THE VIOXX LITIGATION: TWO CASE STUDIES

Michael E. Tigar
Research Professor of Law, Washington College of Law
Visiting Professor of Law, Duke Law School

In 1999, pharmaceutical giant Merck released a new drug, Vioxx, to treat chronic pain. Vioxx and the competitor drug Celebrex, marketed by Pfizer, seemed like good news for arthritis sufferers. Vioxx was sold in more than 80 countries. In 2003, Vioxx sales were $2.5 billion. Most arthritis pain sufferers had been taking some form of NSAID, or non-steroidal anti-inflammatory drug, such as ibuprofen or aspirin. The problem with most NSAIDs is that they cause stomach bleeding. The incidence of stomach bleeding is higher among elderly people who take NSAIDs. The effects on the stomach can include bleeding to death, puncture of the stomach wall, and other fatal events.

The chemical and physiological explanation for these side-effects is something called Cox-inhibition. Before the research work that led to Vioxx, it was believed that there was one "Cox enzyme," which did two things: It sent signals to pain receptors and it also helped to curb inflammation of the stomach wall. NSAIDs were thought to suppress this enzyme, which was why they both treated pain and caused gastric bleeding. Drug company scientists discovered that in fact there were two enzymes at work, Cox-1, which protected the stomach, and COX-2, which aided communication with pain receptors. Vioxx was claimed to be revolutionary because it suppressed or inhibited the COX-2 enzyme while leaving the Cox-1 enzyme alone.

However, physicians began to question the safety of Vioxx. Within six months of Vioxx entering the market, initial results of a study that compared Vioxx to an NSAID known as Naproxen – marketed as Aleve among other names – showed that those taking Vioxx had a greater risk of cardiac episodes connected with blood clots than those taking Naproxen. Merck evaluated the results and made the claim that the difference was due to the anti-clotting, cardio-protective effects of Naproxen rather than to any increased danger from taking Vioxx. One might think that the best way to see for sure would be to do a trial where some patients took Vioxx and the others a placebo or sugar pill. Such an approach was not considered feasible because all candidates for the study were people suffering pain and it would be unfair to insist that sufferers give up medication for the six months to a year that a study would take. This study, which has played a central role in all Merck litigation, is known by the acronym VIGOR.[1] Plaintiffs' counsel and Merck see the VIGOR results from opposite ends: did Vioxx cause more heart attacks, or did Naproxen lower the risk?

Some cardiologists disagreed with the way that Merck interpreted the VIGOR data. One of these was Dr. Eric Topol, head of the Cleveland Cardiology Clinic. He published his findings in the August 2001 New England Journal of Medicine. Dr. Topol became an important figure in the Vioxx litigation. He refused to accept employment by either side of the dispute. He also refused to accept service of process for court appearances outside his home state and the 100 miles provided for in Federal Rule of Civil Procedure 45(b)(2) and its state counterparts. Therefore, the parties have taken his

[1] Vioxx GI Outcomes Research.

deposition, which is played for juries. The New York Times has described Dr. Topol as "a Naderesque crusader against drugs he deems dangerous, as well as their makers."[2]

From this controversy emerged a central issue that is common to every Vioxx story and every Vioxx trial: What effect does Vioxx have on the patient's blood? To see this issue, we might begin by noting that many adult males take a small daily dose of aspirin because medical research shows that aspirin has an effect on red blood cells. It seems to make the cells more "slippery," and therefore inhibits the formation of clots that cause heart attack and stroke. Aspirin is a nonselective Cox-inhibitor – there is pain relief but clotting is impeded. As noted above, too much aspirin can actually cause gastrointestinal bleeding. Did the Merck scientists do enough studies for long enough to see if their product would have an effect on the blood that would promote clotting? When they had "early warnings" that there was such an effect, did they take steps to warn physicians, or did their interest in marketing Vioxx overcome any thoughts of doing that?

As the controversy continued and some lawsuits were filed, Merck scientists were conducting a clinical trial to evaluate whether Vioxx was helpful in preventing a recurrence of colon and rectal polyps. This trial, known by the acronym APPROVe,[3] produced some disturbing information. As a Merck press release of September 30, 2004 announced:

> In [the APPROVe] study, there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking Vioxx compared to those taking placebo. The results for the first 18 months of the APPROVe study did not show any increased risk of confirmed cardiovascular events on Vioxx, and in this respect, are similar to the results of two placebo-controlled studies described in the current U.S. labeling for Vioxx.

In the same press release, Merck announced that it was withdrawing Vioxx from the market worldwide. Because Merck is a public company, and Vioxx was so important to its financial performance, there is a great deal of information in the public domain about the legal decisions that Merck faced in responding to the inevitable large number of lawsuits claiming that Vioxx had caused injury or death. As of September 30, 2006, on which date the statute of limitations would have run for a large number of potential plaintiffs in two-year statute jurisdictions, there were about 17,000 Vioxx lawsuits on file. Some of these are class actions. The federal lawsuits have been consolidated for pretrial purposes as a multi-district litigation under 28 U.S.C. §1407.

Merck's general counsel is Kenneth C. Frazier, formerly a litigation partner in the Philadelphia law firm of Drinker Biddle. With the advice of outside counsel, Merck announced that it would defend all the lawsuits, and as of October 2006 had resisted

---

[2] See Ties to Industry cloud a Clinic's Mission, New York Times, December 17, 2005, online edition, http://www.nytimes.com/2005/12/17/business/17clinic.html?ex=1292475600&en=d44d70e27af8c3e5&ei=5090&partner=rssuserland&emc=rss. In October 2006, Dr. Topol announced that he will be leaving the Cleveland Clinic to join a medical school faculty in California.

[3] Ademantous Polyp Prevention On Vioxx, a study of the drug's effect on colorectal polyps.

efforts to engage in large-scale alternative dispute resolution procedures that would acknowledge liability and set up mechanisms for payment.

The Vioxx damages suits are being tried one by one, in different forums. In 2005-06, there were a total of about a dozen trials in Texas and New Jersey state courts, and in federal courts in Houston, Texas and New Orleans, Louisiana. The trial results were about evenly divided between plaintiff and defense verdicts.

Writers on tort policy have wondered whether the civil justice trial system is an appropriate mechanism to deal with large scale product liability cases of this kind. In this book, the focus is on advocacy decisions. I have chosen two Vioxx cases as illustrative. One is Ernst v. Merck, tried in Brazoria County, Texas state court. The plaintiff was Carol Ernst, widow of Bob Ernst, who died in May 2001. Bob Ernst's doctor had prescribed Vioxx for him, and he had taken it for about a year before he died. The exact cause of his death was the subject of intense dispute at trial. Opening statements took place on July 14, 2005, and the jury returned its verdict on August 19, 2005: compensatory damages of $24 million and punitive damages of $229 million. Under Texas law, the jury's punitive damage award must be capped at $26.1 million. Merck announced that it would appeal.

In Ernst, tried under Texas law, the jurors' verdict was in the form of answers to questions. First,

> was there a defect in the marketing of Vioxx at the time it left the possession of Merck and Company, Inc., that was a producing cause of the death of Bob Ernst? A marketing defect includes a failure to give adequate warnings. A producing cause is "an efficient, exciting, or contributing cause that, in a natural sequence, produces the injury. There may be more than one producing cause.

Second,

> was there a design defect in Vioxx at the time it left the possession of Merck and Company, Inc., that was a producing cause of the death of Bob Ernst?" A design defect renders the product unreasonably dangerous. The jury must consider and weigh the risks and benefits of the product, and the plaintiff must show that there was a safer alternative design.

Third,

> did the negligence, if any, of Merck and Company, Inc., proximately cause the death of Bob Ernst?" A proximate cause is "that cause which in a natural and continuous sequence produces an event and, without which cause, such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a person using the ordinary care would have foreseen that event or some similar event might reasonably result therefrom. There maybe more than one proximate cause of an event

The Ernst jurors were instructed that compensatory damages would include pecuniary loss, loss of companionship, and mental anguish. They were told that they could award exemplary damages by way of punishment based on culpability.

For purposes of contrast, I selected Plunkett v. Merck, which was tried to a federal jury in Houston, Texas. The case was moved to Houston from New Orleans because the federal courthouse there had been damaged in Hurricane Katrina. The plaintiff was

Evelyn Plunkett, widow of Richard "Dicky" Irvin, for herself and on behalf of the minor children Richey and Ashley. She alleged that Mr. Irvin's death was due to Vioxx. Mr. Irvin had taken Vioxx for about 30 days. The jury failed to reach a verdict and was discharged. On retrial, the jury returned a verdict for Merck.

The Plunkett case was tried under Florida law. The plaintiff's three claims were first, failure to warn, as to which the plaintiff must prove that Merck knew or should have known that Vioxx was or was likely to be unreasonably dangerous; second, Merck failed to exercise reasonable care in warning Dr. Schirmer [Plunkett's prescribing physician] of Vioxx's dangerous condition; and, third, Merck's failure to warn was a legal cause of the plaintiff's injury." Legal cause is the same as proximate cause under Texas law.

The second claim was "defective design," under which the plaintiff must prove that "Vioxx was a defective product due to a defective design," and that "Vioxx's defective design was a legal cause of the plaintiff's injury. . . . A product is unreasonably dangerous if the risk of danger in the design outweighs the benefits."

The third claim was negligence, and under Florida law the jury was asked to consider the potential comparative negligence of Merck, Dr. Schirmer and the decedent.[4]

The nine-person Plunkett jury was unable to reach a verdict. On a retrial, Merck won. Given the scant evidence of causation in Plunkett, why did at least one juror hold out for the plaintiffs? The answer probably lies in the very damaging evidence of internal Merck documents and attitudes about drug development and safety issues. The trial excerpts will allow you, the reader, to judge for yourself.

The two cases present sharply contrasting lawyer styles and strategies. The different results are due in large measure to the differences in the way the advocates approached their cases. Of course, other elements are also important, such as choice of forum, federal v. state procedure, and the different factual scenarios of the two cases. For example, in Texas state court, cross-examination is not limited to the scope of the direct, as it is under Federal Rule of Evidence 611(b). This distinction makes a big difference in trial strategy. However, I believe that studying the two cases side by side yields important insights. The combined trial transcripts of the two cases run to almost 7,000 pages. It is thus a challenge to tell the trial stories and to present some insights about the trial process.

ERNST v. MERCK IN ANGLETON, TEXAS STATE COURT

The plaintiff's lawyer in Ernst was Mark Lanier, of Brazoria County, Texas, which is near Houston. Lanier is a part-time preacher and a powerful and charismatic jury lawyer. His law office has many Vioxx cases, and it appears at this writing that he will try them all in state court, if possible. Also on the plaintiff team was Dallas lawyer Lisa Blue, a veteran of many plaintiffs' cases and a partner at Baron & Budd.

The Merck defense team for Ernst was drawn from Williams & Connolly of Washington, and Fulbright & Jaworski of Houston, among other firms. The Merck team included two lawyers who also hold M.D. degrees.

Lanier's strategy for the first week of the Ernst trial put him in control of the trial issues and process and put his story of the case powerfully before the jury. The trial transcript suggests that Merck was never able to catch up, and this conclusion is echoed

[4] Plaintiff withdrew two additional claims, based on fraud and breach of warranty, at the close of her case-in-chief.

by several experienced trial observers including members of the trial teams speaking off the record.

Lanier's opening began with the theme of Merck as an irresponsible profit-seeking corporate entity. He moved from there to a vivid description of the warning signs he said one could find in Merck's studies concerning Vioxx. These were Lanier's strongest points. He discussed the alleged causal link between Vioxx and Bob Ernst's death, but not in great detail. As the trial evidence unfolded, it became clear that causation was the weakest part of Lanier's case, and he waited until the jurors had heard much evidence about Merck and Vioxx safety in general before fully unfolding the theory that a Vioxx-induced clot caused Bob Ernst's death, even though no clot was found during the autopsy.

Lanier began by talking about Bob and Carol Ernst. Bob had been married before he met Carol, and she had been married and divorced. Lanier talked about their lives together, focusing on how they were active and engaged in many forms of outdoor exercise together. The unspoken focus here was that Bob Ernst was not a candidate for a coronary event. He then turned to the themes of his case. Read how he empowered the jurors, acknowledged and embraced his burden of persuasion, and outlined the 1-2-3 of his proposed proof:

> He was 59 years old when he died. And what you've got to do is basically be the detectives here. You've got to figure out why he died. That's your job: figure out whether or not, of the reasons he died, Vioxx is one of those causes. And that's your job. This is -- if we were going to put it into a TV show, this would be "CSI Angleton" because this is your chance.
>
> And I think the way you do it is going to be real easy. What you're going to do is, you're going to follow the evidence, like any good detective would. You follow the evidence. And the evidence is going to lead you to one place. It's going to leave you -- lead you to Merck. It's going to lead you to Merck, one of the largest pharmaceutical companies in the world. And when you got anything big, there are lots of different ways it can be painted.
>
> You were told yesterday [during voir dire] by Ms. Lowry, Merck is a good company with good people. I have no doubt there are good people at that company. But you're going to hear a tale where it's not just an e-mail that she was referencing of, gee -- do you understand sometimes you put things in e-mails they wish they hadn't put. You're going to see the evidence. And not just from somebody. You're going to see it from the head of science as he cusses out the FDA and says what he really thinks about it.
>
> You're going to hear all of this evidence because what you've got -- your job to do is to get us to justice. There isn't anybody else. The way our country is set up, there is no one else, no one else that can find out whether or not Merck is a cause but you. That's it. That's the calling. This is what's on your life right now. Nobody else has this power. A judge can't do it. This is not a bench trial. Judge can't do it. Politicians

can't do it. Nobody else can do it. This is something you've got. This is where you can make a difference in the world, absolutely can.

How are you going to do it? My suggestion to you is, again, you've got to follow the evidence. First of all, I'm going to show you a motive. I'm going to show you the means. I'm going to show you the death. And I'm going to show you ultimately the alibis and how the alibis don't fly.

I'm going to show you the motive, and I'll prove it to you. And my burden is to prove it by 51 percent, but I got to tell you, I'll prove it to you. There's not going to be that doubt in your mind. You're going to see the motive. You're going to see it clear.

The means, I'm going to show you Vioxx was a cause. That's my burden of proof. That's what the Judge makes me do. That's what I'm glad to do. I'm going to show you the death and that the Vioxx -- the motive and the means combined to cause the death of Carol's husband, Bob.

And then we'll walk through their alibis, at least the ones, I'm guessing, based on what I heard yesterday and what I've been reading in the papers and what I've been hearing. We'll look at their alibis. We'll show that those excuses don't work.

Let's start with motive. Merck had the motive. What was the motive? The motive was money. Don't get me wrong. I think it's fine for a corporation to exist to make money. That's how we have jobs. That's how we have products. I think that's a good thing. But what companies have to do is, they have to watch to make sure that money doesn't take a priority position over health and safety.

Merck had new management that came into play in 1994, and this new management took the company and they tried to turn Merck into an ATM machine, a machine that's spitting out the money, a machine where they could punch the buttons and they could draw out all the cash they want and need. This is 1994.

Let me tell you about it. This is a new direction for the company. Merck -- you heard the expression, "The changing of the guard"? That's what happened here. The guard changes. Okay? Merck flip-flops.

See, the historical company Merck had been a family-run company. It had been a good company. I'm going to tell you, the history of Merck before this is a good history. Founded by George Merck. They put out real nice books on it (indicating). This was a company that was really working hard to find good drugs over the years.

This is a company that stumbled upon[5] a drug that cured an African blindness, River blindness, and the people who could be cured with the drug. They didn't have money to buy it. They didn't have insurance. And so Merck gives it to them to try and take care -- all right. They did get tax

[5] Careful choice of words. Not “through scientific research that cost a lot of money,” but “stumbled upon.”

benefits and all that kind of stuff. It wasn't totally gratuitous. But Merck gives it to them, and I applaud them for that.

They had been a good company run by scientists. There was this fella. In fact, he wrote the foreword to this book, Dr. Vagelos or Vagelos. And I don't know how to pronounce it. I've never met him, but I've read about him. And he was a good scientist, a doctor, one of the best doctors in the country, running this drug company, and he did a good job. But what happened?

It is in 1994 -- in 1994, Merck broke with tradition and they hired a new CEO. This is the fella right here (indicating), Ray Gilmartin. That's the new CEO hired in 1994. I say they broke with tradition because, historically, Merck had always had the guy running the company -- they brought him up through the ranks so he understood the company values. He understood how the company worked. He was one of their top scientists. He was one of their top doctors. But in 1994, the family is not running the company any more. That's over. This is now this big international concern. And what the board did is, they chose to be a new kind of company in 1994. They hired Ray Gilmartin.

`Now, you might be thinking, "All right. I wonder what kind of a guy Ray Gilmartin is. Was he a top-flight doctor? Was he another -- like Dr. Vagelos, was he one of the best doctors in the country?" No, he wasn't. Well, if the board didn't turn to a doctor, maybe they turned to a chemist, because they're doing chemistry, right? Maybe they turned to a chemist and got one of the best chemists in the world to help this company develop good chemicals. No, they didn't hire a chemist either. Maybe they hired a pharmacist. It's a pharmacy company. Maybe they hired a pill expert, a drug expert. Maybe that's who Ray Gilmartin is.

No, Ray Gilmartin is not any of those things. And those were not the priorities Ray Gilmartin brought to the company when he came. What the company did is, they went and they hired Ray Gilmartin, and Ray Gilmartin is a Harvard-trained businessman, not a scientist. There's nothing wrong with a businessman running the company if he runs it right, but you're going to see what he did. If a Boy Scout has a compass or a Girl Scout has a compass and the needle is supposed to always point north, Ray Gilmartin took this company and made the needle always point to the dollar sign, and that's how they chose their direction.

Ray Gilmartin made it not science first like it had always been, not health first, not medicine first, not drugs first. Ray Gilmartin made it profit first. He turned a good drug company into a business-first company.

Studded with exhibits that the trial judge had found admissible during pretrial proceedings, Lanier went through the elements of his case. In the Ernst case, the plaintiffs were allowed more leeway than in the Plunkett case in presenting evidence of Merck's disputes with the FDA over labeling of drugs other than Vioxx. This difference illustrates the role and value of pretrial motion in limine practice.

On the issue of motive, Lanier pointed to evidence that in 2000 and 2001 a number of Merck drugs were coming off patent and that there was pressure to get Vioxx to market.

Defense counsel's opening statement poses a special challenge. Defense counsel must seize the jurors' attention and pose an alternative story to the one presented by the plaintiff. Jurors come to see the case as a story. They take a tentative view of what happened and more readily accept evidence that tends to support that view. Jurors need guidance, so that they can see the most important issues in the case, and what significance they should attach to items of evidence they will hear or see. It seems obvious, but bears repeating that, in opening statement, a lawyer must acknowledge unfavorable evidence and must focus on the case-winning issues. When, as here, plaintiff's counsel portrays the case as presenting a significant moral and social issue, defense counsel must choose the response carefully.

In the Ernst case, Merck's counsel's opening was disappointing. Merck had powerful evidence that Vioxx did not cause Bob Ernst's heart attack. Their lawyers also knew that there would be a lot of evidence about Merck's actions and attitudes that a jury might find unsettling. But all of that would be irrelevant if Merck could win on causation. Defense counsel in criminal cases are familiar with the problem that Merck's counsel faced: the defendant may not be a sympathetic person, but he or she did not commit the charged conduct, or at least the proof falls short on that score. Of course, counsel seeks to portray the defendant in the best light. But there is a time and place for that work.

Merck's counsel's opening began with

> Good afternoon, ladies and gentlemen. My name is David Kiernan, and I'm pleased to speak with you this afternoon on behalf of Merck. As you might imagine, we wouldn't be here today if there weren't two sides to this story. If it were an open and shut case, as plaintiffs have suggested, this case would have been over long ago. As Judge Hardin mentioned during jury selection, this will be a somewhat lengthy case, lots of evidence to be presented, documents, and witnesses, some live, and some who gave their sworn testimony before trial and videotape. You'll see both during this trial.
>
> We appreciate the important job that each of you have ahead of you. It's a tough job to sort through and weigh all of the evidence, to tell the difference between allegations and proof; and we appreciate you undertaking that responsibility here. We believe that at the end of this case you will see that the scientists and leaders at Merck conducted themselves prudently and responsibly. I don't ask you at this early stage to take my word for it. At this juncture, all I ask is that you keep an open mind until all of the evidence is in.
>
> This case comes down to four issues. First: Was Merck responsible in its development of Vioxx? What you will learn in this case is that Vioxx was one of the most carefully and extensively studied pain relievers in history, not only before the medicine was put on the market, but after, as well. Merck continuously monitored the safety of Vioxx.

Second: Did Merck share, or as plaintiffs have suggested, hide, the scientific information on Vioxx? The evidence will show that Merck's safety studies were supplied and analyzed by the United States Food and Drug Administration, the FDA, that reported adverse reactions, including cardiovascular events, were monitored by Merck and noted right on the label for doctors to review and that Merck made public the results of its studies.

The third issue: Did the people at Merck, like Mr. Gilmartin,[6] make their decisions based on science? The evidence will show that at the time Mr. Ernst started taking Vioxx, around October of 2000, scores of studies involving thousands of patients had shown that Vioxx presented no more risk of heart attacks or strokes than taking a sugar pill. Even today, after a recent break-through in the science, the evidence is that Vioxx presents no risk until after continuous, day-in, day-out, long-term use for as much as 30 months or longer. And even then, the risk is very small and about the same as other pain relievers that you can buy at your local drug store, like Advil, Motrin, or Ibuprofen. We now know that the risk that we've talked about this morning is roughly the same with all of the medicines in this class. This will prove important because you will hear that before Mr. Ernst was taking Vioxx, he was -- he was, in fact, taking one of those pain relievers; and it was Advil, or Ibuprofen, and he was taking 16 pills a day.

The fourth issue -- and I ask you not to lose sight of this point -- did Vioxx cause Mr. Ernst's death? After all is said and done, this issue should decide the case. I feel for Mrs. Ernst. She lost her husband. I do. But the evidence will show you, no matter what you think about Vioxx at the end of the case, it had nothing to do with Mr. Ernst's death. Mr. Ernst died from an arrhythmia, which is an irregular heartbeat. He did not have a heart attack, which occurs when a clot interrupts the flow of blood to the heart. The two are entirely different. Be wary, please, of attempts to blur the distinction between the two. And no one, not any study or legitimate scientist anywhere, suggests that Vioxx increases the risk of arrhythmia. It doesn't.

These are the four issues that we will ask you to focus on during this trial. We will avoid presenting to you snippets or tidbits of data so we won't mislead you about what the science clearly says. Please watch out for that. We will show you all of the data so that you can make a judgment about what it tells you and whether Merck's scientists were making reasonable decisions. We will avoid trying to suggest that ten

[6] Counsel spent five minutes of a one-hour opening defending Ray Gilmartin's character, with references to his background, public service, church-going and family life. Gilmartin would not appear at the trial as a live witness, but rather by deposition. It is arguable that the issue is not Mr. Gilmartin's personal characteristics, but whether he ran Merck efficiently and effectively, and whether in fact science-based decisions were made by people qualified to make them.

years of scientific investigation can be explained with a handful of e-mails taken out of ten million e-mails amongst 62,000 employees.

What's wrong with this picture? The opening statement lacks drama. The lawyer doesn't talk about his strongest point – causation – until the end. The lawyer tells us little or nothing about why Vioxx was a revolutionary drug, how Merck is science-driven, or how risks and benefits are a part of every drug profile.

One good way to see the missed opportunities in this opening is to look at Phil Beck's opening for Merck in the Plunkett case. Mr. Beck began:

> Thank you, your honor. Mr. Birchfield [plaintiff's counsel] talked for about 60 minutes. While he was talking, about 60 people across the United States died from exactly the same thing that caused Mr. Irvin's death and not a single one of them was taking Vioxx. I'm going to talk for about 60 minutes, and while I'm talking another 60 people across the United States will die of the same thing that caused Mr. Irvin's death, and not a single one of them is taking Vioxx. The reason is that the thing that caused Mr. Irvin's death is the leading cause of death in the United States of America. That was true before Vioxx ever came on the market, and that's true today after Vioxx is no longer being sold. Several-hundred-thousand people a year die from having arteries that are clogged up with plaque, then having a rupture in the plaque, and then having a blood clot form in the artery so that not enough blood gets to the heart. It's the leading cause of death in the United States.
>
> Lots of people who die from this cause are people like Mr. Irvin: men in their 50s; men who are a little overweight; men who don't get enough of the kind of cardiac exercise that doctors say you should get in order to protect your heart. Meanwhile, Mr. Irvin only took Vioxx for less than 30 days. Just for less than 30 days. Now, you saw a lot of Vioxx studies, and you'll hear about them during the trial. With most of the studies that were done on Vioxx, there is no indication of a higher risk of any sort of cardiac problem no matter how long anybody takes Vioxx. there was one study that showed that there may be a higher risk taking Vioxx, but that was only for people who took it every day for a long period of time, for at least 18 months, and the risk did not become what they call "medically significant" until people had been taking it for over 30 months. That study showed no difference at all for people who were taking Vioxx for short periods of time, certainly for something like one month. In fact, there were lots and lots of studies done on Vioxx, and not a single one of them -- not a single one -- shows an increased risk of any heart attack problems for somebody who uses it for only a month or so.
>
> Now, that brings us to the two things that the evidence is going to show in this case, and these are going to be the two focuses of our presentation of evidence. The first one is that Vioxx did not cause Mr. Irvin's death. The second one is that Merck acted responsibly when developing and testing Vioxx.
>
> Actually, I'm going to come back to number 1 a little bit later. I'm going to start with number 2. What did Merck do when developing and

> testing Vioxx? To start with the development of Vioxx, it's important to understand what Vioxx was developed to do. Vioxx is medicine that was researched and developed in order to treat pain. You heard a little bit about that from Mr. Birchfield. Now, all of us have experienced pain in our lives, and most of us have experienced severe pain, the kind of pain where it hurts so bad that it's hard to concentrate on anything else. It's hard even to be around other people. Happily, for most of us, that kind of pain passes. In fact, the knowledge that that pain is going to pass is the thing that makes the pain bearable for most of us. To some people, they have that kind of real bad pain, but it doesn't pass, and they know it's not going to pass. They have it minute after minute, day after day, night after night, week after week, and it never goes away. It interferes with their ability to lead a normal life – just simple things like going for a walk, picking up the grandkid, writing a "thank you" note. The pain that people have who have severe arthritis and other conditions can be so severe that they can't lead a normal life. This kind of chronic pain is a big problem in the United States. There are, the estimates are, 70 million people in America suffer from osteoarthritis, one of the kinds of conditions that have this kind of pain. So people need relief. Lots of people in America need relief from serious pain. I would like to spend a little bit of time talking about how our bodies work, how it is that you feel pain, and how it is that medicines and -- including Vioxx – go about relieving that pain, and the example that I'm going to use is just somebody jamming their finger.

Beck then discussed the uses of morphine, aspirin and ibuprofen as pain relievers. For aspirin and ibuprofen, he set out the risks of stomach bleeds from continued use, and outlined how Vioxx suppressed the pain transmitter enzyme but did not interfere with the stomach protective enzyme.

Let us return our focus to Ernst. When a corporate or other entity is a party to litigation, it can designate a representative to sit at counsel table. Merck chose Dr. Nancy Santanello for the Ernst case. She is a physician who worked on the development of Vioxx. She no longer practices medicine. Lanier called her as as an adverse witness immediately after opening statements, and examined her as though on cross-examination.[7] He began with questions that established that Ms. Santanello was chosen by Merck from among 62,000 employees to be the corporate representative and that she was not a senior executive of Merck or any of its divisions.

Lanier then went after Merck's opening statement. Ms. Santanello said that she had been in the courtroom for both openings. Merck counsel had chosen to reply to Lanier's claims that Merck mislead the public, and that the FDA had sent warning letters. Merck counsel put up an FDA letter that complained about the type size and type face of a disclaimer on a Merck ad for a high blood pressure medication. With Ms. Santanello on the stand, Lanier showed her another warning letter, concerning Vioxx and addressed to Mr. Gilmartin.[8]

---

[7] On the use of adverse witnesses, see Michael E. Tigar, Examining Witnesses, ch. 7 (2d ed. 2003)(hereinafter "Examining Witnesses")

[8] These warning letters had been either pre-admitted in evidence or their admissibility ruled upon or agreed. Counsel is entitled to considerable leeway in "publishing" to the

Q. Well, let's look at the letter and see if it's about the use of color or the spacing or the headlines or see if it is, in fact, from scientists at the FDA. Do you have the letter in front of you?
A. Are we looking at the letter to Mr. Gilmartin, the one that's the warning letter?
Q. Yes, ma'am, the one that we started with.
A. Okay.
Q. Okay. You got it in front of you?
A. I do.
Q. It says on the second paragraph, "You have engaged in a promotional campaign for Vioxx that minimizes" -- do you see the word "minimizes" there?
A. I do.
Q. -- "minimizes the potential serious cardiovascular findings." Let's stop for a minute. "Cardiovascular findings." That's your heart and your blood system, right?
A. That's correct.
Q. That includes heart attacks, right?
A. It does, uh-huh.
Q. It includes sudden cardiac death, doesn't it?
A. Yes, it does.
Q. Just like Mr. Ernst had a sudden cardiac death, right?
A. That's my understanding, yes.
All right. So you've "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx gastrointestinal outcomes research." You-all nicknamed that VIGOR, right?
A. That's right.
Q. That was your VIGOR study. "And, thus, you've misrepresented the safety profile for Vioxx." Is that what it says?
A. Yes, sir, you're reading that correctly.
Q. Now, ma'am, this is not just a concern over the use of the color or the spacing or the headlines, this is pretty serious stuff, isn't it?
A. This, sir, is a warning letter.
Q. Yeah, they're warning you you're violating the law, right?
A. But the issue was that you were portraying all the letters as if they were warning letters, and they were not, sir. This is a warning letter.
Q. No, ma'am. And if you go back and look at my opening -- you can read it word for word -- I said very clearly what these things were --
A. Okay.

---

jury the contents of admitted exhibits. Counsel can generally read from the exhibit, subject to the opponent's right to require other portions to be read if necessary to put matters in context. Counsel can ask a witness to read the exhibit. With the court's permission, counsel can display portions of the exhibit on an enlargement or, in a courtroom equipped with video monitors, on a screen. See Examining Witnesses 156-84.

Q. -- with great exactitude. I'm just going from what Mr. Kiernan said that these are about color and spacing. Just so we're clear, this isn't about color or spacing, this is something very serious, isn't it?

A. This is a warning letter, and Merck certainly takes warning letters very seriously. I think that Mr. Kiernan also pointed out that Merck has a very, very well-known reputation for not receiving warning letters. This is not anything that Merck is used to receiving, and we took it very seriously.

Q. It's not your only warning letter from the FDA. You've gotten others, haven't you?

A. I don't know.

MR. LANIER [to an assistant]: Pull the other warning letter, please.

What is going on here? Lanier used part of his opening to display and refer to a series of FDA warning letters that Merck had received over the years on various issues, including relatively minor issues such as type face in advertisements. The court had ruled that these warnings, most of which did not refer to Vioxx, were admissible. Kiernan, opening for Merck, directly attacked Lanier's opening and displayed the letter that complained about the type face. He did not significantly address the more serious warning letters. It is always risky for defense counsel to make a direct reference to part of the plaintiff's opening. The gambit might be seen as a personal attack on opposing counsel, thus inviting a rebuke from the court or retaliation, as happened here. The personal credibility of the lawyers becomes an issue. Some judges outright refuse to let counsel start down that road.

Also, the defendant's opening is an opportunity to tell the defendant's story, based on careful preparation. Turning the opening into a defensive response to the other side foregoes the opportunity. Also, the responses that a lawyer crafts "on the spot" may turn out to have flaws, or provide additional ammunition to the opponent. The advocate should hesitate before abandoning a solid and well-considered case theory and trial plan. Some opponents will be provocative in an effort to force tactical misjudgments. Rising to their bait can be dangerous.

Ms. Santanello had not been prepared to deal with Merck's business decisions, its relationships with the FDA, or with the broad policy issues that Merck faced in deciding to bring Vioxx to market and eventually to withdraw it. Like many long-time employees of large organizations, she was a loyalist, accustomed to thinking well of her company and her colleagues, and very defensive when it or they were under attack. Her defensiveness might come across as hostility, anger or even lack of candor. Merck did not anticipate well in advance that Ms. Santanello would be called as the first plaintiffs' witness, nor prepare her well for that experience.

Lanier continued to focus on the VIGOR study, using the FDA warning letter:

Q. You started selling the drug before you finished the VIGOR test; am I correct?

A. Well, the drug was on the marketplace while VIGOR was ongoing.

Q. In other words, yes, Mr. Lanier, we started selling the drugs before we got the final results of VIGOR, true?[9]

[9] What has happened here? Lanier has asked a leading question, seeking a yes answer. The witness has seemed to him to waffle a bit. To impose his control of the cross-examination, he insists on getting the answer he seeks.

A. That's true.
Q. Okay. Now, the VIGOR study came back and had some pretty shocking findings. Would you agree with that?
A. Well, it depends on who you talk to as to whether or not the findings were shocking.
Q. Okay. Because y'all suspected these findings might actually occur, so maybe you-all weren't shocked. Is that fair to say?
A. Well, it's very consistent with the mechanism of Naproxen to be cardioprotective.
Q. Well, now, ma'am, that's the very kind of statement that the FDA got on to you-all for making, and you're still making it today. Did you read the bottom paragraph of this letter?
A. Well, I personally believe Naproxen has a cardioprotective effect, so --
Q. Ma'am, if you read -- my question was: Did you read the bottom part of this letter where the FDA says quit saying that kind of stuff?
A. So it says -- the part where it says the exact reason for the increased rates of MIs --
Q. Yeah.
A. -- observed in Vioxx treatment is unknown?
Q. Let's do it this way. Let's get there gradually. But let's first explain why it's important.[10] Okay? If you look at what the FDA said, they said that your promotional campaign on this study up there that we put on the board misrepresents the safety profile. It discounts the fact that in that VIGOR study patients on Vioxx had four to five times as many heart attacks as those that were on VIGOR, right? That's what it says, doesn't it?
A. Yes, it does.
Q. So you've got four to five times as many heart attacks happening in the group taking your drug as the group that's taking Naproxen, true?
A. Yes.
Q. And the FDA warning your company because you-all are misrepresenting that truth?
A. Well --
Q. That's what it says, doesn't it?
A. Yeah. But I think you have to look at what actually makes up that misrepresentation.
Q. All right. That's the next paragraph. "Although the exact reason for the increased rate of MIs" -- and, again, that's the heart attacks we're talking about, right?
A. Those are heart attacks, correct, yes.
Q. "Although the exact reason for the increased rates of MIs observed in the Vioxx group" -- that's the far part of my tablet, right?

[10] He now has the FDA letter before the witness, but wants to ask his questions in an order and at a pace that makes the jury aware of the reason he is exploring this subject. It is easy for a lawyer who is very familiar with the case to skip steps or "start in the middle." Lanier is reminding himself and the witness to slow down.

A. Yes.
Q. -- "is unknown, your promotional campaign selectively presents the following" -- what's that word after following?
A. Hypothetical.
Q. Yeah, "hypothetical." That means it's not anything anybody has proven. It's a hypothetical. It's an idea, right?
A. It's a hypothesis.
Q. Okay. "Your promotional campaign selectively presents the following hypothetical explanation for the increase in heart attacks: You assert Vioxx doesn't increase the risk of heart attacks. The VIGOR finding is consistent with Naproxen's ability to block platelet aggregation like aspirin." That's what it says, isn't it?
A. That's correct.
Q. And that's what you just told this jury just now. You said, well, we don't -- I am personally of the opinion that it's the Naproxen was helping the heart instead of Vioxx was hurting it, right?
A. Yes, correct.
Q. The FDA warned you about that and they said that's a possible explanation but you failed to disclose that it's hypothetical, that it's not been demonstrated by substantial evidence and there's another reasonable explanation.

Lanier kept Santanello on the stand from the afternoon of July 18, all day July 19, and most of July 20. There was a break to present two plaintiff's witnesses, then Lanier recalled her for another two days of testimony. Using plaintiff's exhibits, he led her from the FDA warnings, through the studies of Vioxx problems, memoranda showing sales and marketing techniques used by Merck, and the profitability of Vioxx. He concluded the examination with a series of questions that brought out that Bob Ernst had few of the risk factors associated with fatal cardiac events.

Merck counsel David Kiernan had concluded his opening statement by saying:

> One final point: Let me conclude with the allegation that the leaders and scientists at Merck were knowingly letting people die from heart attacks and hiding their knowledge to make more money. Here are some of the people at Merck who took Vioxx before it was withdrawn from the market. These are folks at Merck who took Vioxx personally. Dr. Ed Scolnick, the head of all science and research at Merck; David Anstice, the head of marketing and U.S. sales that Counsel referred to this morning; Dr. Alan Nies, who was head of the Vioxx development program; Jeffrey Mason, one of the reps who actually saw Dr. Wallace and detailed, as they say, Dr. Wallace, the prescriber in this case; Dr. Louis Sherwood, the physician that was accused of trying to -- you know, the Merck physician who was accused of trying to intimidate people who were criticizing Vioxx; Dr. Peter Kim, the current head of all science at Merck; Dr. Nancy Santanello, who's with us here today. All of these folks took Vioxx before withdrawal. And I leave you with that thought.

One may question whether restating the "allegation" is effective, even to rebut it, and whether it was wise for counsel to end the opening with this claim. In the end,

however, it was perhaps unwise to make the claim at all. Lanier brought out towards the end of the adverse examination that Dr. Santanello had taken Vioxx over a period of many months, but only sporadically – once or twice a month for specific conditions.

Merck's counsel Gerry Lowry conducted the cross-examination, which for an adverse witness is like a direct examination in the sense that the examiner may not use leading questions. After some introductory questions, Lowry began by asking who had worked on the development of Vioxx, eliciting a list of people with their various titles and roles. I invite the reader to imagine the situation at this trial juncture. Lanier had used Santanello to go over almost every aspect of the plaintiff's case. When Merck's counsel stood up, it was important to give the jury a sense of direction.

I have written of the use in direct examination of loops, prologues, and transitions:

> A loop is a repetition of a part of a previous answer to underscore the answer and to help guide the witness to the next event. A prologue sets out themes in advance. A transition is a statement or question that signals a change in subject matter. All three devices can be used in direct and cross-examination--and with any type of witness. They are among the most important devices for focusing on important elements of proof and providing context.[11]

Lowry's examination of Santanello came at a crucial trial stage. Lanier had seized the advantage of primacy. Merck needed to recapture the momentum of the case, and to reassert its story of events. Santanello had the experience and knowledge to assist in that undertaking. Lowry might therefore have introduced the examination with a prologue that stated the themes she was going to explore. Her examination should have been driven by exhibits that she would show the witness, to make Santanello comfortable with the process and to provide a basis to remind jurors of where Santanello's testimony had taken them. Instead, the friendly cross was broken up by the testimony of other witnesses. Counsel took the witness through some important areas but seemingly without an overall plan.

Of course, one might contend that Santanello was so shaken by the adverse examination that she would not be able to fulfill Merck's expectations. The point, however, is that the trial was then in plaintiff's case, and examining Santanello was virtually the only option available in the search to regain control.

After Santanello's testimony, the plaintiffs turned to Dr. David Egilman, a medical doctor who teaches, lectures and practices in the fields of internal medicine and preventive medicine. He is noticed as an expert in hundreds of asbestos and pharmaceutical cases being handled by Lanier's firm, and has testified for several hundred trials in the past 25 years. Lanier used a chart contrasting Egilman's qualifications with Santanello's, as a basis for arguing that Egilman was more qualified.

Lanier's direct examination on Dr. Egilman's qualifications took about two hours, and by the end of it, the jurors were ready to listen. Here is a sample of the questioning:

> Q. Let's talk about your educational background. Did you go to college?
> A. Yes.
> Q. When did you graduate from college?
> A. 1974.

[11] Examining Witnesses 61-63.

Q. What was the name of your college?
A. Brown University.
Q. Where is that?
A. Providence, Rhode Island.
Q. Is that one of those Ivy League schools?
A. Yes, sir. . . .
Q. What did you get your college degree in?[12]
A. I got a bachelor of science in molecular biology.
Q. In molecular biology.[13] Would you please explain to the jury what your college degree means to us, especially in terms of a case like this? What does it mean?
A. Okay. My -- basically what I did was study how substances -- let's use drugs as an example – get into the blood, how do they get from the blood into the cells, how do they change the cells and have effects on the cells, so that kind of process.
Q. And you have a college degree in that?
A. Yes.
Q. In addition to that college degree, you got any other college degrees?
A. That's it.
Q. Okay. What's your next schooling then? I thought you had, like, a medical degree. Isn't that a college?
A. It's -- medical school is a postgraduate.
Q. But it's still college, isn't it?
A. I'm willing to go with you on that.
Q. All right. I just mean -- all right. Give me your next educational thing.
A. Okay. I went to medical school, graduated in 1978.
Q. All right. College was -- you said '74?
A. Yes.
Q. Then you went straight into med school?
A. No.
Q. What did you do first?
A. I was a Vista volunteer, which was the domestic part of the Peace Corps.
Q. How long did you do that?
A. A year.
Q. Then a year later did you go to med school?
A. Yes.
Q. What did you do as a Vista volunteer?

[12] Notice how Lanier breaks down the information into small pieces, rather than having the witness say "I got a degree in molecular biology from Brown University in Providence, Rhode Island in 1974. The witness is prepared to answer each question with just the information requested and let the examiner ask the next one. The witness has been prepared to listen carefully to each question, a trait that stands him in good stead on cross-examination.

[13] Lanier has used a "loop," repeating the answer as a prelude to the next question to emphasize this item of information.

A. I worked in community clinics in Providence.
Q. When you went to med school, where did you go?
A. I went to Brown.

Some judges require that the qualification process be brief. That was the case in the Plunkett trial, where the trial judge directed that each expert could prepare and read to the jury a three-page summary of background and qualifications at the start of the direct examination.

Dr. Egilman's qualification to testify as an expert witness had already been ruled on before he took the stand. Therefore, Lanier could begin the examination – even before getting to qualifications – by letting the jury know the main point that Egilman would be making:

Q. Dr. Egilman, is it important for drug companies to tell us what they know about their drugs?
A. Absolutely. . . .
Q. . . . Why is it important that the drug companies give us the information that they have about their product safety?
A. Well, first, the -- the first question is, who has the information? And the drug companies do the testing.
Q. Does the FDA do the testing?
A. No, sir. Nor can private doctors or academic doctors, on their own, do the testing unless they're part of a company-sponsored trial. Before a drug comes to market, the company that owns the drug controls the drug, how it's tested and where it's tested. They get all the test results first.

On the failure to warn claim, Lanier would eventually present the testimony of the prescribing physician, Dr. Brent Wallace, and he had explored with Dr. Santanello the way in which pharmaceutical salespeople call on doctors and use incentives to get doctors to prescribe particular products. Dr. Egilman had personal experience with Merck sales representatives:

Q. . . . Did Merck send salespeople into your office?
A. Yes.
Q. Salesmen and saleswomen?
A. Yes.
Q. All right. Did they try to talk you into writing Vioxx prescriptions?
A. Absolutely.
Q. Did they tell you Vioxx was safe?
A. Absolutely.
Q. Did they tell you Vioxx was safe on the heart?
A. Yes.
Q. Did they send you a letter about this?
A. Yes, because I was disputing that fact. . . .
Q. Why were you disputing the fact?
A. Well, actually, around the time -- this is 2001 -- there was another drug company selling Celebrex, which you've heard of. And there was a large story about how Celebrex had done a one-year study to try to prove that their drug saved people from getting ulcers. And they published that study after six months. And at the six-month time frame, it looked like their

drug prevented ulcers, and that's the results that were published. But at the time they published those results, they had their 12-month results. And the 12-month results, which they did not publish and hid, showed the opposite. So the analogy I use for my students is, it's like wanting to know if falling off a tall building will kill you, and you count people at the seventh floor, saying "So far, so good. Nobody dies from falling off this building." And so when they had done that, that had keyed me into, all of these drugs may have problems. And so I didn't want to use any of them.

Because Dr. Egilman was not qualified as an expert in clinical trials, he was not permitted to give his complete critique of the Merck studies, but his main points came through. He focused on the disturbing aspects of the VIGOR study. Then, he turned to a discussion of causation. The jury had not yet seen the autopsy results on Bob Ernst, which are seriously debatable on the issue of causation. Rather, Lanier put the plaintiff's theory out first. This tactic may have gained effectiveness considering that the Merck opening had not made causation the centerpiece of the discussion.

Dr. Egilman provided an overview of his theory about Vioxx causing heart attacks like the one sustained by Bob Ernst:

Q. Okay. Do you believe Vioxx can cause a heart attack?
A. Yes.
Q. How can Vioxx be a cause of a heart attack, sir? . . .
A. Well, I'm going to give you a -- I guess the abbreviated fast version. [Witness draws a picture.] We have plaque in here, and you have platelets. Those are the things that cause your blood to clot and they cause -- so, if you cut yourself on your arm, it's the platelets that get in there and close it up and make it a thrombus clot in your forearm. Same thing can happen in your heart. Basically a heart attack means that the supply of oxygen is not enough to feed the work of the heart. You can get there two ways or both. That means that you can have too little oxygen or you can start beating your heart fast and you don't get enough because your heart's working too hard and the work outstrips the oxygen supply. That -- you've heard, you know, people are exercising -- that's an example of somebody who's exercising -- and they have a heart attack. If they were just walking, they wouldn't have had a heart attack. When your heart works harder, it needs more oxygen. And if you have plaque in here, enough plaque, then the blood can't get by to get enough oxygen to the heart. So, that's how a heart attack happens. That's how -- that's a -- that's basically a supply and demand problem.

Now, your platelets are always circulating around in your blood. Sometimes a platelet may come by; and if a platelet goes by and you get a cut in your finger, the platelet says, "Okay. We've got a cut."

And what a platelet does then is it puts -- it activates a COX-1 enzyme, and that activities a bunch of other things. And it basically says, "Okay," calls for all the friendly platelets in the neighborhood. "We've got a cut here. We've got to stop it. We've got to put a thrombus in there. We've got to clot it off." And there's a bunch of enzymes that do that.

> Now, that thrombus stops eventually because, otherwise, every time you've got a clot that clotted a cut off, you'd just clot your whole body off. So, the body has another mechanism that says, "Okay. That cut's fixed. We can stop now." Okay? And that enzyme is prostacyclin, and actually it works as a feedback cycle.[14]
>
> Q. Time out. Is that one that says "stop the clotting" -- the prostacyclin, is that the same prostacyclin that Dr. Santanello told us Vioxx reduces in your body?
>
> A. That's right. So, that brake -- let's think about it like an accelerator and a brake in a car. The accelerator is the platelet producing that thromboxane, saying "Let's get all clotting going." But this -- instead of it being a car that you've got to put the brake on, the brake is automatic. So, if you're going too fast, that brake puts it – it does it itself, and it stops the clot from forming. And then eventually you get thrombolysis, which means the clot breaks away. That's why you don't have your permanent -- every time you get a cut, the clot goes away. Same thing if you clotted a vein off, it would eventually go away, because you've got your own body system corrections to rechannel the veins and arteries if you get a clot.

This formulation supported the theory that there might have been a clot that caused Bob Ernst's heart attack, but this witness has not yet explained why the autopsy did not reveal any evidence of a clot. However, Dr. Egilman set out his conclusion with the last question and answer that the jurors heard on a Friday afternoon:

> Q. Okay. Dr. Egilman, based upon your analysis and the studies, scientific liability -- I mean, scientific plausibility, the epidemiology, all of the different things that you've looked at, do you have an opinion, based upon reasonable medical probability, as to whether or not Vioxx was a cause of Bob Ernst having a heart attack?
>
> A. Yes, sir. . . .
>
> Q. And what is your opinion, sir?
>
> A. That his taking Vioxx caused and contributed to -- and/or contributed to his heart attack.

On the following trial day, a Monday, Lanier got permission to put on Dr. Isaac Wiener, out of order. Dr. Wiener is a cardiologist and cardiac electrophysiologist. He is an expert in the installation of pacemakers. Lanier spent an hour or so going through Dr. Wiener's relevant qualifications, focusing on his work with patients and on his publications related to arrhythmias. Dr. Wiener then used a model of a heart[15] to show the jury the heart structure and the blood vessels that surround it. Dr. Wiener is not an epidemiologist, and had not read all the studies relating to Vioxx and its potential side-effects. The trial judge overruled defense objections to opinions based on epidemiological considerations.

However, Dr. Wiener had read Bob Ernst's chart and the coroner's report. First, he said that Vioxx could cause the type of cardiac event that Bob Ernst experienced,

---

[14] Many judges would not permit such a long narrative answer on direct, but there was no objection.

[15] The model was one that Merck supplies to physicians.

specifically that "the heart suddenly doesn't get enough blood." Vioxx was "a significant contributing factor in causing this event."

Given that there was no autopsy evidence of a clot that cut off blood supply, Dr. Wiener reasoned that since statistically most sudden cardiac events in situations like Bob Ernst's are caused by clotting, it is therefore likely that there was a clot. Dr. Wiener disagreed with Dr. Santanello's testimony that a clot would have been found had it been there. He thought it might have broken up – "lysed" is the word he used – and not been found.

If there was a clot, then the diagnosis would have been a myocardial infarction, or MI. On cross-examination, Merck lawyer David Kiernan first established the standard medical criteria for MI, including chest pain, pain radiating down the arm and so on. Then, he asked the crucial question:

> Q. In fact, the criteria for diagnosing a myocardial infarction or heart attack, were not present at the time of Mr. Ernst's death; isn't that correct, Dr. Wiener?
> A. My answer is the same that, yes, the criteria were not present, but on the other hand, there are limitations to the criteria in this setting. And, therefore, I think we cannot say one way or the other whether he had a myocardial infarction.
> Q. You can't say?
> A I think it's possible, but it's also may not be. We just cannot say.
> Q. You were actually provided with [the tissue] slides [prepared during the autopsy] in this case, weren't you?
> A They sent me the slides, yes.
> Q. But you didn't even look at them?
> A I didn't have a place to look at them, and I wouldn't know what I was looking at.
> Q. All right. So you don't specialize in pathology?
> A I've answered that. No, I don't -- I don't even have a sub-- you know a minor interest in pathology. I work with some great pathologists.
> Q. Okay.
> A. And they're very, very useful and very, very helpful, and I defer to them.
> Q. All right. The microscopic examination was done by the coroner, and here, again, there was no evidence of recent or remote infarction, correct?
> A. The report says there's no evidence of recent or remote infarction. And, again, I think the information about remote infarction is very, very important. The evidence of recent infarction is not something we can rely on.
> Q. Okay. In this case, at least, both in looking at the heart grossly, as you did this morning in front of the jury, and looking at the tissue under the microscope using both examinations, the coroner did not find any evidence of an old or new myocardial infarction, correct?
> A. That's what the report says.
> Q. Okay. And there's also no indication anywhere in the report that there was any evidence of a thrombus or a clot, correct?

A I did not see mention of a thrombus.
And later:
Q. Now, just so we're clear, there are drugs that can be used to dissolve clots in patients who had heart attacks or strokes, correct?
A There are several drugs.
Q. And they were not used with Mr. Ernst, correct?
A. No.
Q. There's no evidence he received any kind of clot dissolving medications of any kind, correct?
A. He did not receive thrombolysis.
Q. And based upon all of the evidence that we've discussed here this morning, Dr. Wiener, you are not able to say to this jury to a reasonable degree of medical probability that Mr. Ernst, in fact, had a myocardial infarction, correct?
A Again, as I said, I think the traditional ways of diagnosing myocardial infarction do not apply in sudden cardiac death. Because the patient dies too soon, we cannot rule it in or rule it out.
Q. Let me ask the question one more time, Dr. Wiener. Based upon all the evidence that you've talked about here today, you are not able to tell this jury to a reasonable degree of medical probability that Mr. Ernst, in fact, had a myocardial infarction, correct, sir?
A. Okay.
Q. You agree with that?
A. Yes, I would agree with that.

Dr. Wiener also conceded that Mr. Ernst had coronary artery blockage, which would have put him at risk for a cardiac event.

After Dr. Wiener's half-day appearance, Dr. Santanello took the stand again for more examination by Merck's counsel. She discussed Merck's position with respect to the studies performed on Vioxx and the various FDA concerns that Lanier had raised. Merck's counsel also asked her to review and rebut some of the medical conclusions that had been offered by plaintiff's witness Dr. Egilman. This of course opened up more adverse examination, during which Lanier compared Santanello's views to those of Dr. Egilman. Egilman's testimony was to resume after Santanello's had finished.

In all, the interruptions in Dr. Santanello's testimony, and Merck's effort to use her against the plaintiff's case, were harmful to Merck's case. Given the trial schedule, she could not have been well-prepared to present a comprehensive rebuttal to the plaintiff's theory. She did not have the qualifications in cardiology or pathology of the other Merck witnesses that appeared in the defense case-in-chief. The jurors' impression of her based on the initial adverse examination was probably not favorable. Merck would have done better to insist on the plaintiff's case going in one witness at a time, with cross-examination to follow direct and then the witness being excused.

After Santanello's testimony,[16] plaintiff called three physicians as experts, and presented the videotaped deposition of Merck CEO Raymond Gilmartin, and the testimony of Carol Ernst's daughter and of Mrs. Ernst herself. In addition, and over objection, plaintiff presented Dr. Maria Araneta, the pathologist who performed the autopsy on Mr. Ernst.

When Dr. Egilman took the stand, Lanier spent more time with him discussing the various studies of Vioxx. During her reappearance after interruption, Santanello had characterized Dr. Egilman's analysis in these words:

> It's mixing apples and oranges and peaches and blueberries and strawberries. It's mixing everything together into the fruit salad.

When he reappeared, Dr. Egilman seized that metaphor in several answers, characterizing documented adverse effects in the Vioxx studies as various kinds of rotten fruit. Figures of speech can be effective in trial advocacy, but in litigation as in life they can also be punctured, or turned against the person who invokes them.

Merck lawyer David Kiernan began his cross-examination by seeking to portray Dr. Egilman as a "professional expert" who mainly supports plaintiffs. Egilman sought to turn Kiernan's questions against him:

> Q. Now, over the course of your career as a testifying expert, you've criticized a number of companies and government agencies; isn't that correct?
> A. That's correct.
> Q. You've accused the petroleum industry and epidemiologists they hired of misclassifying workers, correct?
> A. That's correct.
> Q. You've accused IBM and Computer and Business Equipment Manufacturers Association of covering up information concerning musculoskeletal disorders associated with keyboards?
> A. That's correct.
> Q. You've accused the Chemical Manufacturers Association of a conspiracy to hide the health effects of chemicals?
> A. I don't think conspiracy, but they've certainly together worked to do that, that's correct.
> Q. March 12, 1999, you testified as an expert that General Refractories was engaged in a conspiracy with other companies to increase profits at the expense of workers?
> A. I don't think I used the word "conspiracy," but it's certainly true they acted together with other companies to do that.
> Q. You've accused the American College of Chest Physicians as being a front for asbestos companies to hide the harmful affects of asbestos, correct?
> A. On one particular issue, that's correct.

[16] As noted, Santanello's testimony was interrupted while plaintiff put on two experts. This accommodation of schedules probably worked to plaintiff's advantage by bringing Santanello back. A trial judge more concerned with courtroom control might have insisted on finishing one witness before another one was sworn, and limited repetitious questioning.

Q. You've also criticized the United States Environmental Protection Agency, the Occupational Health and Safety Agency, and the Food and Drug Administration, correct?

A. That's correct.

One might ask how these questions were impeaching. The questions do not suggest, nor the answers tend to show, that Dr. Egilman was doing anything improper or that his opinions in those cases were somehow invalid. He begins to look like a public-spirited person, at least to a jury that by this time has been tuned in to a basically populist, anti-corporate, anti-bureaucratic message.

Kiernan continued the cross-examination by reading parts of an adverse student evaluation from one of Dr. Egilman's courses, criticizing his anti-corporate bias, and by mentioning that "courts" had criticized Dr. Egilman's testimony. Although Lanier did not object, these questions raise hearsay issues. More significantly, it may be that Kiernan was trying to use cross-examination to do more than it can. Cross-examination is about immanence,[17] that is, what is inherent in the witness-lawyer exchange. If Dr. Egilman has a bad reputation, witnesses in the defense case can comment on his lack of credentials and the unreliability of his conclusions.[18]

Kiernan then moved on, eliciting that Dr. Egilman had never participated in designing a major clinical trial or designing a label for a pharmaceutical product, or in several other areas relevant to the opinions he offered. Kiernan brought out that American Medical Association ethical standards limit expert testifying to subjects on which the witness is qualified. He continued:

Q. Now, let me ask you about your experience with NSAIDs and pharmaceuticals. You've never published an article on Vioxx in a peer-reviewed medical journal, correct?

A. Published? That's correct.

Q. You've never published an article on NSAIDs or non-steroidals in a peer-reviewed medical journal, correct?[19]

A. That's correct.

Q. You've never published an article on any pharmaceutical drug in any peer-reviewed medical journal; isn't that correct, sir?

A. That's correct.

Q. You're not a practicing pathologist?

A. That's correct.

---

[17] On the idea of immanence, see Examining Witnesses 200.

[18] Kiernan also asked questions about Dr. Egilman's standard fees for expert services. Egilman said he was not getting a fee in this case, and Lanier brought out on redirect that Egilman had directed that any fee to which he was entitled be donated to a local cardiac care facility. This is the sort of thing that a lawyer opposing an expert must be careful to learn from pretrial discovery, so that questions about compensation do not backfire.

[19] It might have been helpful to use a series of leading questions to describe for the jurors the role of peer-reviewed publications in the medical profession. Alternatively, one can discuss this issue in opening statement and then use defense experts to talk about it. Kiernan would also have been entitled to elicit from Dr. Egilman that Baylor College of Medicine, from whence the defense experts come, is a leading teaching and research facility.

Q. You're not a practicing cardiologist?
A. That's correct.
Q. In fact, you don't have a regular clinical practice of any kind?
A. That's correct.

Kiernan turned to the issue of causation:

Q. According to the death certificate, the immediate cause of Mr. Ernst's death was cardiac arrythmia, correct?
A. That is correct.
Q. And this occurred, according to the death certificate, minutes before his death, correct?
A. That is correct.
Q. According to the death certificate, sir, cardiac arrythmia was due to coronary atherosclerosis, correct, sir?
A. That is correct.
Q. And according to the death certificate, Mr. Ernst's coronary atherosclerosis had been present for several years, correct?
A. That is correct.
Q. The death certificate does not say that Mr. Ernst died from a heart attack, correct, sir?
A. That's correct.
Q. In fact, the death certificate states that Mr. Ernst died of an arrhythmia, correct?
A. That's correct. . . .
Q. You were provided with a set of pathology slides to look at in this case; isn't that true, sir?
A. That's correct.
Q. But you didn't look at them?[20]
A. That's correct.

There were other areas of cross-examination, directed to Dr. Egilman making conclusions and agreeing to be an expert witness even before he had looked at all the documents. It is clear from the trial record that Dr. Egilman works closely with the Lanier firm on a number of lawsuits, and is a sort of "all-purpose" medical expert.[21] In any jurisdiction, there would be a serious admissibility issue, both as to some of his conclusions in fields where he lacks education and experience, as well as based on his meager record of relevant peer-reviewed publications.

The plaintiffs then presented, by videotape deposition, Dr. Maria Araneta, who I,n her capacity as assistant medical examiner for Johnson County, Texas performed the autopsy on Bob Ernst. She had no independent memory of the autopsy, and could testify

[20] These are all good leading questions. What's missing here is one or two leading questions on each item to define and explain "atherosclerosis" and "arrhythmia." Granted, they have heard these terms throughout the trial, but what's important here for the defense is that the autopsy supports the idea of death being caused by events that antedate and are irrelevant to Vioxx usage. One would not ask those "conclusion" questions, but those objective facts can be brought out.

[21] Merck also accused Dr. Egilman of violating pretrial protective orders by sharing Merck discovery documents with government agencies.

only from the autopsy report and the other information in the autopsy file. Her primary function as medical examiner was to rule out foul play and suicide. She did see an indication on the emergency room record that Ernst might have had a myocardial infarction. She examined his heart and the associated blood vessels. She noted her autopsy report conclusion on the cause of death: "cardiac arrhythmia secondary to coronary atherosclerosis." Nothing in her report suggested a myocardial infarction because "it wasn't there to be seen."

Dr. Araneta then delivered the opinion that supported the Ernst case:

> So, in this case the logical situation is an acute ischemic event. Something blocked that artery that was already narrowed, either a clot, a fissure, block, a ruptured atheroma, none of which I saw, but it -- these things could be dissolved. He was resuscitated very vigorously. Emboli could have been dislodged, you know. And they fractured his ribs. They were pounding on his chest. The MI could be before me, but I can't see it. So, how can I put it down?

In short, there could have been a clot that either "dissolved" or was dislodged in the resuscitation efforts. Under examination by Lanier, Dr. Araneta stated categorically that Ernst died from a myocardial infarction, that is, from a clot that set off the chain of events that led to his death. Whether this possibility and Dr. Araneta's qualifications to opine on it, have enough scientific support to sustain the Ernst verdict will be debated on appeal. The trial judge allowed the Araneta testimony and that of plaintiff's experts who supported this view.[22]

Lanier presented the video deposition of David Anstice, president of the Merck Human Health division for Canada, Latin America, Japan, Australia and New Zealand.[23] Anstice had been president of Merck North America. He has a business background, and Lanier focused on Vioxx sales and marketing issues. One can get the flavor of this adverse examination from the following exchange:

> Q. . . . I understand you're the president of some part of Merck. What part are you the president of?
>
> A. Human Health for Canada, Latin America, Japan, Australia, New Zealand.
>
> Q. At some point, were you the president of Merck America or something like that?
>
> A. Yes, I was.
>
> Q. When was that?
>
> A. From the period late '94 through to the end of 2002.
>
> Q. You're the president of Human Health, and you don't have a medical degree?

---

[22] When Merck learned of Bob Ernst's death, a Merck employee spoke with Dr. Araneta and made a memorandum of the conversation. In that memorandum, Dr. Araneta is quoted as saying that she felt that Ernst's death was not related to Vioxx, although Mrs. Ernst was concerned about that possibility. Dr. Araneta did not remember that conversation, and Merck lawyers did not call as a witness the employee who had the conversation.

[23] Merck objected to the broad-ranging inquiry into sales and marketing practices as irrelevant and as repetitious of other evidence.

A. I do not.
Q. Well, did you go to any medical school at all?
A. No, I did not.
Q. Well, as the president of Human Health, what kind of human health schooling do you have?
A. I -- I'm responsible for sales and marketing activities, and I have the training and skills developed -- in 31 years at Merck.
Q. Okay. That wasn't my question, sir. What kind of schooling do you have in human health if you're going to be the president of the Human Health division?
A. I have schooling -- I have tertiary education in economics. And I joined Merck and -- typical with many people on the business side, I do not have a medical degree or a medical background.
Q. So, the president of Human Health is a salesman?

Lanier again brought out, through Anstice, that in the 1999-2000 period, several important Merck drug patents were running out and the company needed new products to maintain growth. Anstice also admitted that he was aware of allegations that Merck scientists and others were attempting to block information about potential Vioxx safety issues from becoming public, and that there were discussions among Merck employees about how to discredit or silence critics.

To support the theory that cardio-pulmonary resuscitation (CPR) might have dislodged a clot, Lanier called Dr. Benedict Lucchesi, a professor of pharmacology at the University of Michigan. Dr. Lucchesi has M.D. and Ph.D. degrees. He had never engaged in the clinical practice of medicine, and had no personal experience with CPR since the 1960s or 1970s. Merck counsel David Kiernan conducted a voir dire examination out of the jury's presence as the basis for moving to prevent Dr. Lucchesi from expressing any opinion about the clot-dislodging effect of CPR. The examination concluded:

Q. Okay. Are you aware of any published literature suggesting that CPR can dislodge or move clots, sir?
A. No, I'm not.
Q. Are you aware of any case reports that would suggest CPR can dislodge or move clots, sir?
A. No, I'm not.
Q. Okay. Are you aware of any publication anywhere in the world that would suggest that CPR can dislodge or move a clot?
A. No, I'm not.
Q. In any recorded human history at any point in any language?
A. No.

The trial judge ruled that Dr. Lucchesi could not offer an opinion about the potential effect of CPR on a clot. However, he could and did testify in support of the theory put forward by Dr. Egilman. Dr. Lucchesi had for many years studied the clotting propensities of drugs that affect Cox inhibitors. He had published on this issue. He also believed that a dangerous clot that caused a blockage could dissolve or be broken up by electrical charges during defibrillation. He summarized his conclusions:

Q. All right. Now, would you please put this all together within the realm of Bob Ernst taking 25 milligrams once a day of Vioxx -- let me first ask it this way: Do you have an opinion, based upon reasonable medical probability, of whether or not Vioxx was a cause of the death of Bob Ernst?
A. Well, I reviewed --
MR. KIERNAN: Same objection.
THE COURT: Overruled.
THE WITNESS: -- the Ernst documents very carefully. And my final conclusion, based on reasonable medical probability, is that he died of an arrhythmia, precipitated by a transient ischemic event[24] leading to ventricular fibrillation.
Q. (By Mr. Lanier) Was Vioxx a cause in that process?
A. In view of the fact that he was taking Vioxx and in view of the fact I know that Vioxx blocks COX-2 and in view of the fact that he had underlying vascular disease, which makes him a candidate, along with Vioxx, for such a serious event, my only conclusion would be that Vioxx contributed significantly to this. And that's beyond any probability. The probability there is in favor of Vioxx having contributed to this. And he's not the only one, because there are many other instances where we've seen similar cases.
Q. Without Vioxx, based upon reasonable medical probability, would Bob Ernst be here today?
A. That's hard to say. He may have been crossing the street at the wrong time or something. But looking at his medical history where he had no symptoms, I don't see why he would not be here today.

On cross-examination, Merck lawyer David Kiernan established that Dr. Lucchesi had conceded publicly that Vioxx should remain on the market, provided adequate warnings were given, and provided that it was used for patients with a high risk of stomach bleeds. He also conceded that some of the literature on which he relied for his conclusions about the clotting effect were based on studies of Celebrex, not Vioxx. He also conceded that there was a substantial debate in medical literature about the proposition that COX-2 inhibitors have an effect on clotting. Turning to the controversial VIGOR study, Kiernan asked:

Q. Okay. In your view, sir, the naproxen group in the VIGOR study probably benefited from some degree from the platelet inhibition, correct, sir?
A. Well, that's a possibility.
Q. Okay. Do you know Dr. Carlo Patrono?[25]
A. Very well.
Q. Okay. You respect him?
A. Pardon me?

[24] The ischemic event referred to here is a blockage.
[25] It is permissible, in examining an expert, to ask him or her to comment on the conclusions of another expert, and to refer to learned articles and treatises. Examining Witnesses 424-28.

Q. You respect him, sir, correct?
A. I did.
Q. Okay. You think he's a good scientist?
A. He is.
Q. Okay. You're familiar with a journal Circulation, correct, sir?
A. I think I am, yes.
Q. You were on the editorial board? You may be on the editorial board today, correct, sir?
A. Yes, I am. . . .
MR. KIERNAN: If we can pull up – do you have Defendant's 454? I think this is already in evidence. Hold on one second. Is 454 in evidence? If it's not, we offer it as a demonstrative, Your Honor. It's an article from Circulation.
MR. LANIER: I don't have any objection to using it, Judge.
THE COURT: It's admitted as a learned treatise.
(Exhibit D-454 admitted.) . . .
Q. (By Mr. Kiernan) This is an article in Circulation by Dr. Capone and Dr. Carlo Patrono. That's the gentleman we've just been talking about, correct, sir?
A. Yes. . . .
Q. (By Mr. Kiernan) Circulation is the journal you mentioned here today, correct, sir? 2004. . . . According to Dr. Patrono, he states that "We found that the chronic administration of a therapeutic anti-inflammatory dose of naproxen, 500 milligrams, twice a day to healthy subjects caused persistent and almost complete suppression of platelet thromboxane production throughout the 12-hour dosing interval that was indistinguishable from that of low-dose aspirin." Did I read that correctly, sir?
A. Yeah. So what?
Q. That happens to be Dr. Patrono's views on the topic, correct, sir?
A. Okay.
Q. Okay. If you could go to the next quote. It says, "In conclusion, the present study demonstrates the pharmacodynamic plausibility of a COX-1 dependent cardioprotective effect of naproxen and contributes to the interpretation of the VIGOR cardiovascular findings." Did I read that correctly?
A. Yes.
Q. Okay. You agree with that, don't you, sir?
A. I know it to be true, yes. I did not need Dr. Patrono to tell me that. . . .
Q. Okay. Thank you. And on Page 245, . . . "While the cause of the apparent excess risk of MI in the Vioxx GI outcomes research trial cannot be conclusively established, a combination of some cardioprotective effect of naproxen and the play of chance does seem to offer a plausible explanation for these unexpected findings. While other mechanisms cannot be discounted, there is currently little evidence in humans to support a pro-thrombotic effect for Coxibs." Did I read that correctly, sir?

A. You did.[26]

When I finished a draft of this chapter, my research assistant Natalie Hirt read it and made a note next to the excerpt quoted above, "This seems difficult for a lay-person to understand." She is right. Kiernan failed to restate the key points and get the witness to agree to an understandable version of matters.

After Dr. Lucchesi's testimony, the plaintiff presented Bob Ernst's daughter Shawna Sherrill to talk about her mother and stepfather's close and loving relationship. Lanier then played brief excerpts from the video deposition of Bob Ernst's treating physician, Dr. Brent Wallace.[27] Because Dr. Wallace had originally been named as a defendant, Lanier could examine him with leading questions. Dr. Wallace was not uncooperative, however. He said that the Merck sales representatives did not inform him of FDA warnings and of possible adverse effects from Vioxx. Had he been fully informed, he would not have prescribed Vioxx for Bob Ernst.

On cross-examination by Merck counsel, Dr. Wallace conceded that many drugs have side effects. Sometimes these effects are serious. Dr. Wallace said that he became aware of the VIGOR study and that Merck representatives visited him to present the view that the study results were accounted for by the cardioprotective effect of Naproxen. Dr. Wallace said that he not only prescribed Vioxx after the VIGOR study, but used it himself.

Plaintiff's next witness was Ken McCoin, an actuarial accountant who presented financial figures projecting what Bob Ernst's financial contribution to the Ernst household would have been if he had lived out his natural life span. The trial judge limited cross-examination that would have pointed out that Bob Ernst had been married five times before marrying his widow and that this fact created some doubt as to whether he would have stayed married to Mrs. Ernst. These financial projections are based on the number of years that Mr. Ernst would probably have stayed in the work force, and what his probable income would have been.

Finally, Mrs. Ernst took the stand. Her direct examination was conducted by Lisa Blue, a prominent Texas trial lawyer and partner in the firm of Baron & Budd. Mrs. Ernst described how she met, fell in love with, married and lived with Bob, and then recited the events surrounding his death. The direct examination was organized and effective, as a few excerpts will show:

Q. I have six areas to ask you about. All right?

A. Okay. . . .

* * *

---

[26] Kiernan's cross-examination of Dr. Lucchesi showed a grasp of the epidemiological issues, and was effective and controlled. Looking at the cross renews the sense that Kiernan's opening statement was a missed opportunity to lay out a story of the case that was positive and not defensive, and that gave the jury a preview of what they would be hearing from Merck. A defendant's opening says to the jury that the defense case begins with cross-examination of defense witnesses. That cross-examination, in turn, keeps the opening statement promises.

[27] Although Dr. Wallace practices in Texas, he was outside the territorial limit of effective subpoena service and could not be compelled to testify in person in Brazoria County, Texas, where the trial was held.

Q. Next subject. Bob Ernst is not able to testify in this trial, so you have to be his voice for a little bit. Okay?
A. Okay.
* * *
Q. Two down. Four to go.
A. Okay.
Q. We've already done some of this next subject, because I want to talk about you and Bob together. Okay? You told us how you met.
* * *
Q. Okay. Ms. Ernst, I want to talk now about what life has been like after Bob died. You -- I'm assuming this was in the middle of the night?
A. Yeah.

Merck counsel Gerry Lowry cross-examined. Reporters who covered the trial have said that Ms. Lowry's tone and manner appeared to alienate the jury. The transcript bears out this observation. Ms. Lowry posed many questions about Ms. Ernst's background and education. She asked questions designed to show that Ms. Ernst was not particularly close to Mr. Ernst's children by a former marriage. She brought out that when Mrs. Ernst first met her husband-to-be, he was not single but was getting a divorce. She had Mrs. Ernst admit that Mr. Ernst's salary had declined over the couple of years before his death, when he lost his job managing a pizza restaurant and then went to work for Wal-Mart. If, as occurred, Merck were to be held liable in this trial for a large compensatory damage verdict, most of these questions could serve only to reduce a relatively small portion of that verdict – the portion dealing the loss of support and companionship. The potential "savings" in damages does not seem to outweigh the substantial risk of alienating the jury and adding fuel to juror anger that might drive up other parts of the award.

After the plaintiff rested her case, Merck presented four live witnesses and the video deposition of Raymond Gilmartin, CEO of Merck from 1994 to 2005. In order, the witnesses were Dr. Alan Nies, who had supervised development of Vioxx at Merck, pathologist Dr. Thomas Wheeler, Mr. Gilmartin, Dr. Alise Reicin, who worked on clinical trials and other studies of Vioxx at Merck, and Dr. Craig Pratt, a cardiologist.

Dr. Nies discussed the atmosphere at Merck and in the pharmaceutical industry in which Vioxx was developed. He defended the development process. On cross-examination, Lanier confronted him with Merck marketing documents about the importance of Vioxx, showing that, at the time Nies was directing the Vioxx effort, Merck was concerned that Searle would get to market first with a Cox-inhibitor – which turned out to be Celebrex – and that Merck expected significant financial benefits from Vioxx:

Q. . . . Sir, when you tell this jury we're not under any race, we're not under any pressure, we didn't have a clue where Searle was in their drug, you-all knew two years earlier or at least suspected that Celebrex, your competitors, would be filing in the fourth quarter of '98, didn't you?
A. That's what it says.
Q. And because of this you-all were under pressure and decided you were going to proceed, let's see, aggressively on developing Vioxx -- "The development of Vioxx must proceed aggressively."

A. That's true. We wanted to get this drug out.
Q. Because of the money, right?
A. We felt this would be a major advance to patients.
Q. No, sir. You wanted to get the drug out because of the money?
A. Not me.
Q. This is your development plan, this is your company and your company wanted to get the drug to market first for the almighty dollar, right?
A. We want to put out drugs that will sell, yes. There's no question about that.
Q. No, sir, that wasn't my question. The reason you-all wanted to get to market first – [quoting from a Merck document] "The development of Vioxx must proceed aggressively to meet this challenge. The primary objective is to achieve the same filing date." Do you see the same filing date?
A. A 4Q '98 filing. That was our objective, yes.
Q. And the reason why, if we go to the end of the document, is because it will make you-all an extra 600 and some odd million dollars if you're first, right?
A. I don't know about that.
Q. Well, let's look.
A. That's not my expertise.
Q. Well, it's in your program, it's in your document and here's what it says on Page 64. It says the best case scenario of Vioxx first to market means you're going to make 889 million. Do you see that?
A. Yes.
Q. In the event Vioxx is second to market, you get beat, however, you're only going to make 278 million. Do you see that?

This brief excerpt reveals once again the inherent contradiction faced by defendants in many product liability cases. The company is in business to make a profit, and its internal corporate documents and public reports to shareholders and regulators will interpret plans, activities and results in terms of profit and potential growth. Employee evaluations will focus on contributions to "the bottom line." At the same time, management will have many reasons to insist that products be safe, effective and well-made. Potential lawsuits, regulatory controls, shareholder dissatisfaction, and reputation in the marketplace are among these reasons. But management can also choose to create and foster an internal culture around certain values. A given management may even have public service goals. One of Lanier's strong points in this trial was his portrayal of a change in Merck corporate philosophy. The contradiction with which Lanier confronted Dr. Nies, though inherent in Merck's position, should also have been clear to Merck lawyers. In their story of the case, they had the responsibility to acknowledge and even to embrace the contradiction.

Dr. Thomas Wheeler is a Baylor College of Medicine professor and a noted pathologist. He looked at the autopsy report, Ernst's medical records and the slides of coronary artery tissue made in connection with the autopsy. He described Bob Ernst's coronary artery as so affected by calcification that one could not cut it with a scalpel. It

had to be soaked in a chemical bath to soften it enough so that microscope slides could be prepared from transverse slices of it. He directly contradicted the Egilman, Araneta and Lucchesi theories about cause of death. Dr. Wheeler told the jury the figures about sudden cardiac death in America, particularly among older men. He showed the jury the autopsy slides:

> Q. And how do those -- are those the arteries where there's most calcification?
> A In this gentleman, yes.
> Q. Okay. All right. Is there anything else of significance on here that you'd like to point out to us that we haven't discussed?
> A There are several pieces of tissue. This is one of three.
> Q. Okay. You can go ahead and show us.
> A And they all show basically similar findings. Here you can actually see the calcification even better. Here's the thick fibrous cap here, the purple -- I mean the pink. It would be like leather, the consistency of leather. And then this is the big rock of calcium. And this actually shows up. . . .
> Q. What else did you see on here that would be important to us?
> A Well, what's significant is what we don't see. We don't see a lipid rich cholesterol plaque which are the ones more vulnerable to rupture, particularly the ones that have a thin cap. This had very little cholesterol, had mainly calcium, had a thick fibrous cap. That's the type of atherosclerotic plaque that is less likely to rupture to initiate the blood clot formation.
> Q. Okay. So what does that tell us in this case bottom line?
> A Well, it tells us that we wouldn't have expected a thrombus to form here.

With respect to Dr. Lucchesi's theory:

> Q. And so when Dr. Lucchesi told us that the clot would continue to dissolve after death; is that true?
> A No, it's absolutely false.

And specifically on Dr. Araneta:

> Q. Now, there's also been some testimony by Dr. Araneta that even though she didn't find a clot that maybe there possibly was a clot that got dissolved or dislodged by CPR. Do you remember that testimony?
> A Yes.
> Q. Could EMTs have dislodged or broken up a clot when they were doing CPR on Mr. Ernst?
> A I don't mean to be disrespectful, but it's a preposterous notion for several reasons.
> Q. Go ahead and explain.

In sum, Dr. Wheeler's presentation was an orderly and illustrated discussion of the defense theory and a reply to the plaintiff's experts. By that time in the trial, however, it may have been too late. David Kiernan had referred to the Ernst autopsy report near the end of his opening statement. He mentioned Dr. Wheeler and cardiologist Dr. Craig Pratt only briefly, and did not give the jury a complete look at their qualifications nor a detailed preview of their conclusions. He therefore missed the

opportunity to put the vital causation evidence into perspective before the plaintiff's parade of witnesses, and to make causation the central theme of the defense story.

On cross-examination, Lanier stressed that Dr. Wheeler's pathology experience had focused a great deal on prostate pathology rather than cardiac pathology. He presented evidence that contradicted some of Dr. Wheeler's use of terminology to describe Bob Ernst's extent of coronary artery disease. Lanier's cross-examination was no doubt structured based on learned treatise materials that plaintiff's own experts had found and put together.

The issue of Merck scientist credibility arose again during Dr. Reicin's testimony. She came across in her direct examination as a committed and concerned scientist. She disagreed with plaintiff experts and discussed the research that preceded and followed introduction of Vioxx to market:

> Q. Dr. Reicin, I'd like to go right to Vioxx and talk about that a little bit if we could. The jury has heard a fair amount about the early studies on Vioxx, and I want to touch upon those as we move forward. But today I'd like to ask you questions primarily as we move from VIGOR forward. Is it possible for you to give us an estimate of the total number of clinical trials or clinical studies that were performed on Vioxx starting from the very beginning up to the present?
> A There have been a lot of clinical trials. Before we submitted the NDA, that's the new drug application which is our regulatory filing, I think there were approximately 58 clinical trials including close to 10,000 patients. That was either the biggest or one of the biggest new drug applications in terms of number of trials in patients that Merck had ever filed. And once we filed it, we didn't stop. The number of trials that we've done post filing have been enormous, again, one of the largest programs that Merck or probably any other pharmaceutical company has performed. I think post filing we've had over 70 studies or approximately 70 studies in close to 40,000 patients. So we are talking about an enormous, enormous database and program for the study of both the efficacy and the safety of Vioxx.
> Q. If my math is right, that's over 125 clinical trials on Vioxx?
> A I think it's something like that; that's correct.

And later:

> Q. We heard from an expert witness called by the plaintiffs, a Dr. Egilman, that the studies leading up to the new drug application were too few. Do you agree with that?
> A I do not agree with that, and the regulatory agencies did not agree with that.
> Q. We heard from Dr. Egilman that the studies were too short. Do you agree with that?
> A Again, I don't agree with that. I think we had extensive long-term data for a new drug application, as I said, several fold more than regulatory guidelines call for.

Dr. Reicin referred to the Patrono study, about which Merck lawyer David Kiernan had asked Dr. Lucchesi, concerning the cardioprotective properties of naproxen. Kiernan's questions went issue by issue over the development and testing of Vioxx, in a

structured and measured direct examination that addressed each of the plaintiff's issues. Dr. Reicin is a vice-president of clinical research at Merck and has a distinguished academic and professional record. She is also a poised and carefully-prepared witness. She knows the science and has a good grasp of the drug development process. She also appeared in the Plunkett case. The direct examination concluded:

> Q. A couple of final questions. Mr. Ernst passed away from a ventricular arrhythmia. Are there any studies that conclude that Vioxx causes ventricular arrhythmias?
> A. No.
> Q. Does Vioxx cause ventricular arrhythmias?
> A. No.
> Q. The plaintiffs in this case claim that Mr. Ernst may have had a blood clot that led to a heart attack and sudden death. And I want you to assume that Mr. Ernst took Vioxx for six to eight months. Are there any clinical trials against placebo or sugar pill that show a statistically significant relationship between the use of Vioxx milligrams for six to eight months and myocardial infarction or heart attack?
> A. No.
> Q. Are there any clinical trials against placebo or sugar pill that show a statistically significant relationship between the use of Vioxx 25 milligrams and sudden death in patients while they were taking Vioxx?
> A. No.
> Q. Finally, have you used Vioxx yourself?
> A. Yes, I have.
> Q. For how long a period of time?
> A. I have lower back problems. And sometimes for a couple days, but I've taken it for prolonged periods of time as well; for, on average, several months, several months.
> Q. Did you take it up through withdrawal?
> A. Yes, I did.
> Q. Looking back, Dr. Reicin, is there anything different you would have done with respect to Vioxx?
> A. I think we did the right thing. We thought the drug was safe. I thought the drug was safe. I took the drug. We continued to study the drug. Doing otherwise would have been against the core of who I am. It would have been against the whole reason I went into medicine. And it would have been against the core of the colleagues I work with at Merck.

On cross-examination, Lanier's attack began with excerpts from Dr. Reicin's personnel records, showing that her superiors at Merck praised her for "defending the Vioxx franchise" and "building the scientific base for a COX-2 business." Lanier showed her an e-mail on which she was copied, referring to Vioxx critics as "barbarians at the gate." He then explored in detail her role in damping internal and external criticism of Vioxx. Recalling that Dr. Reicin had been asked to comment directly on Bob Ernst, Lanier asked a question about Ernst's health history:

> A. I really can't comment on the details of Mr. Ernst's case because I'm not aware of them.

Q. Did you not -- you have not looked at the medical records?

Q. So before you came in and testified to this jury that Vioxx wasn't linked up to anything he had or any problems he had, you hadn't even read his medical records?

A. I have not been asked to read his medical records.

The trial judge allowed, over objection, questions about marketing and labeling disputes of which Dr. Reicin had no personal knowledge or professional connection. Lanier kept Reicin on cross examination for more than a full trial day, more than twice the time she spent on direct examination.

Cardiologist Dr. Craig Pratt was Merck's final witness. He is a well-respected Houston, Texas practitioner and teacher. He is also an electrophysiologist, and serves as chair of his hospital committee on pharmaceuticals. Merck lawyer Gerry Lowry took Dr. Pratt through his qualifications, and then asked him a series of questions about the plaintiff's experts. Pratt fairly but pointedly compared his own qualifications to theirs. He mentioned that Dr. Lucchesi is "a brilliant basic scientist" whose "primary work is in animal models."

Dr. Pratt deconstructed the plaintiff's experts' theories, while offering his own view of Bob Ernst's death as unrelated to any condition that Vioxx might have caused or contributed to.

Lanier's cross focused on Dr. Pratt's professional connections to pharmaceutical companies and the proportion of his income derived from being an expert witness. These were areas of cross-examination that might better have been anticipated in the direct examination.

Over defense objection, the trial judge permitted the plaintiff to recall Dr. Lucchesi as a rebuttal witness, once again to put forward his theory about a clot being responsible for the events leading to Bob Ernst's death. The judge also allowed Lucchesi to give some opinion concerning the possible effect of vigorous CPR in dislodging any clot that might have been present. Lucchesi also said that because the clot might have been in a small peripheral vessel, it might have been too small to detect during the autopsy. On cross-examination, Merck lawyer David Kiernan focused on Dr. Lucchesi's lack of publishing and research experience on human blood that would have permitted him to form scientifically-valid opinions on the subjects of his rebuttal testimony.

The summations in Ernst did not seek high drama. Lanier focused on the questions the jurors were to answer, and on Merck's alleged misconduct. The defense began its summation with a discussion of causation then ranged over the various scientific and marketing issues. Gerry Lowry summed up for awhile, then David Kiernan, then Ms. Lowry again. Whether it is a good idea to divide summation in this way is open to debate.

Towards the end of her final appearance, Ms. Lowry made an argument that trial observers claimed was a tactical error:

> Now, Mrs. Ernst, when she testified, told you that she feels tremendous guilt because she recommended that her husband go and ask about Vioxx. And I'm sure that guilt hasn't been lessened in this case by all these lawyers telling her that Vioxx killed her husband. But you have a chance to do the right thing, and that is to release Mrs. Ernst from that guilt, to tell her the truth, which is that Vioxx had nothing to do with her husband's

> death. What caused her husband's death was something that started long before she ever even met Mr. Ernst, and you have a chance in this case to tell her that and send her that message and relieve her of that guilt that she feels so she can go on with her life. Don't let her continue to carry this wrong impression with her.

This argument led Lanier to launch his rebuttal in this way:

> I do want to take your attention away from what's been said for just a moment because it bothers me. I'm bothered by a lot that's been said over the last -- I think they used an extra ten minutes, but over the last two hours and 50 minutes. I'm bothered because we've hit a point now where it's not just discredit the doctors. And Dr. Egilman, you can handle this. You've had them at your doorstep before. Dr. Lucchesi, he can handle it. I got really miffed when they went after Mrs. Ernst, and I got miffed when they did it again today because that's not right. For them to have the audacity to stand up here and say, please vote for Merck for Carol Ernst's sake, so Carol Ernst can go away from here knowing she's guilt free, that's bad. That's bad.

As mentioned at the outset of this essay, the jurors voted for the plaintiff.

PLUNKETT v. MERCK IN FEDERAL COURT, HOUSTON, TEXAS

The trial judge in Plunkett, Eldon Fallon of the U.S. District Court for the Eastern District of Louisiana, is also the judge conducting the federal multi-district litigation pretrial proceedings. He has a nearly encyclopedic view of the issues and personalities that are common to Vioxx cases, including many of the expert and fact witnesses who will make appearances in more than one trial.

Judge Fallon's trial style shows a keen understanding of the Federal Rules of Evidence. He is also a judge who keeps the trial moving, by imposing time limits on lawyer argument, discouraging speaking objections, and reminding lawyers not to be repetitious. Judge Fallon excluded some evidence of events after Mr. Irvin's death, although he did allow mention of the 2004 Merck withdrawal of Vioxx from the market. He limited sales and marketing evidence. As noted above, he applied Federal Rule of Evidence 611(b), limiting cross-examination to the scope of the direct. The Rule 611(b) limitation does permit parties more control over the content of their respective cases, and arguably sets up a more coherent adversary process. All of these factors contributed to Plunkett being a shorter trial than Ernst, some 9 trial days[28] as opposed to more than 20 for Ernst.

Plaintiff's lead counsel in Plunkett were Jere Beasley, Andy Birchfield, and Paul Sizemore of Montgomery, Alabama. Merck counsel were Philip Beck and Tarel Ismail of Chicago. We have already seen a sample of Mr. Beck's opening. Mr. Birchfield began:

> If Merck had warned of heart attack risks, we wouldn't be here. You heard judge Fallon talk about a failure to warn claim. You'll hear at the end of the case an instruction a drug company has a responsibility -- a duty – to warn about risks of its drug, and all drugs have risks. So who bears the

[28] Excluding voir dire.

> responsibility when those risks turn into serious injury or death? It depends. If a drug company warns, then that responsibility shifts from the company to the doctor or patient. If the drug company doesn't warn, the responsibility remains with the company. In this case, Merck made a deliberate premeditated financial decision not to warn. Why would a company do that? If they could shift responsibility by simply warning, why would they not do that? You're going to hear the evidence in this case that answers that question of motive. Here is Ms. Evelyn Irvin Plunkett. She remarried about three years after his death. She had been married for 31 years. Together, through thick and thin, they raised four children together. At the time of his death, their marriage was as good and as strong as it had ever been.

Birchfield set out his themes:

> Now, I want to talk to you about the evidence, and I think it would help at this point if we divide it up into four categories. We want to look at first the medicine, then the man, then the marketing, then the motive.
>
> Dicky Irvin was 53 at the time he died. He worked for a seafood shop, loading and unloading boxes delivered to his workplace and from there to restaurants and stores. He suffered a back injury while working. His son-in-law, Dr. Chris Schirmer, is an emergency room physician. He prescribed 30 days worth of Vioxx. Dicky Irvin took 22 Vioxx tablets in 24 days and had what Mr. Birchfield called "a Vioxx heart attack." The case therefore raised not only autopsy-based cause of death issues, but the epidemiological issue of whether Vioxx taken for such a short time raised a realistic probability of adverse effects. Despite the evidently weaker Irvin facts, the Houston jury failed to reach a verdict. On retrial in New Orleans, there was a Merck verdict.

Plaintiff began with Dr. Benedict Lucchesi. In Judge Fallon's court, an expert begins by reading to the jury a short statement of background, qualifications and experience. Counsel is not given the chance to spend time on these issues in question and answer form. However, opposing counsel has the right to take the witness on what is known as a "voir dire" to inquire about qualifications. A lawyer will often take advantage of this opportunity, even knowing that the witness is going to be accepted as an expert, as a way of undercutting the value of the proposed testimony.[29]

> Mr. Beasley: We tender him as an expert. . . in the area of cardiovascular pharmacology; physiology; and pharmaceutical research and development, including clinical trials.
>
> The Court: you may cross-examine him.
>
> Q. (by Mr. Beck). Doctor, how long ago as it that you graduated from medical school?
>
> A. 1964.
>
> Q. After finishing medical school, did you enter a formal residency program?
>
> A. No, sir.

[29] Dr. Lucchesi had given a deposition in the Merck litigation, so counsel knew the answer to all of these questions before asking them.

Q. Have you ever been licensed to practice medicine?
A. No, sir.
Q. Are you allowed to prescribe medicine?
A. No, sir.
Q. Are you aware that the FDA had an advisory committee, committees that were appointed to look at Vioxx and other COX-2 inhibitors?
A. Yes.
Q. Did the FDA ask you to be on the 2002 advisory committee?
A. No, sir.
Q. Did they ask you to be on the 2005 advisory committee?
A. No.
Q. Has the FDA ever asked you to be on any FDA advisory committee for any drug?
A. No.
Q. On the subject of labeling, have you ever written a drug label?
A. No.
Q. Have you ever participated in drafting a label for a prescription drug?
A. No, I have not.
Q. Have you ever even read the regulations from the FDA on labeling?
A. Not that I recall.
Q. And you don't consider yourself to have any expertise in that area, do you, sir?
A. No, sir.
Q. Also, on consumer advertising of prescription medicines, have you ever reviewed the FDA regulations on that subject?
A. No.
Q. Have you ever reviewed Merck's submission to the FDA concerning direct-to-consumer advertising?
A. No.
Q. Have you ever reviewed the FDA's response to Merck concerning consumer ads?
A. I have read the letters in which the FDA has reprimanded Merck on some of their ads.
Q. Did you read the response from Merck to that letter and then the FDA's resolution of that issue?
A. I recall reading it, but I don't recall the detailed response from Merck.
Q. When you were doing your work for this case, did you review the backup material that Merck submitted to the FDA when it made its new drug application, the NDA?
A. I don't recall.

After a few more questions of this nature, and some redirect examination, Judge Fallon accepted Dr. Lucchesi as an expert in "his chosen field.[30]

[30] Judge Fallon follows the general practice of saying that the witness may testify as an "expert." He does remind the jurors that they are the ultimate judges of whether to accept his opinion and whether the opinion has a sound factual basis. Judge Richard P. Matsch, of the District of Colorado, has a different practice. He does not tell the jury that the

Dr. Lucchesi's theory about Vioxx was the centerpiece of plaintiff's case. Irvin had a clot. The clot killed him. Dr. Lucchesi provided an answer to the question whether short-term low dose use of Vioxx could plausibly be the cause or a contributing "but for" cause of this event. It would be up to a pathologist to say whether Vioxx was in fact the cause. Given that Dr. Lucchesi's views are very controversial in the scientific community, would the plaintiffs have been better advised to begin with one of the anti-Merck witnesses who appeared later?

Dr. Lucchesi began with an overview of his conclusions:

> Q. Specifically, I want you to tell the jury what your opinions are, then we're going to go back to –
>
> A. The first thing I said, I believe COX-2 inhibitors, Vioxx, can produce blood clots. Secondly, I believe that Merck either was aware or should have been aware that the potential for this existed. In literature, it's well documented the fact that this could occur, if you interfered with a COX-2. I'm of the opinion that the hypothesis that Merck came up with to defend their position on the VIGOR study, that the drug naproxen, which was the drug that was used as the comparative drug against which they compared Vioxx, they compared that naproxen was cardio-protective. And thus it made it look as if Vioxx was cardio-damaging. I don't agree with that opinion, and I don't agree with the fact that naproxen is cardio-protective. I think Merck -- my opinion is that Merck should have invested more in basic studies as well as designing some specific clinical trials in which it specifically tests this hypothesis whether or not blood clots were potential in this situation. Overall, I think a drug like Vioxx carries a specific risk in a very select group of patients. Patients who are at risk of cardiovascular disease, although they may not be aware of the fact that they have an underlying cardiovascular disease, I think a drug like Vioxx poses a danger.
>
> Q. Specifically, did you form an opinion as to whether or not Vioxx would be unreasonably dangerous for that segment of the population that would be at risk?
>
> A. That is right.
>
> Q. What is that opinion? . . .
>
> A. Patients who have cardiovascular risks, underlying cardiovascular risks, are going to be a greater risk of having a thrombo-involving event in the presence of Vioxx.
>
> Q. That would be the formation of clots?
>
> A. The formation of clots, yes, sir.
>
> Q. And do you have an opinion specifically whether or not Vioxx can cause a heart attack?
>
> A. Oh, yes, I do.
>
> Q. And what is that opinion?
>
> A. I believe that -- I believe it has that potential to do that, yes.

---

witness is an "expert," but rather says that the witness may offer "opinion" testimony. Judge Matsch believes that the judge unduly interferes with the jury function by using the word "expert."

Dr. Lucchesi's theory is that when the blood platelets become agitated, there is a potential for clotting, and that Vioxx inhibits prostacyclin and this causes clot formation or prevents dissolution of clots that have already formed. This phenomenon can produce a heart attack even without arterial plaque rupturing. Another way to see it, Dr. Lucchesi says, is with a teeter-totter analogy, reflecting the natural bodily balance between prostacyclin, which inhibits clot formation, and thomboxane, which encourages it. Aspirin and ibuprofen inhibit the two substances equally, Vioxx does not. So a patient taking Vioxx is upsetting that balance and encountering increased clotting risk.

Two plaintiff experts had examined the Irvin autopsy slides. One of them concluded there was plaque rupture, and other said there might have been; plaque rupture could cause a heart attack independent of any effect from Vioxx. Dr. Lucchesi is not a pathologist., and he had to concede that he did not have the qualifications in examing autopsy slides that a pathologist would have.

Dr. Lucchesi is discursive. Judge Fallon called counsel to the bench and complained, "We're going to have to go a little faster. You're asking him a question and he's making a speech for ten minutes. If we do that, you'll never get through. You'll be out of time and you'll still have him on."

This exchange provides an insight into Judge Fallon's trial management technique. Judges have different means of expediting trials, including as here the use of time limits on lawyer argument and witness presentation. A trial judge who, like Judge Fallon, had extensive experience as a trial lawyer, can craft rules that save juror time and yet not interfere with effective advocacy. A common juror complaint is that lawyers waste time being repetitious. However, some trial judge limits on lawyer presentation undervalue the role of advocacy and undermine the advocate's role in choosing how best to persuade the jurors. Trial speed is not an end in itself.

A little later, when it appeared Dr. Lucchesi had not heeded the message, Judge Fallon said to him in the jury's presence:

> Okay, doctor, you're still under direct. Doctor, we're going to try to finish your testimony today, and I really need your cooperation. So if you'll listen to the questions and focus on the questions, just answer the question, please.

The cross-examination focused on the two main issues – evidence of harm from short-term use, and the risks of clotting.[31] Excerpts from the examination show Beck's technique:

> Q. Now, out of the hundreds of peer-reviewed articles that you've authored, have you ever written one on the subject of whether Vioxx can cause heart attacks in short-term use?
> A. No, sir.
> Q. And before you talk about how you looked at some other COX-2 inhibitors such as Celebrex, have you ever written a peer-reviewed article on whether Celebrex can cause heart attacks in short-term use?
> A. Yes, I have.

[31] Merck witnesses would address the reasons why the clotting issue was not the subject of more studies than were conducted.

Q. And the one article, I think you've written about Celebrex . . . that article doesn't have any conclusions whatsoever about whether Celebrex can cause heart attacks in human beings in short-term use, does it, sir?
A. That article was done in an animal model. It's the same model that Merck used to test their drug.
Q. Does your article contain any sentence that somebody could read that talks about whether Celebrex can cause heart attacks in human beings in short-term use?
A. My article describes the biology which applies in human as well as to the animal. And one comes to, by deductive reasoning, could make that assumption.
Mr. Beck: I would like an answer to the question, Your Honor.
The Court: Doctor, you're going to have to help us out here. Listen to the question and try to answer the question. If you need to explain yourself, I'll let you explain it.
The Witness: Thank you. I'm sorry.[32]

Later in the cross-examination:

Q. Would you agree with this statement that for the vast majority of people, Vioxx is perfectly safe?
A. Yes.
Q. And would you -- and I think you've testified before that, as far as you're concerned, it's -- Vioxx has a place on the market; is that right?
A. Yes.

And still later:

Q. But I asked a different question and I really would appreciate an answer to it. My question is, is there a single piece of peer-reviewed literature in the world that actually demonstrates that Vioxx contributes to plaque rupture in the coronary artery?
A. An animal study or human studies or both?
Q. Let's start with human studies.
A. I don't know of any human studies that have been done. I don't know of any, any clinical trial that could be designed to address this particular hypothesis. How do you test it? How do you put together an informed consent that the patient has to sign in which it says we're determining whether or not the --
The Court: Doctor, what's your answer to the question?
The Witness: The answer is, you cannot do such a study.
Q. But you could do such a study on animals if you wanted, right?
A. Yes, sir.
Q. And isn't it also true that there is not a single piece of peer-reviewed literature in the world that demonstrates that in an animal model Vioxx contributes to plaque rupture?

[32] By this point, Dr. Lucchesi has been corrected often enough for discursive and unresponsive answers that he is apologizing. The imagery of this turn of events will not be lost on the jury. This is the plaintiff's first witness.

A. You can demonstrate that Vioxx, well, not Vioxx, but you can demonstrate that COX-2 inhibition leads to enhancement of atherogenesis in an animal. Dr. Fitzgerald has done that.
Q. Was your deposition taken in this case on October 18, 2005? . . .
Q. And you were under oath just as you are today, correct?
A. Yes, sir. Yes.
Q. At page 331, line 21, through page 332, line one, were you asked this question and did you give this answer under oath: "Question: Would you agree, sir, that there is not a single piece of peer-reviewed medical literature that demonstrates even in an animal model that Vioxx contributes to plaque rupture in the coronary artery? "Answer: There may not be today." Is that your sworn testimony?
A. If you're referring specifically to Vioxx, the answer is what I gave last time. That would be the answer today. But --
Q. That's all I've been asking you about for the last 15 minutes, doctor.

To testify on the cause of Dicky Irvin's heart attack, plaintiffs called Dr. Colin Mercer Bloor, a well-qualified pathologist and emeritus professor at the University of California, San Diego, Medical School. Plaintiffs counsel began by asking Dr. Bloor to give a summary of his opinions, to orient the jury on what was to follow.[33]

Dr. Bloor concluded that Vioxx was a contributing factor to forming the clot that caused Dicky Irvin's fatal heart attack. On cross-examination, Beck confronted Bloor with the expert report that the doctor had furnished in discovery.[34]

Q. I am also showing defendant's exhibit 1029 up on the screen here. I would just like to walk through a chronology here to look at what work you did. First of all, the report that you have up there, your expert report, what's the date of that expert report?
A. That is dated the 24th of September, 2005. . . .
Q. Okay. So are your notes -- and am I right that you were first contacted in this case or at least signed a retainer agreement in this case in August of 2005?
A. That's correct.
Q. And that was with a lawyer named John Restaino?
A. Yes.
Q. And then the next thing that happened is you had a phone conversation with Mr. Restaino, right?
A. That's correct.
Q. But then the first real work you did was when you met with Mr. Restaino in September, right?
A. Yes.

[33] Plaintiff's counsel objected to a defense expert being in the courtroom when Dr. Bloor testified and asked the court to impose "the rule" under Federal Rule of Evidence 615. The judge pointed out that experts are exempt from the rule, and in fact that one expert may comment on another's testimony.

[34] This is a good example of examination technique for an expert who is retained and quickly supplies an initial opinion with a lawyer's assistance.

Q. And the first real work that you did in the case was on September 24, 2005; is that right?
A. That's correct.
Q. And that is the same day that you submitted an expert report was the very first day you started working on the case, right?
A. Actually, I had some preliminary material on the report because I knew the format it needed to be put in. The reason the work was not done before this date is that I was out of state for a period of about three weeks during September, and that was the first that we could get together.
Q. But the first time that you ever looked at any of the materials that you talked about this morning concerning Mr. Irvin, and you looked at the coroner's report, that sort of thing, that was on September 24, 2005. Right?
A. Yes.
Q. And on that very same day, you submitted an expert report in the case, right?
A. Yes.
Q. And the reason that you submitted an expert report on the very same day that was the first day you ever looked at anything was because you understood that the expert reports were due in the case just two days later, right?
A. That's correct.
Q. So you really only had one day to spend on it, right?
A. I spent quite a bit of time on it that day, as a matter of fact.
Q. Six hours or so, I think you testified to before?
A. Yes. . . .
Q. Now, in your report -- your report itself is 18 pages long, right?
A. That's correct.
Q. And am I correct, sir, that of the 18 pages on your report, only two of them actually have anything to do with this case?
A. In regard to the materials that he brought down that day for me to review and the like, that would be true.

Beck took Dr. Bloor through the first fifteen pages of the report, noting that they deal with the doctor's qualifications and with general issues about pathology and heart disease.[35]

A. I used as a template or format for this report essentially the -- I believe you call this a Rule 26 in federal court, or this type of report that I had done before, and so I knew that certain parts of this are necessary to include.
Q. So when you talk about a template, basically what that means is that the first 15 pages were cut and paste from other reports you've done in

[35] This rather extensive excerpt shows a method for cross-examining on omissions or inconsistencies in a prior statement, and that sometimes it is useful to restate the direct examination as a prelude to attacking it. Note that at one point, Beck actually uses a whiteboard to write down key points for emphasis.

other cases, and you've just dropped it in as the first 15 pages in the case. Right?
A. They were not simply cut and pasted. I mean, they were also brought up-to-date too.
Q. Cut and pasted and brought up-to-date?
A. Yes.
Q. And then we finally get to two paragraphs about Mr. Irvin in your expert report, right? . . .
Q. Then the first paragraph that you talked about, paragraph 35, that's just a list of the stuff that the lawyer brought for you to look at. Right?
A. That was the materials that I reviewed at that time in preparing this, yes. . . .
Q. And so, then, it's two paragraphs that actually talk about Mr. Irvin, right?
A. 36 and 37, yes.
Q. Now, tell me if I am getting sort of the headlines correct of the opinion that you expressed today. As I listened, you said that Vioxx contributed to Mr. Irvin's death. That's what you testified to today, right?
A. Yes. I think it's a substantial contributory factor.
Q. And as part of your analysis, you said, I think -- did you say that there was no plaque rupture?
A. In the slides that I have looked at, there is no plaque rupture. Definitely in the location where the acute thrombus is.
Q. And you said that since there -- in your opinion that you expressed today -- is no plaque rupture, something else must have caused the clot, right? We know there was a clot.
A. Yes.
Q. And the opinion that you're giving today is that, since there was no plaque rupture, the something else that caused the plaque must have been Vioxx. Right?
A. Well, since there is no plaque rupture at the site where this nonattached thrombus is located, I considered what other factors may be. And knowing that the patient was on Vioxx and on the assumption, the basis for which I've stated before, that it's a prothrombotic agent, that this is why I've considered it to be a substantial contributory factor to the cause of death.
Q. So is that a long way of saying, yes, what you're saying today is that, since there was no plaque rupture, according to you today, there must have been something else, and the something else was Vioxx?
A. Well, when you say it that generally. Again, I said, "at the site where this nonattached thrombus is located."
Q. And in your 18-page report, how many times do you mention Vioxx?
A. I didn't mention it at that time.
Q. So the expert report that you filed two days before the expert reports were due, after having spent all this time with the -- Mr. Restaino, you didn't make one mention of Vioxx anywhere in your report, did you?

A. At that particular time, I became aware there was another set of slides that I had not yet seen.
Q. Did you, in your report, mention Vioxx anywhere?
A. No, I did not.
Q. And in your notes that I handed you, that report on work that you did, is there any mention in your notes of Vioxx?
A. No.
Q. You said that Vioxx is a prothrombotic agent. Does prothrombotic mean something that can cause or accelerate a blood clot, a thrombus?
A. The formation of that, yes. Another term that is sometimes used is "thrombogenic."
Q. And in your report, when you talk about Mr. Irvin in those two -- two paragraphs, is there anything in your actual expert report that says that there was some prothrombotic agent at work?
A. No, there is not.
Q. And in your notes that you've prepared when you spent that day with Mr. Restaino going over the materials, is there any mention that there is some prothrombotic agent at work?
A. There is not at that time.
Q. And is there any mention in either your report or your notes that there is a COX-2 inhibitor -- even though you wouldn't know which one that was -- at work?
A. No.
Q. In your report, do you say that there was no plaque rupture?
A. Can you phrase that again, please.
Q. In your report, do you say there was no plaque rupture?
A. No, I did not say that.
Mr. Beck: If I may, can I step up here to the board?
The Court: Yes.
By Mr. Beck:
Q. I just want to contrast what you put in your expert report with what you're testifying to today. And in your report you do not say no plaque rupture, right?
A. Yes.
Q. And, in fact, you don't take a position in your report on whether there was plaque rupture or not, right?
A. That's correct. Because I was aware that there was another set of slides that I had not seen.
Q. You didn't say that in your report, though, did you?
A. No.
Beck then focused on Dr. Bloor's reliance on Dr. Lucchesi:
Q. When you come to that conclusion, you are assuming, are you not, that using low-dose Vioxx, 25 milligrams, somehow increases the risk of blood clots even if the duration of use or length of time is less than a month. That's one of your assumptions, right?
A. Yes.

Q. Because you know that from everything we understand from Mr. Irvin's family, that he took Vioxx for less than a month, right?
A. That's what I'm aware of, yes.
Q. And the low dose, the 25-milligram version, right?
A. Yes.
Q. But the truth is you don't really know anything yourself about Vioxx, do you?
A. I have not studied Vioxx, and so the assumptions I made in arriving at that opinion, as I've already stated, are based on Dr. Lucchesi's expertise and his testimony in deposition and in his report and also on what statements are made in the APPROVe study. And going beyond that, I would defer to an epidemiologist about what he would have to say about the duration required.
Q. So just so that we're clear, then, you're kind of standing on the shoulders of Dr. Lucchesi, right?
A. I think I can stand on his shoulders because, as I recall, he still is very strong, although maybe not that tall.
Q. Analytically, when it comes to your opinion, for your opinion to have any validity at all, Dr. Lucchesi's opinion has to be accepted, right?
A. For that part of it, yes.
Q. So for your opinion to have any validity about the cause of death, Dr. Lucchesi, his opinion has to be correct that low-dose Vioxx taken for a short period of time causes blood clots, right?
A. I cannot comment on that specific nature. I am talking about his statements on the prothrombotic activity of Vioxx in terms -- but you also used the term "cause of death." If we go back to my cause of death, I am saying that it was the acute nonattached thrombus that occurred at the site, where he already had significant narrowing by a plaque, led to an acute ischemic state that, in turn, introduced the fatal arrhythmia. And then the next step is what potentially caused that acute thrombosis, and that's where I looked at Vioxx as having a substantially contributory factor.
Q. Have you ever prescribed Vioxx?
A. No, I have not.
Q. And you've done practically nothing to familiarize yourself with the scientific evidence that addresses this question about whether Vioxx could cause clotting when used at low doses for short periods of time, right?
A. No, I have not.

After Dr. Bloor, plaintiff's counsel called Dicky Irvin's daughter Lesley. She and her older sister Allesha were over 21 at the time of Mr. Irvin's death. Lesley talked about the family. She also provided information about her father's back pain. The next witness, Richey Irvin, was a minor when his father died. By the time of the trial, he had gone to work in the seafood business where his father worked.

Plaintiff then played a video deposition of David Anstice, this one taken by California lawyer Mark Robinson. Robinson was co-counsel in Plunkett, though he did not play a major role. In 2006, he was lead counsel in another Vioxx case in New

Orleans, and obtained a substantial plaintiff's verdict. His approach to Anstice was similar to that used by Mark Lanier in the Ernst case.

In the continuing effort to establish a relationship between Vioxx and fatal clots, plaintiffs called Dr. Thomas Frederick Baldwin, a well-qualified cardiologist. Merck challenged his credentials to offer the opinion that the plaintiffs were seeking. Merck lawyer Tarek Ismail took him on voir dire and brought out that he has never diagnosed a patient as having a Vioxx-related thrombosis, is not an expert in epidemiology, and has not since 1988 done any clinical research into sudden cardiac death. Based on this questioning, Judge Fallon allowed Dr. Baldwin to testify as an expert, but said he would be open to objections as to specific areas of inquiry.

Later in the direct examination, Judge Fallon ruled during a bench conference that Dr. Baldwin could not testify about the specific alleged relationship between Vioxx and Dicky Irvin's death. Using the Federal Rules of Evidence standards, the judge ruled that Dr. Baldwin's methodology in coming to a Vioxx-related conclusion was adequate, in that the doctor had read medical journals and other materials about Vioxx. However, the doctor was not "qualified" within the meaning of Federal Rule of Evidence 702 (which Judge Fallon called "the first hurdle") to give an opinion because he has no personal experience with Vioxx, is not an epidemiologist, and "knows nothing about COX-2 inhibitors other than what he has read." The plaintiff argued that the doctor was qualified by "knowledge" and this is an alternative basis for accepting his expertise. Judge Fallon disagreed. This ruling came as a surprise to the plaintiff's lawyers and they took a break to let the doctor know not to talk about Vioxx.[36]

Dr. Baldwin looked at the autopsy slides and said that Irvin's 60% coronary artery blockage was not "flow-limiting," thus suggesting that by itself it would not be a significant contributor to Irvin's death. Judge Fallon did permit Dr. Baldwin to testify that he had, on a consulting basis, seen about 100 patients who were taking Vioxx and that he had generally counseled the referring physician to find alternatives to Vioxx, based on a "risk-benefit analysis." This testimony was, Judge Fallon said, related to the doctor's own experience. Dr. Baldwin also said that Mr. Irvin did not have significant risk factors for a heart attack.

The defense, having succeeded in blunting Dr. Baldwin's direct testimony, did not cross-examine him. They no doubt felt that his limited testimony had not badly hurt them, and that they risked "opening the door" to areas held inadmissible if the cross-examination for some reason strayed too far.

The plaintiff then called Dr. Alan Nies, a retired Merck scientists who played a leading role in Vioxx development. They could subpoena Dr. Nies because the trial was being held in Houston, within subpoena range of Nies's home. His direct examination – by leading questions as an adverse witness – and cross-examination went over the ground that he covered in the Ernst trial.[37] In Ernst, the defense had called Dr. Nies, and Mark

---

[36] One wonders why Dr. Baldwin did not simply say, as had Dr. Bloor, that he was relying on Dr. Lucchesi's expertise.

[37] For cross-examination, defense counsel gave Dr. Nies two binders containing the exhibits to which counsel would refer in the examination. This technique has several advantages. First, it eliminates the need for counsel to traipse back and forth between the lectern and witness box with each exhibit. Second, in a courtroom equipped with video monitors for exhibits, it lets the witness focus on counsel and the jury more easily than if

Lanier did an effective job of cross-examination in an effort to tear down the image of science-driven research at Merck. It is an open question whether the plaintiff calling him as an adverse witness was worth the risk. Certainly Irvin's lawyers were able to introduce a great deal of good evidence through Dr. Nies. However, the "friendly" cross-examination gave the defense a chance to go step by step through the development and testing of Vioxx, and Dr. Nies comfortably talked about this material.

To support the theory that Merck knew Vioxx was dangerous and that its risks outweighed its benefits, the plaintiffs called Dr. Wayne Allen Ray. Dr. Ray holds a Ph.D. degree in computer science. He is a pharmacoepidemiologist, a specialty he described:

> Pharmacoepidemiology is the study of the risks and the benefits of medications, particularly after they have been marketed and with respect to outcomes that affect patients' health. So, for example, a pharmacologist might study what effect a drug like Lipitor has on your blood, what it does to the cholesterol in your blood. A pharmacoepidemiologist might study is the drug likely or actually prevents heart attacks or if it, as some people think, has other benefits. That's kind of, in a nutshell, what we do. We study the risks and benefits of medications in real human users of the drugs in terms of the health outcomes that are tangible like heart attacks and ulcers.

Dr. Ray had never before testified in litigation. He is a tenured professor at Vanderbilt Medical School, and has taught at several other universities. He is a reviewer for more than a dozen leading medical journals, has been a consultant to the FDA and to leading pharmaceutical companies – including Merck, and has specifically focused on NSAIDs, including Vioxx. From the standpoint of a first impression on the jury, he is an ideal witness. He has none of the "professional witness" baggage, and no apparent stake in whether Merck wins or loses. The defense did not ask him any questions on voir dire about his qualifications.

In November 2000, Merck asked Dr. Ray to comment on the VIGOR trial, which compared Vioxx to Naproxen. Plaintiff's counsel Jere Beasley led up to this testimony by questioning Dr. Nies on redirect about Naproxen.

> Q. So has Merck actually sought your assistance as a consultant?
> A. In the past, yes.
> Q. In what specific areas?
> A. The occasion was a meeting that I was invited to discuss the cardiovascular outcomes of the VIGOR trial. That would be in November of 2000.
> Q. Who actually invited you, from Merck, to attend the meeting about the cardiovascular outcomes of the VIGOR trial?
> A. Dr. Harry Guess.
> Q. What happened in this meeting, doctor?
> A. The results of the VIGOR trial, particularly with respect to the cardiovascular results -- that is, the effect on heart attacks -- were

---

the witness is constantly turning to a video monitor in the witness box. Third, it gives the jurors a visual picture of a witness handling paper exhibits just as they will be handling them in the jury room during deliberations.

presented and the various explanations for those results were put forth and the persons at the meeting were asked to comment on those explanations.

Q. Did Merck scientists or Merck employees ask your opinions or your conclusions about the VIGOR study?

A. Yes, they did.

Q. What were your opinions at that time, doctor?

A. My opinion was that the theory that naproxen was a very effective drug for preventing heart attacks, the theory that that explained the VIGOR findings, I thought that was speculative. I said that it was speculative and dangerous to assume that that explained the results of the VIGOR trial.

After this disclosure and a discussion of qualifications and experience, plaintiff's counsel Paul Sizemore asked Dr. Ray for a summary of his opinions.[38]

Q. Doctor, I want to move on to your opinions in this case while we are here. Have you developed expert opinions in reference to this case, doctor?

A. Yes, I have. . . .

Q. Having reviewed the medical and scientific literature, doctor, and then having conducted studies in this area, are you prepared to offer your opinions to a reasonable degree of scientific certainty today?

A. Yes, sir, I am.

Q. Did you develop your opinions utilizing the same care and diligence that you ordinarily exercise while practicing in the field of pharmacoepidemiology?

A. I certainly did my very best, sir.

Q. Doctor, would you, then, tell us what opinions you do have in this case in a summary fashion so we can, therefore, move on.

A. Yes. My first opinion is that Vioxx causes heart attacks. . . . My second opinion is that the benefits of Vioxx, with regard to preventing ulcers, are less than the excess risks of heart attack and other serious cardiovascular disease. My third opinion is that the increased risk of Vioxx for heart attacks is present for people who use it between one and 30 days. My fourth opinion is that even people who already are at risk for heart attack because they have something we call risk factors will have their risk of heart attacks increased by Vioxx.

Q. Any others, doctor?

A. My final opinion . . . , that is, in patients who are taking Vioxx and have a heart attack, the Vioxx is more likely than not the cause of their heart attack.

Dr. Ray then worked through the various clinical studies of Vioxx and evaluated the results. Merck lawyer Philip Beck's cross-examination dwelt to some extent on Dr.

[38] Doing this at the outset of an expert examination, and indeed in other contexts as well, helps the jury prepare to receive what is to follow. In the excerpt above, there was an interruption as the defense sought to limit the scope of Dr. Ray's opinions on causation. The quoted response on that issue was tailored to the judge's ruling, which forbade Dr. Ray from giving an opinion on what caused Dicky Irvin's heart attack.

Ray's having consulted for Merck competitors and on Dr. Ray having at one time written that low dosages of Vioxx did not seem to contribute to cardiac events.

However, Beck focused more at length on an area where Dr. Ray would be sure to support Merck's position: the dangers of stomach bleeding from the traditional NSAIDs such as ibuprofen and aspirin, the nonselective Cox inhibitors, and the deaths that resulted from NSAID use by the elderly. Beck then questioned Dr. Ray about studies showing relative risk assessments between Vioxx and Celebrex on the one hand and traditional NSAIDs on the other. Dr. Ray did not become defensive under cross-examination. However, he would not be moved from his principal conclusion, as the first questions on redirect showed:

> Q. Doctor, Mr. Beck talked to you about the risk and benefits of Vioxx. Have you examined this issue?
> A. Yes. There is one clinical trial, the VIGOR study, where you can compare the clinical benefits to the clinical risks, and I've examined those findings.
> Q. Do you have an opinion whether the risks of Vioxx in causing heart attacks and death outweighs the GI [gastrointestinal] benefits?
> Mr. Beck: I object, Your Honor.
> The Court: I overrule the objection.
> The Witness: The findings of the VIGOR study clearly show that it was. There were 9.4 extra cases of serious cardiovascular disease per thousand patients, and 7.8 serious ulcer complications prevented. So it's more serious heart disease caused than ulcers prevented. And that's pretty clear-cut.
> Q. Let me ask you a simple question, doctor. Is Vioxx a cure for NSAID-related deaths?
> A. No. It's not, really. And you know, we have to be sure that -- and I as much as anyone would love to see a pain medication that, you know, is freer of side effects than the old NSAIDS. And everybody thought that Vioxx might be, but unfortunately, it causes more cardiovascular disease than ulcers prevented. so those are the facts.

Dicky Irvin took Vioxx prescribed for him by his son-in-law, Dr. Christopher Schirmer. The plaintiff offered Dr. Schirmer's testimony by deposition. Dr. Schirmer's wife Allesha, who was Irvin's daughter, told Dr. Schirmer of her father's back pain and asked him to phone a prescription from his Florida office to the pharmacy nearest the Irvin home in Alabama. Mrs. Schirmer is a cardiopulmonary technician. Irvin was not Dr. Schirmer's patient. The two men saw each other perhaps twice or three times a year. Dr. Schirmer's testimony was essential to establishing how Irvin came into contact with a regular supply of Vioxx. Dr. Schirmer testified that he did not see any warnings connected with Vioxx that would lead him to avoid prescribing it. However, he was not an expert on the subject. The only medical "conference" he had ever attended on COX-2 inhibitors was a steak and "twelve year old Scotch" dinner given by Pfizer to discuss the merits of Celebrex. He received most of his information about Irvin's physical condition from Mrs. Schirmer. He had not reviewed Irvin's medical records.

However, Dr. Schirmer did say that as a treating physician specializing in emergency medicine, he relies on the pharmaceutical companies to give him complete and accurate information so that he can evaluate the risks and benefits of drugs.

Plaintiff's counsel decided to wind up their battle of the experts with two video depositions from Dr. Eric Topol, the cardiologist who has been active in criticizing Vioxx and Merck,[39] and Merck scientist Dr. Edward Scolnick, who also appeared by deposition in the Ernst trial.[40]

Dr. Topol testified that when Merck looked at the VIGOR study results, its scientists should have seen the risk that Vioxx was contributing to clotting and therefore to cardiac events. He drafted an article setting out his concerns, and gave a copy of it to some Merck scientists, including Dr. Alise Reicin. Dr. Topol has criticized Merck and the FDA for failing to appreciate Vioxx risks for patients with cardiovascular problems. He summarized his central concern:

> A. Well, in 1999, in May, the FDA approved Vioxx for commercial use, so that is an important time, time line. That was also at the time when the FDA had a formal review of the medicine, where the primary reviewer already had expressed in her document, Dr. Villalba, that there was a concern regarding clotting events with Vioxx even at the time of approval in May 1999.

---

[39] The medical journal discussions of Vioxx include articles co-authored by Dr. Topol, e.g., E.J. Topol, Failing the Public Health: Rofecoxib, Merck and the FDA, New England Journal of Medicine, vol. 351, p. 1707 (2004); E.J. Topol, et al., Risk of cardiovascular events associated with selective COX-2 inhibitors, Journal of the American Medical Association, vol. 286, p. 954 (2001). The Merck results were reported in Reicin, et al., Comparison of gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis, New England Journal of Medicine, vol. 343, p. 1520 (2000).

[40] By this time in the trial, the jury had heard many hours of video deposition, as had the Ernst jurors. Because of territorial limits of subpoena service, most federal and state civil cases that involve complex facts require the lawyers to present deposition testimony. Before the days of video, lawyers or paralegals would read deposition testimony, with the "witness" on the stand and the interrogator reading the questions. This is still the practice with testimony that has not been preserved on video. One must ask, however, whether jurors will truly pay attention to video monitors that feature a "talking head" for more than twenty or thirty minutes. Most video depositions focus only on the witness. The jury misses the chance to evaluate the interplay between witness and examiner. Anecdotal evidence suggests that juror attention flags after awhile. Trial lawyers should consider editing video depositions down to preserve the important answers, and some of the questions, and offering edited versions that compress the examination. In oral testimony at trial, the witness is not permitted to narrate. The examination must proceed with questions and answers, if only to permit the trial judge to exercise control and prevent inadmissible matter from reaching the jury. That risk is gone when the deposition has been concluded and the parties have chosen the parts they want the jury to hear. Dr. Topol's testimony provides an example of what "might have been." His video deposition took an entire trial day, yet the "meat" of it was perhaps a couple of hours. On the other hand, one might argue that the information he is presenting is difficult to put into perspective and a slower pace aids understanding.

Q. You write here that, "the approval was based on data from trials lasting three to six months and involving patients at low risk for cardiovascular illness." Do you see that?
A. That's right.
Q. What is the significance of that fact?
A. Well, this is one of the most significant parts of the whole clinical development of the Vioxx medicine, and that is that patients with heart disease were not tested in any meaningful way, and we know from multiple databases and surveys that at least 40 to 50 percent of the patients who actually took this medicine when it was in clinical use actually did have known heart disease.

In response to Dr. Topol's draft paper speaking of the VIGOR study results, Dr. Reicin wrote an e-mail note to her Merck colleagues, saying "We prefer to flip the data and say it was reduced on naproxen" and another saying "Conclusion needs to be toned down.[41]" Dr. Reicin and other Merck scientists came to Cleveland to meet with Dr. Topol and his colleagues. Dr. Topol testified that he believed they were not really concerned about the science but were trying to influence him to change his conclusions. They suggested to Dr. Topol that his publishing his paper would be "an embarrassment" to the clinic he heads.

The deposition cross-examination of Dr. Topol did little to blunt the force of his comments. He did say that he had taken Vioxx over a period of time for knee arthritis, and acknowledged that he sent a note to a Merck scientist thanking the Merck people for "insightful" comments on his draft paper, and that he would incorporate some of those in the final version.

Plaintiff concluded the battle of experts with the video deposition of Dr. Edward Scolnick, who was president of Merck Research laboratories during the Vioxx development period. On adverse examination, plaintiff's counsel Birchfield confronted Scolnick with damaging e-mail communications about Vioxx. On June 1, 1998, Dr. Scolnick sent an e-mail to a number of Merck employees saying that he would resign if Merck did not beat the competition to market with a COX-2 inhibitor.

Scolnick was aware that a potential Vioxx study focusing on cardiac events – the very point that Dr. Topol raised -- was talked about but never done. Birchfield then confronted him with a March 2000 e-mail, in which Scolnick reacted to the VIGOR study:

Q. As of March 2000 you, Edward Scolnick, knew that the CV events -- the heart attacks and strokes -- were clearly there; and you, Edward Scolnick, knew that they were mechanism-based with Vioxx, true?
A. That was my very first reaction when I saw the data from the VIGOR trial.
Q. You knew it from the get-go; it was your first reaction, right?
A. It was my first reaction before other data was available.

And to follow it up:

Q. So after you studied the data, you went through it, you sent a memo out to everybody -- even though you hold yourself to a high standard --

[41] In this as in many recent cases involving corporate or other organizations, hastily-drafted and ill-considered e-mails come back to haunt their authors and the organization.

telling everybody that the CV events are clearly there, and that was in March of 2000, wasn't it?
A. Yes, it is.
Q. You never sent out an order at that point in time for a CV outcomes study, did you?
A. I did not send out an order for a CV outcomes study. We took many immediate actions to try to understand the cardiovascular events since we couldn't conclude what was going on in the trial because there was no placebo in the trial.

Indeed, within 18 days of his first reaction to the VIGOR study, Scolnick had changed his mind and adopted the view that Naproxen's cardioprotective effect accounted for the VIGOR results and that Merck should put out a press release saying so. Birchfield also showed Dr. Scolnick an e-mail in which he wrote "the FDA, they are bastards," referring to a proposal to put a cardiac warning on Vioxx.

Birchfield's adverse examination continued for almost an entire trial day. While there is no doubt that Dr. Scolnick is a distinguished scientist who has had a productive career, his manner of expression and his company loyalty made him good material for the plaintiff's case.

The defense cross of Scolnick was brief. Counsel went over his qualifications and experience, and then had Scolnick discuss the risks and benefits of Vioxx. The cross-examination was perhaps designed to show Scolnick in a more favorable light. It would not have been tactically sound to end his appearance with the plaintiff's questions.

Evelyn Irvin Plunkett appeared as the final plaintiff's witness, to talk about her close and loving relationship with her husband, his athletic activities, and his good health. During cross-examination, Merck counsel Beck made one of those rare – for him – missteps that sometimes come from insufficient preparation. He brought out that the Irvins had lived apart for a time, perhaps to suggest that their relationship was not as close as Mrs. Irvin had claimed. It turns out that in 1996 Mr. Irvin lost his job and the family could not afford to keep their home, so Mrs. Irvin moved in with her mom to take care of the kids and Mr. Irvin would live closer to his place of work. The family continued to work as a unit and pursue all its regular activities.

The defense case consisted of four live witnesses:

- Dr. David Silver, a rheumatologist who practices and teaches in Los Angeles. Rheumatologists, Dr. Silver explained, deal with "diseases involving pain, inflammation such as arthritis, diseases of the joints, muscles, bones, and autoimmune diseases." Dr. Silver is also board-certified in internal medicine. He is associate medical director of a nonprofit center that conducts clinical trials of new medicines, and is on the staff of hospitals as well as a faculty member at UCLA Medical School. He has written peer-reviewed articles and a popular book on coping with arthritis.
- Dr Briggs Morrison, a Merck vice president who had some oversight responsibility for Vioxx development. He had been at counsel table during the trial as Merck corporate representative and testified as a fact witness rather than as an expert.
- Dr. Alise Reicin, who appeared in the Ernst case, discussed Vioxx development and responded specifically to Dr. Topol's statements about his draft article and to

his claim that Merck ought to have conducted a clinical trial with patients with cardiovascular problems.

- Dr. Thomas Wheeler, the pathologist who also testified in Ernst, who spoke about the cause of Dicky Irvin's fatal heart attack.

Dr. Silver was a good choice. He is involved in patient care. He understands how to communicate his views. He is not a Merck insider. He has written thousands of prescriptions for selective and nonselective NSAIDs, and has given dozens of medical school lectures on Cox inhibitors. In contrast to the witnesses in the Ernst case, he presented graphic testimony about the benefits of Vioxx and why it represented an important advance in medical research.

Granted, as plaintiff's counsel brought out on the voir dire, Dr. Silver is not a cardiologist, hematologist, pathologist epidemiologist, or pharmacologist; he is not an expert in drug label warnings, except that he works with those warnings when deciding what to prescribe for patients. He was, Judge Fallon ruled, qualified to give opinions in his areas of practice with specific reference to the risks and benefits of COX-2 inhibitors.

Beck introduced the subjects of Dr. Silver's direct:

> Q. Have we asked you to come here today -- and it looks like tomorrow, as well -- to discuss with the jury the subject of the importance of treating chronic pain and inflammation?
>
> A. Yes.
>
> Q. Have we also asked you to come here and discuss with the jury the subject of the contribution that Vioxx and other COX-2 inhibitors have made to treating pain and inflation (sic)?
>
> A. Yes.
>
> Q. Inflammation. I'm sorry. I guess inflation you really can't do much about.
>
> A. No. I don't proffer myself as an expert in that, no.
>
> Q. Then we asked you to come and discuss with the jury the subject that we have alluded to here of whether the benefits of Vioxx, in your professional judgment, outweigh the risk?
>
> A. Yes.

Dr. Silver described the consequences of stomach bleeding that can be caused by ibuprofen and other nonselective NSAIDs, when patients take enough of them to get the pain relief they need:

> Q. So explain, then, what happens.
>
> A. What happens is this ulcer erodes into this blood vessel, goes down, and the blood vessel starts bleeding. This is usually an artery which is under high pressure, and blood just starts spilling out. Unfortunately, usually patients don't have a warning sign. In the majority of cases, there's nothing to tell them that this ulcer is going to occur until they just start vomiting blood or having blood coming out their other end, and this can happen very quickly and they can hemorrhage and bleed enormously.
>
> Q. Have you seen this, yourself, with your own eyes?
>
> A. Unfortunately, I have. Even back in times when I was a medical student and a resident, I recall seeing patients in the intensive care unit who would be just basically bleeding out, bleeding to death, from these

horrible ulcers. I've actually seen, unfortunately, patients die from this. I've looked at them with the gastroenterologist, looked through one of these scopes. You can put a scope down through the mouth and the stomach called an endoscope and you can see these ulcers that are bleeding. You can just see the blood sort of shooting out. It's almost like a faucet. It's coming out and it's a horrible sight, it really is.

Q. You said there were two main problems. One of them is if the acid starts to eat through the wall and hits one of these arteries. What's the other most significant problem that can come with these nonselective NSAIDs?

A. The other serious problem is something called a perforation. Basically, the ulcer goes completely through the entire wall of the stomach and the stomach perforates. What happens is all the contents of the stomach go into your abdominal cavity -- that's your abdominal area -- and cause a condition called peritonitis, which is a horrible life-threatening infection.

Then, said Dr. Silver, came the COX-2 inhibitors:

When the COX-2 inhibitors came around, this opened a whole new opportunity of treatment to our patients who were suffering with this chronic, terrible pain from a number of different causes, including arthritis, and now we were able to treat them.

For the remainder of Dr. Silver's direct examination, Beck used a chart that he had shown the jury in opening statement about the risks and benefits of Vioxx compared with other pain relievers, ticking off points on the chart as the examination proceeded. This was an excellent way to remind the jury of the first things they had heard from the defense.

Dr. Silver described a physician's role as reviewing all the available literature on a product and assessing the risks as to each patient. He said he assessed cardiovascular risks as to Vioxx.

Q. As a treating physician, a medical researcher, and a professor who teaches both doctors and medical students, do you have an opinion as to whether the disclosure of the cardiovascular risks was adequate for folks like you to make the risk-benefit analysis?

A. Yes, I do believe it was appropriate.

Q. Why is that?

A. Because it sums up what the opinions were at that time. It basically states, here is the results, you know, you can make your interpretation, but that the feeling at that time in the medical community is that the significance of those results was unknown.

Dr. Silver was aware of the basic hypothesis that Dr. Lucchesi embraces, which in this trial was sometimes called the Fitzgerald hypothesis, but he did not agree with it. Here is how he put the matter:

Q. Have you heard of the -- something called the Fitzgerald hypothesis?

A. Yes.

Q. That COX-2 inhibitors may cause some sort of an imbalance between thromboxane and prostacyclin?

A. Yes.

Q. When did you first become aware of the Fitzgerald hypothesis?
A. In the late 1990s.
Q. How did you become aware of it?
A. It was talked about in the literature, in published papers, I believe starting back in 1999, as well as it was discussed at, you know, scientific meetings and other venues.
Q. In the world of medicine, what does the word "hypothesis" mean?
A. Hypothesis is basically a theory that someone -- we hear about these all the time -- that somebody will say, "I believe based on what I'm looking at that this may occur." We hear theories all over the place. There are theories that COX-2 actually, because of their anti-inflammatory effects, lower the rate of heart attack. We heard about the Fitzgerald hypothesis and a number of other things that were floating around.
Q. Does the fact that something is out there with the phrase "hypothesis" attached to it; does that mean that it's been proven or supported by any actual medical data?
A. Not necessarily, no.
Q. Does an unproven hypothesis affect how you practice medicine?
A. Absolutely not. I mean, the problem is, if we looked at every hypothesis that was available and just accepted it, our hands would be tied as a doctor. We would never be able to practice medicine. We have to look at all the clinical data, what all the clinical data is, and make a decision whether or not this hypothesis applies to my patients when I'm looking at the individual patient in my office.
Q. Did your knowledge of the existence of the hypothesis, of the Fitzgerald hypothesis, cause you not to prescribe Vioxx or Celebrex to the patients who needed pain relief?
A. No.[42]

Dr. Silver also reviewed, for the jury, literature showing that the FDA doubts Dr. Lucchesi's hypothesis, and work by other researchers casting doubt on it. In doing the examination, Beck did not himself take on the role of an expert talking to a colleague, but was seeking to be the jurors' surrogate, asking the questions he thought they would want to ask.

The cross-examination confronted Dr. Silver with the opinions of plaintiffs' experts. Counsel Mathews also focused on Dr. Silver not being a cardiologist, to which Dr. Silver replied that he understood that Mr. Irvin had severe pain and that was something within his specialty and with which he deals regularly in his practice, where he sees patients with pain symptoms who also have cardiovascular issues.

Dr. Morrison began by talking about his parallel professional interests, ever since medical school, in both patient care and laboratory research. In addition to talking about aspects of risk and benefit, Dr. Morrison directly addressed reasons why Merck did not do a specific cardiac risk Vioxx study, and why he had himself counseled against such a study. He said that a principal reason was that such a study would have to include people at high risk for cardiac events, and that in order to isolate any potential effect of Vioxx,

[42] This is a good approach when the other side has the burden of proof – to characterize the opponent's theory as an unproven hypothesis.

the study group could not be taking low-dose aspirin. If that were done, Dr. Morrison said, it would pose an unacceptable risk to that patient population. In addition, in the group that was deprived of aspirin, there might well be an increase in cardiac events and that result might unjustly be blamed on Vioxx. Dr. Morrison held up well on cross-examination that focused on the issues that all Merck witnesses faced.

Dr. Alise Reicin[43] was the next-to-last witness. Beck conducted the direct examination. Reicin used an analogy to show how she viewed the VIGOR results:

> Q. Now, just to back up a bit, you said that one of your first projects with respect to Vioxx was setting up or designing a GI outcomes trial with respect to the drug?
>
> A. That's correct. One of the serious toxicity of NSAIDs, traditional NSAIDs, is that they cause serious gastrointestinal side effects. We were trying to prove that Vioxx, a COX-2 inhibitor, would have a significant reduction in those serious GI side effects compared to traditional NSAIDs.
>
> Q. What I want to talk about, doctor, is what the state of science was at the time that you were designing this GI outcomes trial in around 1997. If there was a clinical trial that put on the one arm placebo and the other arm aspirin, what would you expect the cardiovascular data from that trial to show?
>
> A. You would see fewer serious cardiovascular events, such as heart attack, in patients who were taking aspirin -- I assume we're talking about low-dose aspirin -- compared with placebo.
>
> Q. Would it be appropriate in such a trial to conclude that a placebo, a sugar pill, was causing an increased amount of cardiovascular events?
>
> A. I think you would assume that the placebo was neutral and that the aspirin was reducing the incidence of heart attacks. It would not be appropriate to assume that placebo was increasing the rate.

Dr. Reicin also discussed the reasons for not conducting a cardiac events study that took potential cardiac patients off of low-dose aspirin. She agreed with an e-mail that Dr. Morrison had sent, saying that if you deprive patients of their aspirin while they are taking Vioxx, there would be more clotting events and this might unfairly be blamed on Vioxx.

Reicin portrayed her meeting with Dr. Topol as collegial. She said that they had a good discussion of the hypothesis that Vioxx might have a clotting effect – the "Fitzgerald hypothesis" that Dr. Lucchesi had embraced.

> At the end of that, he actually told me that he found the data to be quite reassuring, but that he still felt that the question of Vioxx cardiovascular

[43] There was also the issue, which has continued to resonate in Vioxx litigation, of whether Merck scientists' article in the New England Journal of Medicine about the VIGOR study was misleading because it left out some of the results of that study. When the omissions were discovered, the New England Journal reacted with harsh criticism of Merck. Dr. Reicin, in the Plunkett case, said that the omissions were caused by late data reporting and would not have altered the significance of the Merck conclusions. Based on this controversy, a New Jersey judge awarded a new trial in a case that Merck won. New Jersey Judge Vacates Merck Vioxx Trial Win, http://jurist.law.pitt.edu/paperchase/2006/08/new-jersey-judge-vacates-merck-vioxx.php

safety needed to be further investigated. He also went out of his way to tell me that he took Vioxx for his knee -- apparently, he is an avid basketball player -- and found it to be a quite effective drug.

Dr. Reicin then described the APPROVe study and the events that led Merck to withdraw Vioxx from the market.

On cross-examination, Birchfield addressed Reicin's opposition to a change in the Vioxx label following some of the early studies. She fielded the question, concluding with a well-crafted statement about how to decide what to put on a drug warning label:

Q. Did you know that adding a CV risk to the product label would have a major impact on sales, correct?

A. It certainly may have had an impact on sales. But as I said before, I didn't care if there was an impact on sales. I was going to do what was right for patients. I didn't believe that it -- that it belonged in the warning section.

Q. You didn't believe that a CV risk belonged in the product label for Vioxx?

A. I didn't believe it belonged in the warning section. I believe that the VIGOR cardiovascular results should be in the label.

Q. Well, you would agree that a heart attack is a substantial, serious risk; right?

A. Yes, I do, but we did not believe that Vioxx was causing heart attacks. I still don't believe that, with short-term use, it causes heart attacks.

Q. But if the rule is first do no harm, wouldn't you advise doctors of any potential risks that is so serious as a heart attack?

A. In drug development, overwarning is just as dangerous as underwarning.

Dr. Wheeler was the final Merck witness. He took the autopsy report on Dicky Irvin and sentence by sentence discussed the autopsy findings. He used the autopsy slides to illustrate his points. He commented on the paucity of Irvin medical records, making it difficult to assess some issues. However, he was sure that given Irvin's arterial blockage and the evidence of clotting caused by plaque rupture, these events accounted for his death. At the end of his examination, Dr. Wheeler specifically commented on Drs. Bloor and Lucchesi. A part of that exchange is worth quoting because it illustrates how one expert can comment on another and still maintain a professional attitude:

Q. Was there anything unusual about Mr. Irvin's plaque rupture, clot forming, and the sudden cardiac death?

A. No. Again, this is really the most common cause of death in the United States. This is the top major health problem in the western world. There's nothing unusual. This whole sequence of events is what we teach medical students about in terms of the beginning basis of -- pathologic basis of disease for the first-year medical student.

Q. Were you here during Dr. Bloor's testimony?

A. Yes, I was. . . .

Q. Why is it that you wanted to be here when their pathologist testified?

Plaintiff's counsel objected to Dr. Wheeler commenting on Dr. Bloor's testimony. Judge Fallon overruled the objection, noting that "fact witnesses are generally not allowed to comment on fact witnesses' testimony, but experts are."

> Q. Doctor, I believe my question was why is it that you wanted to be here and be here physically present to see Dr. Bloor's testimony?
> A. Well, Dr. Bloor is a pathologist, like I am, and whenever there's a disagreement, I would like to reconcile that and give the opportunity for him to explain what he sees and correlate it with what I see. So I had hoped that he would show some slides and maybe make that explanation, but it turns out there were no slides demonstrated.
> Q. Did you hear Dr. Bloor testify that if, in fact, there was plaque rupture, that that is what lead to the clot and, thus, to the death of Mr. Irvin? Did you hear his testimony on that?
> A. I did, yes.
> Q. Do you agree with Dr. Bloor that if, in fact, there was plaque rupture, that's what caused the clot and ultimately Mr. Irvin's death?
> A. Yes.
> Q. Did you read Dr. Lucchesi's testimony?
> A. Yes.
> Q. Did you read where Dr. Lucchesi said that if, in fact, plaque rupture takes place, the normal response of the body is, when this lipid goo comes into contact with the blood, to form a clot?
> A. Yes, I remember that.
> Q. That that would happen in somebody who never took Vioxx in their life?
> A. Yes.

Cross-examination was brief and focused to some extent on what Dr. Wheeler was being paid. On redirect, Beck brought out that the plaintiff's experts were also paid. When Dr. Wheeler finished, Beck at first said Merck had another witness and then changed his mind and rested.

Plaintiff's counsel in this civil case delivered an opening and a rebuttal summation. The trial judge limited summation time to about one and one-half hours total per side. The plaintiff reserved about 40 minutes for rebuttal.

Andy Birchfield gave the first plaintiff summation. His initial theme was to count the scientists who "stood up" to Merck. He counted off Dr. Topol and Dr. Ray, and identified them as whistle-blowers, people who raised responsible questions without expectation of reward and at some professional risk. He then took jurors through the special issues on the verdict form, suggesting what evidence supported positive answers to each question. He concluded by returning to the "stood up" theme:

> I want you to know that this family has suffered a loss, but this case is more than just about the money. This is about standing up and making a difference. You'll have to answer those questions about the appropriate amount to compensate them and make them whole, the same questions for Richard Irvin and Ashley Irvin. They stood up. Now it is your turn. . . . You've heard the Vioxx story. You have heard about how Merck, in search of a blockbuster drug to fill their coffers, they were losing patents

and they needed a blockbuster drug to fill the gap. That's Dr. Scolnick's testimony. What did they do in pursuit of that blockbuster drug? They ignored serious cardiovascular events. They ignored those heart attack risks. They didn't stop and do a CV outcomes study before they went to market with this drug. They didn't stop when VIGOR, their big first study, showed a fivefold increase in heart attacks. They didn't stop. They kept pushing forward with an aggressive marketing campaign, all at the expense of the public. You can make a difference. Dr. Topol stood up. He stood up for public health. Dr. Wayne Ray, another whistle-blower, stood up for public health. Now, it's your turn. Thank you.

Phil Beck began with causation, as he had in opening:

Good morning. Was there plaque rupture? That's a big important question in the case. The reason it's such an important question is that if there is plaque rupture, then the damage case is over. The reason is because the plaintiff's experts agree that if, in fact, there was plaque rupture, then Vioxx did not play any role in the death of Mr. Irvin. Both of them agree to that.

Dr. Lucchesi, you remember him. He was the first witness in the case, an elderly gentleman from the University of Michigan. He's the one who believes in the Fitzgerald hypothesis about the imbalance, and he described that for you. What he also said, when I was asking him questions, was that if there is plaque rupture -- and I'm going to use a term that's not very scientific, "goo." I said, "if it's the kind of plaque that's got that lipid core" -- that has that goo -- "and if there is plaque rupture and the blood comes into contact with the goo" -- with the lipid core -- "what's the body going to do whether somebody has ever seen Vioxx or not?" He said, "That's going to start the clotting cascade." He agreed that if there is plaque rupture, then the body's natural reaction is going to form that kind of clot that we saw; and that clot is going to cut off the blood to the heart, and that can result in sudden cardiac death. Dr. Lucchesi said that's been happening since time immemorial, happening before Vioxx was ever around. It's been happening after we stopped selling Vioxx. He said it has nothing to do with Vioxx if, in fact, there is plaque rupture.

Dr. Bloor was even more direct. Now, Mr. Birchfield said that Dr. Bloor testified that Vioxx contributed to Mr. Irvin's death. He did say that; but, of course, he said, that based on his assumption that there was no plaque rupture. Remember, we went back and forth, Dr. Bloor and I did, on that. He said that if there was plaque rupture, Vioxx played no role . . . . He said that several times. I liked that answer, so I kept asking the same question over and over and over again, and he kept saying over and over and over again, "You're right. If there was plaque rupture, Vioxx played no role."

Beck went on to spend perhaps half of his summation on the pathologist evidence about why Dicky Irvin had a fatal heart attack.

For summation, Beck used the same visual aid he had used in opening statement and with some of the witnesses. It was a magnetic board with refrigerator magnets

showing each of the significant issues in the case. A chart of this kind, with or without magnets, can be a significant help. In opening, one makes a first impression and a promise of evidence to come. In the trial, one keeps the promise with cross-examination and by calling witnesses. In summation, it is helpful to look back and say, here are the promises I made to you and here is how I kept them.

Beck's summation also illustrated one of the dangers a party can court with overstatement. Recall that Dr. Topol had said that the Merck scientists had treated him disrespectfully, in their writings and in a meeting. In his direct examination on video deposition, he was quite exercised about this. Beck picked up on this issue and went after Topol for exaggerating about the meeting. And, the reasoning would be, if Dr. Topol would exaggerate about that, one might question his scientific conclusions. This is always the problem with the "believer" witness – a tone and manner that creates a negative impression that can influence evaluation of the witness's underlying message. See how Beck addresses it:

> I know you were paying close attention. You know, I listened to Dr. Topol and he's so vehement. I think he said he's written more articles than anybody in America. He's the kind of guy who not only counts how many articles he writes, he counts how many articles other people write beside his articles. He knows it off of the top of his head. He's an important guy and he thinks of himself that way, but he kept contradicting himself during the testimony. He kept contradicting in his sworn testimony today what he actually wrote down back in 2001 when he was talking about the VIGOR study. I talked about the e-mails. They are not the biggest deal in the world, but they reflect a little bit on Dr. Topol. You know, he set up the meeting. He said, "This mean Dr. Reicin came in and tried to intimidate me, scare me off of writing my article." You saw Alise Reicin. you saw Dr. Topol on the screen. Do you think Alise Reicin, 98 pounds sopping wet, is going to intimidate Dr. Topol when he's sitting there in his big office at the Cleveland Clinic? Of course, while he said that it was very unpleasant, his e-mails said, "It was very nice to meet you. Thank you for coming." My pal, Andy Goldman, was the guy who was asking the questions. He said, "Well, didn't you later say, 'Thanks for the suggestions. They were helpful, and I'll see if I can incorporate this,'" he said, "Absolutely not. I never got any suggestions in the first place; and if I did, they weren't helpful." He got angry at the very thought that he received suggestions. Andy said, "But here is your e-mail where you say, 'Thanks for the suggestions. The helpful ones, I'm going to try to put them in the manuscript,'" and he got angry at Andy for showing him an e-mail that contradicted what he said under oath. So the e-mails, as I said, not the biggest deal in the world, but interesting insight into the guy.

Beck addressed questions about Merck's conduct. He ticked off the names and accomplishments of the Merck scientists who worked on Vioxx, the outside experts Merck had called in, and the Merck analysis that eventually led to withdrawing Vioxx from the market because of some possible risk among patients who took it for 36 months.

As noted above, the jury failed to agree and on retrial Merck got a verdict.