

# INSIDE DRUG AND MEDICAL DEVICE LITIGATION

*Your monthly source for effective litigation & compliance strategies*

## POST-CONFERENCE DEBRIEF

### Sold-Out Drug and Medical Device Litigation Conference Preps Attendees for 2006

ACI's 10th Annual Conference on *Drug and Medical Device Litigation* took place December 12-14, 2005, with more than 350 attendees participating at the world-renowned Waldorf Astoria hotel in New York City. This sold-out event was packed with useful content for in-house counsel and litigators alike, and several sessions were standing room only.

The evolutionary nature of drug and device litigation was discussed at length and in detail over the two full days of presentations and break-out sessions. Allen Fudim, a partner at Harris Beach LLP and a speaker at a past installment of the conference, said, "I learned something new. Sitting and listening to practicing experts always prompts interesting thoughts

and ideas, and helps me develop new and better strategies to assist my clients."

This report encapsulates the general themes that emerged during the conference, and lists the primary take-away points that can form the basis for your litigation and compliance strategies in the year ahead.

#### Drug and Device Industries Need Integrated Approach to Legal Challenges

If there was a single overarching theme to the proceedings, it was that the current climate requires drug and device manufacturers to take an holistic approach to dealing with legal challenges, and the attorneys that repre-

sent them must do likewise.

This theme emerged from the very beginning, as the conference co-chairs opened with a discussion of the virtual law firm. Doedy Klar, Associate General Counsel of Alcon Laboratories, and Allen Waxman, Senior Vice President and Assistant General Counsel of Pfizer, Inc., spoke about their need for outside counsel that can respond to the multiplicity of challenges – legal, financial, and regulatory – that drug and device manufacturers are facing. Both agreed on the attractiveness of constructing legal "dream teams," typically composed of lawyers from several firms with complementary areas of expertise, as well as professionals from other disciplines. Waxman stated that a multidisciplinary

*(continued on page 2)*

## IN THIS REPORT

**Drug and Device Industries Need Integrated Approach to Legal Challenges**  
pg 1

**Leadership Key to Business/Litigation Success**  
pg 3

**Plaintiffs' Attorneys Find New Allies, Put Forward New Theories**  
pg 4

**VIEW FROM THE BENCH**  
**Judges in Mass Tort Cases Request Creativity, Flexibility**  
pg 5

**Poor Public Perception of FDA Has Big Impact**  
pg 6

**5 Key Tips to Successfully Combat Industry's Poor Public Image at Trial**  
pg 7

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(cont. from page 1)

approach is necessary to tackle the diversity of plaintiffs and claims presented. Klar and Waxman each emphasized the importance of the individual members of the team working in concert with each other – and with in-house counsel – to achieve litigation solutions that make sense from an overall business standpoint.

The idea that previously unrelated functions have become intimately intertwined – with serious litigation implications – recurred throughout the conference. The drug or device manufacturer's advertising, public relations efforts, product promotion strategies, securities filings, clinical trial protocols, adverse event disclosures, and even its human resources policies, affect litigation results and business viability. So each member of the legal team must have sensitivity to the impact its work will have on other aspects of the company's business, and must be willing to accept the input of other lawyers and nonlegal professionals in crafting a litigation strategy that will produce a desirable and achievable outcome for the company. "We need advocates who are creative in identifying solutions and are practical in implementing them in a cost-effective manner," Waxman said.

Several speakers noted that traditional products liability law has morphed into something completely different, necessitating a wide range of talent and expertise. Plaintiffs' attorneys, state attorneys general, and prosecutors are working in concert to develop new theories of liability, with some striking success. George Lehner, a partner with Pepper Hamilton LLP, pointed out that today the typical drug and device claim is likely to be a series of claims that may include RICO allegations, assert securities law violations, claim injury under various state consumer protection laws, or allege violations of the False Claim Act. Defending such claims requires attorneys and consult-

ants with expertise in more than just traditional products liability — they also need to be up to date on FTC issues, consumer fraud, advertising, and market research. Many of these state actions can be brought as class actions, and as courts struggle to find efficient ways to handle bulging dockets, the judiciary has begun to favor certifying classes in mass torts generally, noted Joseph Hetrick, a partner at Dechert. So the successful drug and device products liability team must have lawyers with experience defending class action lawsuits.

Michael Harrington, Assistant Deputy General Counsel with Eli Lilly and Company, and Gary McConnell, Vice President and Assistant General Counsel at Bayer Corporation, noted that a successful integrated team will require players with expertise in several other areas of law, including:

- Securities law;
- White collar criminal defense;
- E-discovery;
- Insurance coverage;
- Qui tam;
- Settlements; and
- Local and regional expertise.

Many speakers pointed out the need for all members of the litigation team, as well as the client, to recognize how the poor image of the drug and device industry affects both the regulatory climate and the litigation climate. Recent drug recalls and other missteps have damaged the credibility of the FDA, which is perceived to be "in bed" with industry. This widely held perception has called the whole process of clinical research into question. Resulting internal FDA initiatives and legislative proposals are having the effect of modifying FDA procedures to skew the safety/efficacy analysis strongly in favor of safety. These developments have had — and will continue to have — a deleterious impact on manufacturers try-

ing to introduce efficacious drugs to market, many speakers agreed.

At the same time, the poor reputation of the FDA and the industry as a whole makes the crisis management message a crucial cog in the wheel of an overall litigation strategy. Advertising and promotion strategies, particularly direct-to-consumer advertising, also have had an impact on jurors, as many speakers expressed a belief that DTC advertising encourages patients to think of drugs just as they do other products, and erodes the respect consumers once felt for the industry. Many speakers noted that these factors require trial counsel to assume from the very beginning of the case that jurors and learned intermediaries have negative attitudes toward industry executives, experts, and attorneys. So, discovery strategy, jury selection, and witness examination skills are more important than ever before.

To litigators who may find defending an embattled industry daunting, or sharing responsibility for a case with other professionals unappealing, many of the speakers stressed the need for defense attorneys and clients to work together to improve the industry's image and defend it against unfair attack. Ultimately, the patient must come first, and has come first for most members of the industry, as Klar stressed repeatedly. Developing an effective strategy to get that message across is one of the industry's primary challenges today, and litigation counsel plays a crucial role in meeting that challenge.

### Leadership Key to Business/Litigation Success

Expert after expert remarked on the general hostility to drug and device manufacturers among the media, the Congress, the population at large — and so, among potential jurors. This

hostility presents myriad challenges to every aspect of these industries, and requires particularly strong, focused leadership when confronting the need to respond to — and attempt to influence — public opinion. Leading defense attorneys and in-house counsel agreed that the current regulatory and public relations climate calls for an integrated, multi-disciplinary approach to meet the spectrum of legal challenges drug and device manufacturers face.

Such an approach requires a strong leader. An holistic approach to the defense of drug and device manufacturers naturally engenders tensions between, for example, the marketing staff and the compliance staff, or the public relations experts and the defense attorneys, or the jury consultants and the expert witnesses. From the time that adverse outcomes become public through the final resolution of the trial phase, responsibility for the strategy and direction of the efforts to mitigate damage and spur the client's continued viability must rest with a strong individual who remains in ultimate control of every aspect of the crisis.

That's because a products liability lawsuit doesn't exist in a vacuum — the outcome of the suit, or even its very existence, affects the company's ability to attract the best employees, conduct cutting-edge research, move new products to market, promote its products, protect its stature in the medical and regulatory community, influence the media and the legislature, and protect its investors. In order for the industry to achieve the best possible outcome in individual cases, each client must:

- take responsibility for the strategy and direction of its own legal defense;
- be accessible and responsive to the defense team it puts together (meaning not just trial lawyers,

but also attorneys involved in other aspects of the case, as well as consultants, experts, and specialists — every member of the virtual law firm); and

- be accountable to the employees and shareholders of the company, as well as regulators, patients, and the general public.

The breadth and diversity of challenges faced by general counsels for drug and device companies mean that needs have changed as these in-house attorneys seek out litigators, several experts agreed. Because so many products liability cases become mass tort cases, and successful defense of mass tort cases requires successfully implementing talent from several different disciplines, managerial skills now are key when selecting defense counsel. Conference co-chair Waxman reported that when seeking litigation counsel, he looks for trial skills, managerial skills, and people skills. Harrington, Assistant General Counsel at Eli Lilly and Company, says that he looks for geographic reach, experience in similar cases, and significantly, “sensitivity to other areas of expertise and willingness to step aside in favor of someone with different capabilities.”

Just as most speakers agreed that a single firm no longer can provide the full scope of expertise necessary to defend a drug or device manufacturer, the speakers cautioned against allowing a coordinating counsel or lead counsel to run a case without direction from the client. “Be careful that virtual law firms don't become virtually leaderless,” said Waxman. He suggests that the general counsel define the leadership structure and share management of the case with the lead counsel, but retain overall responsibility for the direction of the case.

Trial consultant Bryan Harston agrees. In an interview during the conference, Harston remarked that “GC also

*(continued on page 4)*

*(cont. from page 3)*

should stand for General Contractor. The GC should be in frequent touch with all members of the team, and ideally will devote a certain amount of time every week solely to discussing issues associated with the defense with the leaders of every discipline engaged to work on the case. The GC must be willing to assign roles, responsibility and pecking order to the members of the team to prevent costly infighting.”

Several speakers over the course of the conference offered tips to in-house attorneys to help them exert leadership and control over litigation, as well as advice for litigation counsel to assist in the process and add value for their clients:

- Plant the seeds of the defense strategy as the drug or device is coming to market, before any claims have been served. Ideally, defense counsel will be hired as the product is coming to market and can assist with this analysis, said Harrington.
- Alternatively, manufacturers can reserve their legal resources and bring in defense counsel early in the process only when the product is likely to spur a large number of suits, suggested McConnell. At the time the product comes to market, the manufacturer should have a good idea of its vulnerabilities and the types of claims that are likely to arise from its use, as well as substantial post-marketing data, he said.
- Craft the corporate message early, and continue to repeat and elaborate on it over time. Be aware that not all crisis messages translate well into trial, and some can be harmful. So design a crisis management message with the idea of eventual litigation in mind. Recognize that the jury pool, learned intermediaries, and others will take the message on board, and make sure it's one that

can be used to support the client's position during litigation. The GC is in a unique position to help create a crisis message that protects and serves the client.

- GCs must ensure that sales and marketing staff — and all others who come into contact with the public — are thoroughly trained, emphasized conference co-chair Klar. She pointed out the way in which simple words in common usage — words like reckless, hazardous, negligent, defective — can negatively impact an attempt to defend a case. Keep such words out of all forms and templates, and instill documentation training procedures to ensure that your staff doesn't undermine your litigation counsel's ability to defend you.
- When faced with significant bad publicity, the client should consider approaching the financial community early in the process. Some damage to the client's stock price and business reputation can be headed off if the financial community realizes that a large percentage of cases brought in a mass tort action aren't meritorious and will be defended vigorously.

### **Plaintiffs' Attorneys Find New Allies, Put Forward New Theories**

Several speakers noted with concern that plaintiffs' attorneys are enlisting the help of state attorneys general, federal prosecutors, federal securities regulators, and even foreign attorneys to bring new causes of action, promote new theories of liability, and assert novel claims for damages. Speakers on several panels emphasized the changing face of drug and medical device litigation, as well as the need for manufacturers to take a long view of all their development and promotion tactics.

Speakers explained that most products liability claims in the drug and medical device arena now have a component claim brought under state consumer protection laws. Typically, these laws bar deceptive or false advertising and assess liability when an advertised product is determined to be unsafe when used as directed. Such statutes usually don't require a plaintiff to prove reliance on the allegedly false or deceptive advertising to establish liability, says Lehner. And in 26 states, plaintiffs can aggregate claims to bring class action suits under these statutes, although plaintiffs have had mixed success in bringing national class action suits under the disparate state laws, he said. However, lack of success certifying a national class suits, which are potentially lucrative for plaintiffs' attorneys, he says.

State attorneys general are beginning to see suits against drug and medical device manufacturers as a revenue source. By asserting theories of liability under the federal False Claims Act and antitrust laws, as well as state consumer protection statutes, state attorneys general are able to threaten criminal and large civil monetary penalties, and to certify classes of consumers damaged by manufacturers' alleged “collusion.”

As plaintiffs and regulators pursue these nontraditional causes of action, manufacturers are finding themselves with some new co-defendants. In their attempts to show that there have been conspiracies to create a market for a product or to promote its use, plaintiffs are suing trade associations and professional associations that represent the industry that created the product or the medical specialty that uses the product. Typically, the suit will assert that the trade association or professional association concealed information and/or misrepresented the risk of a particular product.

In responding to the threat of these lawsuits, the drug and device industries must be extremely careful about the way they promote their products, several speakers agreed.

Prosecutors, jurors, regulators, and the media are looking for apparent improprieties in research and promotion, and industry must realize that prosecutors will bring claims under state deceptive advertising laws if perceived improprieties are found.

Several speakers emphasized the general public's perception that drug and device manufacturers knowingly send unsafe products to market in order to earn profits. Defense attorneys and clients once could combat this image by emphasizing the rigor of the FDA approval process, but as the reputation of the FDA is tarnished, these discussions have little resonance with the media or the public anymore. Therefore, the industry

must be keenly sensitive to the way its promotion and advertising efforts will "read" to the public.

For example, pricing incentives run the risk of being perceived by jurors and learned intermediaries as over-promotion for a pure profit motive. Similarly, speakers on several panels noted that direct-to-consumer advertising runs the risk of setting consumers' expectations too high, and may tarnish manufacturers' status.

*(continued on page 6)*

## VIEW FROM THE BENCH

### Judges in Mass Tort Cases Request Creativity, Flexibility

Attendees had the rare opportunity to participate in an interactive panel discussion with several distinguished jurists. Panelists included the Honorable Michael J. Davis of the US District Court in Minnesota, New York Supreme Court Justice Helen Freedman, the Honorable Richard Kramer, Superior Court Judge in the Complex Litigation Department in San Francisco, Calif., and the Honorable Barbara Jacobs Rothstein, US District Court Judge in the Western District of Washington and Director of the Federal Judicial Center.

Each of the judges has significant experience handling mass tort cases. Responding to questions posed by audience members and the moderator, Joseph M. Price, a partner at Faegre & Benson, LLP, the judges focused on the logistical challenges of handling the volume of data and testimony in mass tort cases, and the difficulties of deciding questions that require a background in science and/or technology.

On the question of efficiently handling a mass tort case that is moving through both state and federal courts, all the judges agreed that cooperation between state and federal judges —

as well as the parties — was difficult to obtain but crucial for expeditious and fair disposition of the matters. The consensus among the panel was that a certain amount of experimentation is necessary to coordinate effectively the efforts of state and federal courts hearing cases on parallel tracks. It was suggested that a piecemeal approach can be easier to implement than a wholesale attempt by one court to "take over" the case. For example, coordinating document production among the courts can lead to such obvious efficiencies that it can be a simple matter to persuade the parties to allow it.

The panel noted that e-discovery is producing unmanageable quantities of documents and other information, and courts must begin to make difficult decisions about how to limit document production, balancing the legitimate needs of the plaintiffs versus the possibility of paralyzing a defendant's ability to do business.

The judges discussed innovations they've tried in attempts to move matters along efficiently. In the PPA cases, for example, one member of the panel held a *Daubert*-style hearing and invited every judge in the country

with a PPA case to participate. This permitted the attorneys to put on an excellent case on the causation issue, with testimony from experts who were willing to give their opinions one time, but not willing to "make a life's work of it." Many judges hearing PPA cases responded to the invitation, appearing in person or participating through video-conferencing. Each was permitted to question the attorneys and witnesses to elicit testimony that would meet the prevailing standard in their respective courts, and on the whole, the experiment was quite successful.

One judge reported that he developed a website that served as an electronic repository for documents in the case, established a lawyers' liaison committee, and made several trips to other regions to meet with parties and their attorneys to speed settlement of the cases. He said that he solicited opinions from the attorneys involved about how best to manage the case, and found their input valuable. All the panelists emphasized the importance of attorneys being willing to try something different in the interests of efficiency, and remarked that attorneys were more likely to go along with new

*(continued on page 6)*

**VIEW FROM THE BENCH (cont. from page 5)**

ways of doing things if their input was solicited from the beginning.

The judges also discussed the difficulty of deciding issues that turn on matters of science and technology, given that most members of the judiciary have little background in these areas. Each conceded that attorneys had a role to play in educating the judge about the information required to decide an issue. Regarding how to teach science and technology to the judiciary in the context of a specific case, one of the judges recommended that attorneys follow the model of

IP litigators at *Markman* hearings. Several members of the panel noted that they had appointed their own experts when necessary (although in general the feeling among the panel was that the testimony of the court's own expert should generally not go before a jury).

The panel pointed out that the Federal Judicial Center and other judicial education organizations hold seminars and educational retreats to teach the judiciary about science and technology issues. All the judges agreed that the judiciary must take some respon-

sibility for learning about the technological issues of the day, but also should inform the parties of any self-education tools the judge is using.

The judges also agreed that as a society we must accept that some matters will be wrongly decided because the judges must make a ruling before the science is sufficiently clear. As one of the panelists pointed out, it is not the job of the judiciary to establish inexorable truths, but rather to resolve disputes between parties.

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DTC advertising may diminish the status of drug and device manufacturers or even promote the idea that manufacturers are hucksters. Such a perception is at odds with the reality of the industry — one that invests tremendous time, energy, and talent into developing efficacious and safe products that make life better for people around the world. Although competitive pressures probably mean that marketing considerations will continue to have significant influence on how products are brought to market, manufacturers must integrate concern for public opinion throughout their promotional efforts in order to combat this new family of lawsuits brought under state consumer protection statutes, many speakers emphasized.

**Poor Public Perception of FDA Has Big Impact**

Another recurring theme of the conference was the deleterious impact the public's low regard for the FDA has on the drug and medical device industries as a whole. The FDA once enjoyed a reputation as an objective agency that used rigorous scientific analysis to carefully weigh the risks and benefits of drugs and medical devices, ensuring only safe and effec-

tive products were brought to market. However, recalls of several widely used drugs and devices, as well as congressional testimony by an FDA staffer that indicated the entire system was in disarray, have led to a perception that the FDA is a weak agency that is a captive of drug and device manufacturers.

As a result of these events, the entire clinical research process has been called into question. Internal and external proposals to "fix" the agency may lead to unintended consequences and further weaken the FDA, several speakers warned.

Stung by criticism that it is incompetent and ineffective, the FDA has introduced internal measures designed to make the drug approval process more transparent and ensure that safety standards are met. For example, the agency has established a Drug Safety Oversight Board to ensure the purity and integrity of clinical research data and the agency's methods of evaluating it. The FDA is considering posting clinical trial results on a Drug Watch website, designed to inform consumers about "emerging" safety concerns.

But many speakers at the conference questioned whether these responses

actually will lead to safer drugs, or whether they will merely skew the safety/efficacy balancing test to the point that effective drugs are prevented from reaching the market because of safety concerns. In addition, several speakers commented on the inconsistencies between the agency's role as a scientific authority on the safety and efficacy of drugs and medical devices, and the presentation of raw clinical information to the public without analysis — in effect ceding to others the FDA's job of balancing safety against efficacy. Several speakers noted that the FDA seems to have lost confidence in its traditional risk-management tools.

The FDA's action has had real public health consequences. Because the FDA seems loathe to rely on post-marketing studies to reveal any potential health risks that may affect the general population, it is slowing down approvals for new drugs, increasing requests for pre-market studies over a broader population, and more frequently imposing detailed and cumbersome risk management plans. As a result, introducing new products to market has become riskier and more expensive, leading to some real public health consequences. For example, the manufacturers of Tysabri have

“paused” in their attempts to bring this effective drug to combat MS to market, and attempts to develop and market bioshield drugs — drugs to combat biological terrorism — have stalled.

Despite these developments, Congress — focused on the agency's recent reported “failures,” and perhaps seeking to make political capital — has made recent attempts to impose external safety controls on the agency, said Steven Irizarry, Vice President of Government Affairs at ML Strategies. Irizarry described recent proposals by members of Congress to create an “independent” center within the FDA that is empowered to conduct post-marketing research and take action if a drug may pose an “unreasonable” risk. Although this particular proposal has little chance of passing, Irizarry is concerned that there is a sentiment among lawmakers that the agency requires additional external or independent safety-focused oversight. When the Prescription Drug User Fee Act comes up for reauthorization in 2006, Irizarry warns that Congress may attempt to attach provisions that may further stifle the agency's ability to move efficacious drugs through the system to market.

Drug and device manufacturers need to recognize that they benefit from a strong and credible FDA. Ensuring that medical research is carried out and reported in an ethical manner, conducting rigorous pharmaco-vigilance programs, and responding quickly and appropriately to adverse events regarding their products can help restore respect for the agency.

### 5 Key Tips to Successfully Combat Industry's Poor Public Image at Trial

There was consensus among most of the speakers that, at least as far as

public image is concerned, the drug and medical device industries are the new tobacco. The image portrayed in movies like the *Constant Gardener* and *Side Effects*, negative editorials in publications like the *New York Times* and the *Wall Street Journal*, are all evidence of a widespread belief in this country that the industry is either willfully malicious, or at least determined to disregard safety in the pursuit of profit.

Although acknowledging that the industry's reputation is poor, and conceding that such a reputation makes every aspect of defense litigation more difficult, speakers from all sides of the industry — in-house attorneys, litigators, trial consultants, public relations specialists, and even judges — agreed that it is possible for a manufacturer to win the war of popular opinion, at least in individual cases.

The experts revealed a number of policies, procedures, and trial techniques that can help ensure that a drug or device manufacturer gets a fair hearing, if the policies and techniques are thoughtfully and consistently applied.

■ **Aim to win before you begin.** The first important concept to remember is that litigation may be won or lost before a lawsuit is ever filed. Linda Svitak, a partner in Faegre & Benson, stressed the importance of rigorous pharmaco-vigilance programs, keeping in mind that such programs are likely to produce self-critical documents that later may be obtained and used by plaintiffs. Despite this risk, she and several other speakers emphasized that programs that track, investigate, and document all reported adverse outcomes can positively influence a jury's perception of the company as credible, and counter any lack of confidence in the FDA approval process.

A rigorous pharmaco-vigilance pro-

gram can lend credence to the idea that the company truly does put the patient first. And the jury that believes the company puts the patient first is less likely to hold the company responsible for any bad outcomes, several speakers agreed.

■ **Act quickly on information.** If a product must be recalled due to a quality issue, it's always better to act quickly and appropriately. Not only is it the right thing to do, it mitigates the likelihood of a claim that the manufacturer knew of the problem and did nothing about it, said Thomas Stukane, Senior Legal Director at Schering Plough. So the pharmaco-vigilance and other systems for notification and investigation must be designed carefully to ensure that all product quality information gets to the people who have the authority to investigate and take appropriate action.

■ **Show marketing restraint, especially early on.** Irizarry noted that the way a product is marketed can have an impact on products liability lawsuits. In response to that fact, companies should be somewhat restrained in the way that they promote their products, at least until they and prescribing physicians have some experience with the product in the marketplace and can fully assess its vulnerabilities, said Klar.

Direct-to-consumer advertising likewise affects the way consumers perceive a product and a manufacturer, and by extension affects the attitude of the judge, the jury, and the learned intermediaries, as several speakers remarked. In light of that fact, it is important that any direct-to-consumer advertising be tasteful, accurate, and fair, so as not to engender any deepening of the public's dislike and distrust.

■ **Establish defenses through depositions.** Lay the groundwork for a learned intermediary defense early in

*(continued on page 8)*

(cont. from page 7)

the litigation, advised Connie Matteo. For example, when deposing the plaintiff, try to elicit that the plaintiff trusts the physician and likely would have taken the product based on the physician's recommendation, even if explicitly warned about the potential adverse outcome. If possible, elicit testimony that the drug or device was effective at relieving the patient's suffering or improving the state of the patient's disease. Seek that testimony from the plaintiff and the physician.

When deposing the physician, keep in mind that the public is suspicious of the industry's practices regarding promotion of products to the medical community. So, attempt to obtain testimony demonstrating that the physician gets information from a variety of sources, not just company sales rep-

resentatives, Matteo suggested. Also highlight how much he or she relies on experience, familiarity with the patient, exercise of independent medical judgment, and review of the medical literature.

■ **Give juries the information they need.** Speaking on a session about expert witnesses, one panelist remarked that jurors are interested in their bodies and eager to learn about causation evidence. Feed this hunger in your messages to the jury, beginning with voir dire and reiterating the message every time you address the jury thereafter. At the same time, recognize that jurors respond more to credibility than credentials and retain very little of what they hear, but they do remember impressions of competence and truthfulness. The panelists stressed that litigators must choose

and question experts accordingly, use compelling visual aids to help the jury understand the most salient points, and concentrate on providing jurors with the three things they want from experts: credibility, causation, and certainty.

In general, the experts agreed that defending drug and device manufacturers is more challenging than ever. However, there seemed to be consensus that if a manufacturer truly behaved in a responsible and responsive manner (putting the patient first), established an integrated response to litigation management early in the product's life cycle, and developed and maintained a compelling message regarding the product, success — or at least avoidance of catastrophic failure — is within reach, even in today's hostile environment.

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