Product Liability Strategies

A roundtable sponsored by MINTZ LEVIN

Mintz Levin Cohn Ferris Glovsky and Popeo PC

© NICKONDR

Transcription services provided by O'Brien & Levine Court Reporting • Photos by Mike Ritter

Joseph G. Blute
Mintz Levin

Ralph A. Campillo
Mintz Levin

Aaron Grossman
General Counsel
ZOLL Medical Corporation

Erin E. Hayes
Senior Corporate Counsel
Boston Scientific Corporation

Yalonda T. Howze
Mintz Levin

Angelo P. Lopresti
General Counsel
IPG Photonics

Steven P. Reynolds
General Counsel
Sensata Technologies

MASSACHUSETTS LAWYERS WEEKLY: Are product liability exposures truly rising? Why do so many product liability claims asserted today carry the risk of being a mass tort or an MDL?

RALPH CAMPILLO, MINTZ LEVIN: On a daily basis we see cases being rushed to an MDL or a state-coordinated proceeding by lawyers who are very sophisticated and know defendants' pressure points, such as e-discovery. It is very rare to see a product liability case involving medical products being filed by a solo practitioner or a general practitioner. Instead, we see very sophisticated lawyers who have had a lot of experience in the mass tort arena. They know how to angle for MDL positions where they benefit from common funds, and which makes their involvement lucrative despite not necessarily having hundreds of cases. We see this happening on a daily basis, which has a tremendous impact on the transactional cost for manufacturers.

Mass litigation has become quite attractive to plaintiffs' lawyers. They now work together much more than they used to. They coordinate well with each other. And the availability of technology, media coverage, access to FDA warning letters and other such information online makes it easy for them to find causes and clients. These developments are indeed having a tremendous impact on the cost of defending products liability cases.

STEVEN REYNOLDS, SENSATA TECHNOLOGIES: I think different industries and different companies will have different experiences with that. Our experience as a component manufacturer, mostly in the transportation market, is that we haven't necessarily seen a marked increase in numbers, but I would absolutely agree that you do see changes. You see waves of types of cases that occur. You see more sophisticated plaintiffs' attorneys. It is an entrepreneurial activity, the plaintiffs' bar. They are using financing tools, and they're using ways of trying to be better positioned. If you can take a common set of facts that you've developed and then be able to leverage that in multiple cases and multiple jurisdictions, it's not a bad business plan, and I think that a lot of what you're seeing is there are increasingly sophisticated business people.

CAMPILLO: One other thing that should be noted is that some jury research has shown the American public really expects products to be 100 percent safe. They believe that's feasible, and they can't understand why a product could get on the market without being put through long-term detailed very thorough testing which we know is not practical or feasible in many contexts. But that mentality makes these cases very attractive to the lawyers on the other side.

LAWYERS WEEKLY: What are the key things a manufacturer should consider to minimize product liability exposure?

YALONDA HOWZE, MINTZ LEVIN: It's important to assess exposure proactively. That's really one of the best things that a company can do — understanding where the pressure points are in terms of exposure, looking at any data that you get from the post-market experience, assessing that data ahead of time, looking at operating procedures internally and making sure that key decision makers in the various departments who are responsible for the product are complying with those Standard Operating Procedures or at least are aware of them.

This is very important because with product liability cases what you're often doing is glancing backwards at what happened in some timeline that has long since passed, and so if companies are proactively looking at the same kind of information that you would be looking at in the event of an actual case and making sure that exposure is minimized, it really prevents the greatest exposure later.

ANGELO LOPRESTI, IPG PHOTONICS: There are several things that are important. The first is obviously good product engineering and testing and making sure the whole team understands the risk that's involved. As lawyers you have to understand the difference between high risk and low risk, and you should approach your executive management and have a frank discussion with them if you think it's a high-risk product and ask for additional testing, if necessary, or additional reengineering.

Second, I think as counsel and chief legal officer one has to instill a culture of honesty with one's peers, as well as the people who work under them, in order to encourage transparency and reporting up of issues. It's important to have relationships with not only your legal department but with business people, and so that way they're comfortable in reporting up to you.

Lastly, you have to get ahead of the issue and sit down during the monthly or quarterly business reviews with your finance and sales teams to find out what's going on, and have your ears open to at least the beginning of a problem. You're not always going to be able to stop it before it goes out the door, but you have to understand and get ahead of the issue and alert your management team.

HOWZE: I would just add that a lot of this can be done internally with existing internal staff. So if you're beginning to hear noises on the street, so to speak, about a particular product, that's really a good time to proactively get your hands around it and not wait for the complaint to hit your doorstep.

JOSEPH BLUTE, MINTZ LEVIN: I think culture is the number one thing in product liability. If you focus on excellence and safety and accident avoidance and that's seen within the company as part of the core culture, companies that can effectively do that are much less likely to have employees writing really stupid e-mails. They're much less likely to have employees do something like backdating a document because they think it's going to help the company or themselves in litigation.

You don't want to create an environment where your employees see litigation as a game where we're the good guys all the time and all plaintiffs' lawyers are in it just for the money and all of these claims are nonsense. I think it's a bad thing for company employees to get that attitude. They have to look at this as, "We're selling products and occasionally they may injure somebody. Let's do the best we can to avoid that. If someone is injured and we're sued, at least we'll be able to present to the world that we did our best."

AARON GROSSMAN, ZOLL MEDICAL CORPORATION: It's not litigation avoidance, it's quality. It starts with quality, and quality is all about culture. And culture, ultimately doesn't rest with the legal department. As highly as I think of the jobs that we do, it starts with the CEO. It starts there, and then it cascades down through the organization. Quality has to be more than a department. It has to be a key goal for the company. People need to feel that if they raise a concern and it stops the line, that that's okay. At the end of the day when you get sued, it's often because either there was a quality breakdown or customer expectations breakdown, and that's all about honesty, transparency, and focusing on doing the best you can to make a good quality product.

> "Quality has to be more than a department. It has to be a key goal for the company. People need to feel that if they raise a concern and it stops the line, that that's okay."
>
> **— Aaron Grossman, ZOLL Medical Corporation**

LAWYERS WEEKLY: What will be the impact of the U.S. Supreme Court's decision in *Bristol-Myers Squibb Co. v. Superior Court of California* on forum shopping by litigants?

BLUTE: This case is important for several reasons. First of all, going back to our discussion about the aggregation of litigation, the plaintiffs' firms for very entrepreneurial reasons and economic reasons prefer to aggregate cases. And they prefer to aggregate them in jurisdictions that are friendly to plaintiffs and to aggregation.

That's given rise to what's called litigation tourism, where the plaintiffs try to aggregate cases in one of these jurisdictions, and they get as many claims as they can. Very often they get them from out of state. This particular case involved the drug Plavix, which is a blood thinner. There were hundreds of cases asserted in California against Bristol-Myers Squibb, and 600 of the plaintiffs had no connection to California. The California Supreme Court said notwithstanding that, since Bristol-Myers did so much work in California generally and since its distributor was a California company, that was enough to exert jurisdiction. But the Supreme Court said no. They said you have to have a connection between the individual plaintiff case/claim and the individual defendant. The jurisdiction has to be established plaintiff by plaintiff, defendant by defendant, and importantly, claim by claim.

CAMPILLO: I think some caution should be exercised by companies before filing dismissal motions. There may be downsides. Do you really want cases spread over 50 states? You will need more and better quality local lawyers and you may lose the value of having coordinating counsel. You run the risk of inconsistent verdicts, and from the company perspective it puts a heavy burden on its people in discovery.

In a coordinated proceeding or an aggregated proceeding you should have a single deposition of key players. But, if you have cases moving forward to the beat of different drums in different states, you're not likely to be able to protect company

witnesses from being deposed and re-deposed. You're going to see different discovery rulings, different breadth of discovery. A potential mess!

REYNOLDS: Sometimes consolidating can be to your advantage. The largest product liability experience that we had was an automotive recall, both the car company and the component maker being brought into the private lawsuit. It actually was very helpful that we ended up with a federal MDL in Michigan and a state MDL in Texas, in Austin, because [there was] one deposition of the key design engineer, then it was used in hundreds of cases. The administrative burden of having to fight wars all over the country and have key talent being forced to spend enormous amounts of time in the discovery process is a mess.

LAWYERS WEEKLY: What are the best ways to handle discovery and e-discovery issues?

ERIN HAYES, BOSTON SCIENTIFIC: Turning first to scope as it pertains to discovery in product liability cases — it's really important that when broad discovery requests come in that the company focuses on the specific product and the specific time period at issue in its attempt to narrow scope. To put it another way, a company may change how a product is manufactured or designed over the lifetime of that product — which could span decades. There may be different product iterations. Components may change. Manufacturing facilities may change. All of these variables should be considered, and the scope of discovery should be limited accordingly whenever possible to the specific product alleged to have caused injury.

It varies by jurisdiction in terms of the scope of discovery that a court may allow, but many courts will utilize the tests of "substantial similarity" or "reasonable similarity" of products when a plaintiff seeks discovery for products beyond those alleged to have caused injury. When a court uses such tests, it is important that the responding company really focus upon the changes to a product that I mentioned earlier in an effort to narrow the scope. Plaintiffs should not be able to gain discovery on products beyond those alleged to have caused injury, or at the very least, are substantially similar to those products. As another consideration, if the "substantially similar" product was also alleged to suffer from some defect in another case, a responding company should also attempt to exclude evidence of defects that are not similar. For example, an alleged defective airbag in one case does not mean that a plaintiff should have access to evidence concerning a defective seatbelt in a prior case.

HOWZE: From the outside counsel perspective we definitely want to be focused on narrowing scope wherever possible, to go back to opposing counsel and have a conversation and reach an agreement about that. It's also important to come to an agreement if you have multiple cases and these cases aren't in an MDL. You still want to get the benefit of that kind of coordination. It's important to try to reach agreement with opposing counsel at the outset as to how we're going to handle witnesses, so you're not having the same witness deposed eight or nine times in eight or nine jurisdictions. And you want to put all of this in writing and not rely on e-mail traffic.

Sometimes it's more cost efficient to work with third-party vendors and not law firms to review some documents, and so it's important from an outside counsel perspective to get an understanding with in-house counsel as to how we want to structure this in a way that really makes sense, that's going to keep costs down and that's going to make sure that they have one bite at the apple for all of the key witnesses.

LAWYERS WEEKLY: What is the effect of testimony from company witnesses on the outcome of product liability litigation? What strategies should be considered regarding the selection, training, and supervision of employees involved in the development, approval, launch, and/or sale of products?

GROSSMAN: The testimony of company witnesses can make or break a case, so it's critical that the company witnesses fully understand the case prior to any deposition and prior to being asked to sign any affidavits or any declarations.

Too many times I've seen people make the mistake of putting documents in front of a company witness for signature not fully realizing that that document may come

up in the future. Before any interaction between a company witness and the litigation, the witness has to have as complete an understanding as possible of the facts and circumstances, the plaintiff's legal theories, the twists and turns the case may take, so that he or she can be completely comfortable with the truth and accuracy and completeness of any statements that he or she is making and understand how it may be used in or out of context.

That comes down to communication with internal and outside counsel, and sometimes removing barriers and disintermediating so that outside counsel is speaking directly with the company witness. I think to the extent you can facilitate those relationships it's critically important.

HAYES: In terms of selecting the appropriate company witness, there's oftentimes a lot of reasons why the person who may be the most knowledgeable isn't necessarily the person that you want to choose. This is where in-house counsel is critical, to select the individual who is going to most appropriately and best represent the subjective opinions of the company that will then be imputed to the company at large.

In terms of just generally preparing individuals who are involved in development and approval, it goes back to having robust policies and procedures in place that relate to quality, that relate to testing, that relate to sales, and then ensuring that these policies and procedures are followed, and the best way to do that is to have appropriate training for those individuals and document the training. Policies are only as good as the training that goes into those policies and procedures.

> "I think as counsel and chief legal officer one has to instill a culture of honesty with one's peers, as well as the people who work under them, in order to encourage transparency and reporting up of issues."
>
> **— Angelo P. Lopresti, IPG Photonics**

GROSSMAN: I would add that in selecting the individuals, their ability to dedicate time to the project is really important. Adequate litigation performance requires a lot of investment in time. Doing a good job in deposition or trial is not a natural skill that most people have. It takes a lot of practice, a lot of study, and a lot of dedication, and if somebody is not going to be able to dedicate themselves to it the way they need to, they're probably not the right person for the job.

CAMPILLO: What I have found is that if upper management lets those employees know that this is important to the company and that they should invest the time to do the things Aaron is talking about, then you get much better results. Getting upper management to buy into the importance of this and having their message passed on to the people who are going to be in the trenches is hugely significant.

BLUTE: As Erin said, the person with the most knowledge may not be the best witness, may not have the skills, because it is a skill. I think you need to really spend time thinking about who your witness is going to be. You've got to think of things like, how do they come across? What's their appearance? Their gender and age might be important in a particular case. Being a witness is not something that people who go into engineering or science study for. So you want to try to get somebody who the lawyer thinks can with preparation handle that.

HAYES: The other point that I want to tackle is making sure that they understand the themes of the litigation because I feel like when the witness is on the stand, you want them really focusing on answering the question as opposed to wondering why the lawyer asked the question and how it plays into the case, because you can almost see sometimes their minds working and trying to think about how it fits in.

Continued on page 22

Continued from page 21

LAWYERS WEEKLY: How do cybersecurity concerns impact your industry? Does the risk of a cyber attack raise any unique concerns?

LOPRESTI: Cybersecurity concerns affect every aspect of our lives: personal, law firms, and certainly our corporations. Depending upon what type of company you are, whether you're a consumer-facing company or a commercial-facing company, there's a different level of concern.

I think facing everyone is the risk of financial fraud and phishing. Corporations are just big pots of money, and we attract cyber criminals. So we have to get down to the nuts and bolts. Even for wire transfers to do a closing, we have to go through additional procedures now to make sure that someone hasn't found a party's e-mail and sent you fraudulent wire instructions. We have to develop new procedures and really educate the staff every time one of these new phishing attempts comes in. We as lawyers have to look at risk mitigation and making sure we defend the reputation of the company and address the concerns of the board because cybersecurity is a big focus of all public company boards these days.

"I think one thing you have to avoid is having the company say, 'Here's my offer. I'm not going to ever go a dime above it,' and later they increase the offer. If you're ever going to take that posture, you really have to stick to it."

— Ralph A. Campillo, Mintz Levin

And I would say for internal counsel: You have to get a seat at the table. If IT is meeting with your business partners on cyber matters, you have to be there and understand what the issues and risks are. Even though they may not be implementing software for you, you have to understand what's going on and make sure that your concerns are being understood.

REYNOLDS: There's no question this is an increasing issue with all kinds of products: consumer products, industrial products, medical device products. Products are increasingly communicating. They're sending data to cloud-based systems. The data's being utilized and monetized. It will change all sorts of industries, and therefore the security of that data is going to become critical. In the automotive industry, it's not only the use of communications protocols to send data out when previously it might have been internal to the car in a wire harness, but rather the entire change of the industry from a product industry to a service industry, the notion that vehicles will become autonomous, vehicles will communicate with each other and will no longer have the human-controlled interface of the driver but rather [will be] computer-run entirely.

Other industries will experience similar change, and the whole notion of liability will change. What happens with auto insurance in a world where it's not an individual driver of a car where the company is evaluating their driving record and accident history, but rather you are sitting in a vehicle that is doing the driving? What's going to happen with products cases in that instance as well? It's a lot easier for a plaintiff's lawyer, I'd imagine, to bring a case against mechanical products than it will be to dive into the world of how a sophisticated algorithm operated or didn't operate in certain circumstances.

LAWYERS WEEKLY: Are there pre-litigation strategies that it makes sense to utilize, for example, providing certain information to plaintiff's counsel early in the process in the hopes of discouraging a filing?

GROSSMAN: I think it's helpful to remember that most plaintiffs are people with valid concerns who don't understand why they're injured or why their loved one has died. They may be in a period of emotional difficulty, and it can be helpful to provide information that may answer some of their questions. Oftentimes, they're in a position of ignorance or uncertainty and as the manufacturer you have information that can answer their questions. Your device may capture certain data or information that might explain the incident that happened, and then that can sometimes satisfy an emotional need and, frankly, address the liability issue.

Also, plaintiff's counsel has an obligation to conduct an investigation. They need to satisfy their own interests to make sure that the case is worth spending their own time on. They need to be able to answer their clients as to what they did. And so to the extent you can provide information early on in the matter that can address people's questions and concerns, I have found it very helpful to do so.

HAYES: It depends on the factual circumstances surrounding the case and the degree of liability exposure, the gravity of the injuries, the specific facts. Did the device fail? Did it work as it was intended? When these things come in to the company, they tend to come in through the Quality channels or through the Sales organization. The doctor is already aware that the device has failed. So I find that you're not typically blindsided by a letter from a plaintiff's attorney; you already know that it's out there.

So, what you share pre-litigation is going to depend upon the strategy that you intend to take with respect to this event based on surrounding circumstances. Is this an isolated event? Is this something that relates to a design? Is this a particular device that failed? Is it the way the physician used the device that caused the problem? Is it on-label? Is it off-label? All of those things would factor into whether I was going to share something. If it's something like the physician placed it off-label, that would probably be information that I would strongly consider sharing depending on the other circumstances of the case.

HOWZE: Sometimes once you talk with the opposing counsel, you're able to get a sense of what their immediate objectives are. Sometimes they are on the hunt, and they want information. Sometimes they want to talk their client off the ledge, and they don't really want to pursue the case, and they need enough ammunition to go back and say, "You know, I don't really think there's a 'there' there. We should really let this go." But I think it takes a good deal of instinct to know what situation you're facing and when it makes sense to turn over some information at the outset or not.

LAWYERS WEEKLY: Should you follow a settlement policy, for example, settling so as not to incentivize other litigants or, on the contrary, settling so as to avoid the risk of creating legal precedent off of bad facts?

BLUTE: I think it depends on the case. For example, if you have a product that's new on the market, patented, and these cases come in, there's a reputational interest, and you don't think there's anything wrong with that product, then I think it's good for the business and the morale of the people you work with to aggressively defend those cases. But if I've got a product that's sort of a legacy thing where the product isn't even on the market anymore, then it may be a different strategy.

You make individual decisions during the course of litigation. If you're early in what could be repeat litigation and the first case that happens to come up for trial [is before] a particular judge or an unfavorable jurisdiction, you may decide that's not the case that I want to try first. So maybe strategically the company decides let's not lead with that one, if possible let's lead with another one. There are no hard and fast rules.

GROSSMAN: I do think it's important to at times take a no settlement approach to certain kinds of cases. If you know there will be a recurring fact pattern that you believe you can adequately defend, I think you can send the wrong signal to be settling that kind of case. Despite the fact that you can assert confidentiality in a settlement, I don't really believe it exists. I believe that some plaintiffs' lawyers talk, and so I would never rely on that.

And there are morale issues when you settle cases, for your internal team. It's very helpful for your sales organizations to understand that you've never had to settle a case involving a certain issue. It gives them more confidence when they're talking to doctors or other potential customers.

CAMPILLO: I think one thing you have to avoid is having the company say, "Here's my offer. I'm not going to ever go a dime above it," and later they increase the offer. If you're ever going to take that posture, you really have to stick to it, or your outside counsel, or your negotiator, loses a lot of credibility, which can impact future dealings as well.