaining the role of the learned intermediary and demonstrating that the prescribing physician made an informed choice for his patient based on what was known at the time will help jurors to accept that the pharmaceutical company acted properly.

- Given the prevalence of anti-corporate sentiments, jurors will often start out with the idea, “Why wouldn’t the defendant put profits ahead of safety?” You need to demonstrate the defendant’s full cooperation and compliance with the FDA regulations, and the diligence of the company’s scientists in testing and risk assessment.

- So, finally, “Why doesn’t this corporation deserve to be punished?” The simple reason is that they rigorously tested the medication, withheld nothing of consequence, and developed something to help people with serious afflictions. This should be an essential theme. But when it comes to the potential assessment of damages, jurors often strive to take away the benefit that they perceived the company gained, or expected to gain, from its conduct; so it may be necessary to take the time to place seemingly tangential or irrelevant documents in their proper context to minimize the influence of economic projections or valuations related to risk assessment.