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Inside the Minds:  
**Product Liability  
Risks**

*Leading Lawyers on Winning Legal Strategies for Defending  
Companies, Understanding Regulatory Proceedings &  
Minimizing Overall Exposure*



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# The Initial Stages of Product Liability Defense

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## **Our Role as Product Liability Attorneys**

Product liability cases require the client, the attorney, and the judicial system to balance a number of competing forces: How will the company present the virtues of the product amid accusations of its risks of harm? If faced with a battery of individual and class action cases, should the company try to dispose of the individual cases quickly to concentrate on the class actions, or vice-versa, or fight them all? How do these questions change if there are parallel regulatory inquiries? And what of new product improvements or related products in development? How should testing of new products proceed, given the document retention concerns that litigation creates?

Given the business and legal constraints, both litigation and regulatory, a good product liability attorney defending the manufacturer needs to be sensitive to all of these issues at the same time. The skill and creativity of the plaintiffs' bar and increasing complexity in the substantive law create new product liability challenges. Although each case, each client, and each product is different, these questions might serve as a set of best practices to be considered at the outset of each new product liability representation and to be revisited periodically for ongoing cases:

### *1. Getting to Know the Product*

In the end, most product liability cases come down to an assessment—by a judge, jury, regulatory agency, the media, or the market—of whether the product is good or bad. Typically, the public, legislators, regulators, and juries are prepared to accept that many products have the potential to cause harm, but want the assurance that the company involved did everything appropriate to disclose relevant information in their possession with respect to product risks. And while there may be compelling scientific evidence that a product's benefits outweigh its harms, if it is perceived as dangerous and the company is perceived as having hidden the risks, all of the evidence of the product's benefits outweighing its risks can sound like after-the-fact justifications and evasions.

That's why a product liability representation should start with immersion into the facts about the product: What is it? Who uses it? Why? Why not use other products, other designs? How was the product tested? How has it changed over time? What do its detractors say are its strengths and weaknesses? What do its biggest champions say? Why do longtime customers stay with it? Where have former customers gone? What are they using now? How is the product distributed from manufacturer to end user? Are there middlemen? Do they alter the product in any way? How is the product promoted? Is there training in product use?

The fact immersion process also must include an exploration of the ways in which products fail. Clients tend to focus on the benefits of the product, and those benefits will likely be the heart of a defense of the product in whatever forum. But if the product has a history of failure, the attorney needs to learn that history. If there are internal documents showing the risks of the product, the attorney needs to be exposed to them and master them as soon as possible. If the product has already been the subject of litigation or regulatory action, the attorney needs to learn the history in detail. Often, the defense will involve showing that the individual plaintiff's injury is different from, and thus may have different causes than, earlier injuries to others.

Although the client will usually present the details of the product to the attorney in the first instance, it is important for the attorney to recognize any client reporting bias. Often, interviews with lower- and mid-level employees of the client will change the attorney's initial understanding. It is typically necessary for the attorney to promptly retain outside experts to provide an unvarnished assessment of the product and its risks.

## *2. Identifying the Type of Claim*

One of the first steps in undertaking a product liability representation is to evaluate the types of claims that have been or may be brought against the client concerning the product in question. Product liability is not a unitary area of law. A manufacturing defect case (in which an individual product causes injury) raises different concerns than a design defect case (in which the whole product line is alleged to be faulty), and both are different than a

failure-to-warn case. In a manufacturing defect case, the focus may well be on the quality controls rather than on the risks and benefits inherent in the product. In a design defect case, the focus is likely to be on inherent risks and benefits and whether there is a safer way to design the product so as to afford the benefits while mitigating the risks. And in a failure-to-warn case, the focus may be on what the company knew about the risks, when it knew it, and when it told the public (and which people in the public it told), rather than on the magnitude of the risks themselves.

But these issues are often not so easily categorized: Sometimes the design of the product is so advanced that it cannot be manufactured without a risk that one unit in every batch, be it 100 or 100,000, will be faulty. And the failure-to-warn analysis is different if the risk allegedly concealed is a risk of sudden death as opposed to some milder risk. Although the client may approach the attorney with a concern about a specific product's failure, akin to a manufacturing defect, investigation may reveal design defect or warnings issues as well.

### *3. Surveying the Legal Landscape*

Product liability controversies can play out in court before regulatory agencies and, in some cases, the legislatures. They may also play out in the media. Adding to the variety, individual lawsuits often exist alongside putative multi-state and single-state class actions. Each type of proceeding implicates different rules of law, different timetables, different disclosure obligations, different types and levels of publicity, and different damages. The product liability attorney needs to be sensitive to the differing arenas in which a case can develop and to the cross-effects of litigating in more than one arena at the same time. These are some of the factors to consider:

Timetable: The timetables for individual actions, class actions, and regulatory proceedings vary widely, which can cause the proceedings to affect one another. Documents produced or testimony adduced in one forum may be usable in another. Thus, the product liability attorney needs to be sensitive to which facts will be developed in which forum at what time, through what means.

Among the questions to be asked are: Where are the lawsuits pending? Which will move the fastest? Where are witnesses likely to testify first, in court—and which court—or at a regulatory hearing? What protections exist in the various forums to shield against disclosure of irrelevant, prejudicial information? How can the client cooperate fully with its obligations without compromising the zealous defense of its positions? How can the client shield trade secrets and other sensitive information from public disclosure?

Choice of Law: The standard of liability varies from state to state, and conduct that may not give rise to a claim in one part of the country may be tortious in others. The attorney thus needs to consider what kinds of claims have been or could be brought, and he or she must be aware of the significant differences in the law across the country.

Choice of Forum: The client and attorney also need to consider what options exist for changing the legal landscape. Although a plaintiff's choice of forum is often dispositive, removal procedures, venue transfer rules, *forum non conveniens* doctrine, and the new Class Action Fairness Act can allow the defendant, in some instances, to affect where the cases against it will be heard.

Regulatory Proceedings: Although criminal prosecutions for the manufacture of defective products are rare, they are not unheard of. And many products—pharmaceuticals and medical devices, among others—are subject to the regulation of administrative agencies. Even if those agencies do not themselves intervene in or commence an action, the company's compliance with regulatory requirements may be the basis of arguments by the plaintiff or by the company, depending on the regulation and the level of compliance. The attorney needs to be familiar with all of the governing regulations.

Foreign Proceedings: While product liability litigation in some foreign jurisdictions is still a developing field, product liability litigation—including, in some cases, contingent fee structures—is alive and well in the United Kingdom and other common law countries. Foreign plaintiffs may also avail themselves of the American legal system, although choice-of-law analyses may affect the issues to be tried. Given the breadth of international

sales in the current marketplace, a product liability attorney must be attuned to foreign law implications as well.

Damages: Finally, the attorney needs to consider the type of damages to which the client is potentially exposed. Are the plaintiffs entitled to lost wages? To pain and suffering? To the cost of medical treatment? To medical monitoring costs? Are punitive damages possible? All of these questions may depend on a choice-of-law analysis as well as on the facts of each plaintiff's case and the company's own conduct. The product liability attorney also needs to be attuned to the possibility of regulatory penalties, which—like punitive damages—can impact a company beyond the (significant) pecuniary harm. Regulatory penalties can affect both reputation and the ability to sell this or other products.

#### *4. Developing a Strategy*

Ideally, the product liability strategy is developed before lawsuits have been filed or regulatory proceedings commenced. As soon as a creator or seller of a product determines that there are unforeseen problems with the product, there is room for assistance from counsel to identify and manage the possible consequences. Calling an attorney in these circumstances should not be seen as an admission of guilt, but can be a means of ensuring that the right outcome is reached efficiently and quickly. Whether lawsuits have been filed or not, the first steps are those outlined above: Learn the products, identify the likely claims, and identify the likely forums for litigation or regulatory proceedings—the last necessarily at some level of abstraction.

With those fundamentals mastered, the client and the attorney need to develop a strategy, viewing the representation as a whole. The strategy should address:

- Redesigning or improving the product, the manufacturing process, or the warnings, if necessary, in a manner that is sensitive to the concerns of the users of the product and that does not compromise its efficacy



- Presenting truthfully and fairly the best face for the client to the courts and, if appropriate, to the media
- Resolving any regulatory inquiries in a manner that permits continued sale of the product, if possible
- Deciding in which forum to litigate, to the extent the defendant may affect that analysis
- Securing documents for production in discovery
- Retaining experts and marshaling evidence in support of the company's defense
- Deciding how best to present the facts of the case in a manner that is easily understood by lay individuals without unnecessary technical complexity
- Resolving pending lawsuits in a manner that disincentivizes the filing of new lawsuits, either by settling at low value or winning at trial

The strategy should reflect that it is not uncommon for product liability cases to take years to reach resolution. During those years, the volume of media attention and public scrutiny will vary, but the company's conduct may never be far from the public eye. Some product liability cases present unsympathetic plaintiffs injured in unusual ways while using important products, such that the public's sympathy lies with the company. In other cases, in which the victims are particularly sympathetic, the attorney's task may simply be to present a reputable public position for the company to the audience involved in the litigation, whether judge, jury, press, government, or press, in order to mitigate any negative light cast on the company by the litigation process. In some circumstances, even if the company believes in the product and has acted entirely appropriately, the cost of litigating and continuing manufacture of a product may be too expensive to continue producing it. Ultimately, the attorney should be most interested in an end result that minimizes any harm to the client, its reputation, and its fortunes to the greatest degree possible.

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Mr. Fagen was selected as a leading commercial litigation attorney by The Best Lawyers in America, Chambers USA, Chambers Global, and The International Who's Who of Business Lawyers. He is a director of the lawyers committee for Civil Rights Under Law and a director of the Kohlberg Foundation Inc. He has served as a member of the board of trustees of Maimonides Medical Center and as trustee, president, and vice chairman of the Educational Alliance Inc., a multidisciplinary social service agency.

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