Time Segment-Based Pre-Litigation Preparedness to Minimize Risk, Maximize Results

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Developing A Crisis Checklist
Strategies to Decrease Risk

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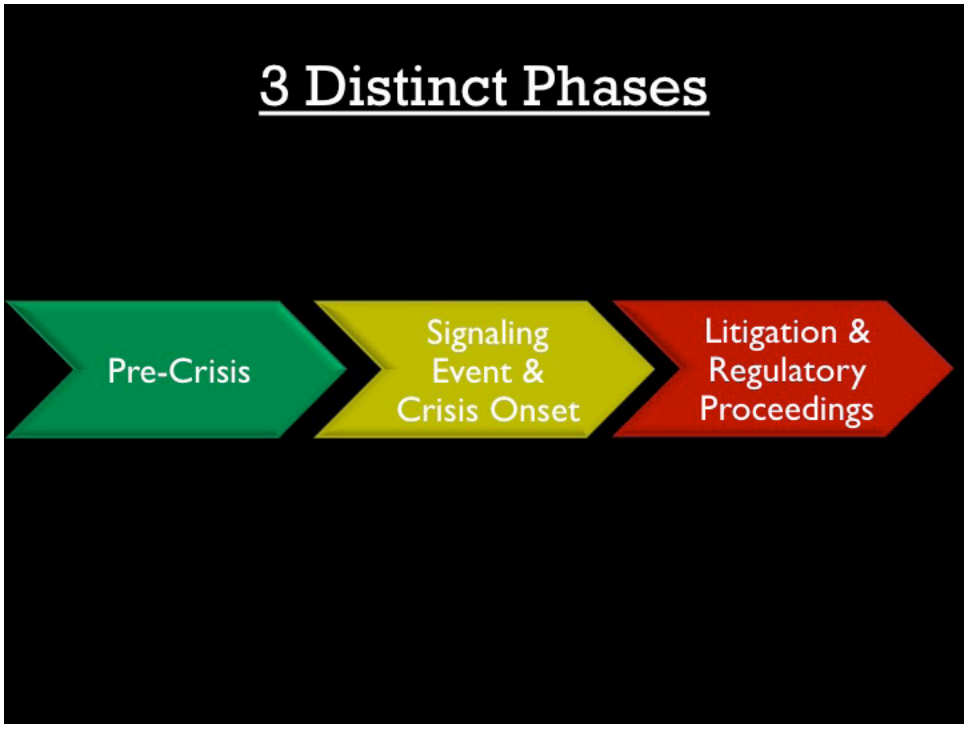
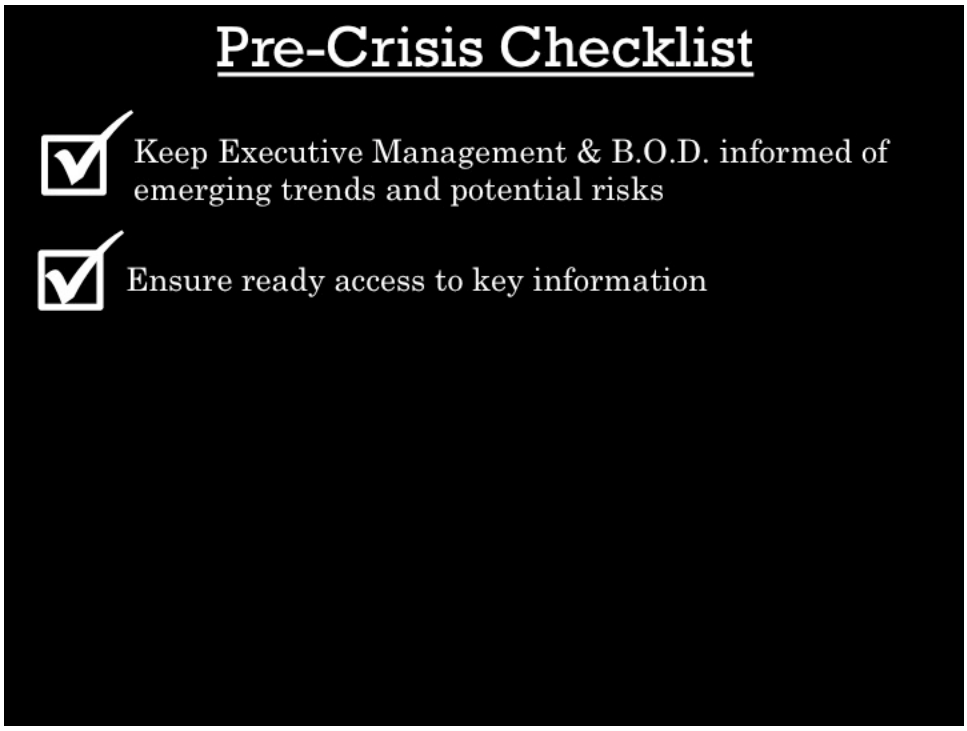

3 Distinct Phases
Pre-Crisis
Signaling Event & Crisis Onset
Litigation & Regulatory Proceedings


Pre-Crisis


Pre-Crisis Checklist
Establish Crisis Management Plan & Crisis Communication Plan
Establish Litigation Hold Policy & Process
Conduct Annual Legal Risk Assessments
Review "Lessons Learned" & Hold Practice Sessions
Conduct Annual Insurance Review
Coordinate and facilitate frequent communication between internal company functions

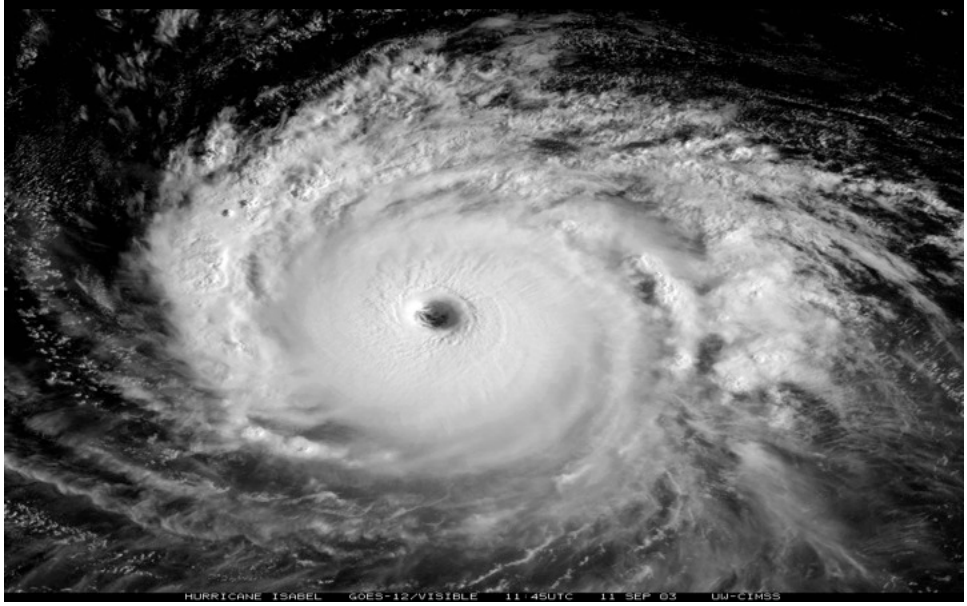

Pre-Crisis Checklist
Keep Executive Management & B.O.D. informed of emerging trends and potential risks
Ensure ready access to key information

"Signaling Event"

Watching For A "Signal"

- ☑ Journal articles & pre-publication presentations
- ☑ Regulatory action (anywhere in the world)
- ☑ Adverse event reporting (and pooling of AER data)
- ☑ Results from company-funded studies
- ☑ Media inquiries
- ☑ Subpoenas/Other government information requests
- ☑ Auditors report irregularities/suspicious activities
- ☑ Reports of suspicious/ illegal activities to company compliance or ethics hotline

CRISIS!



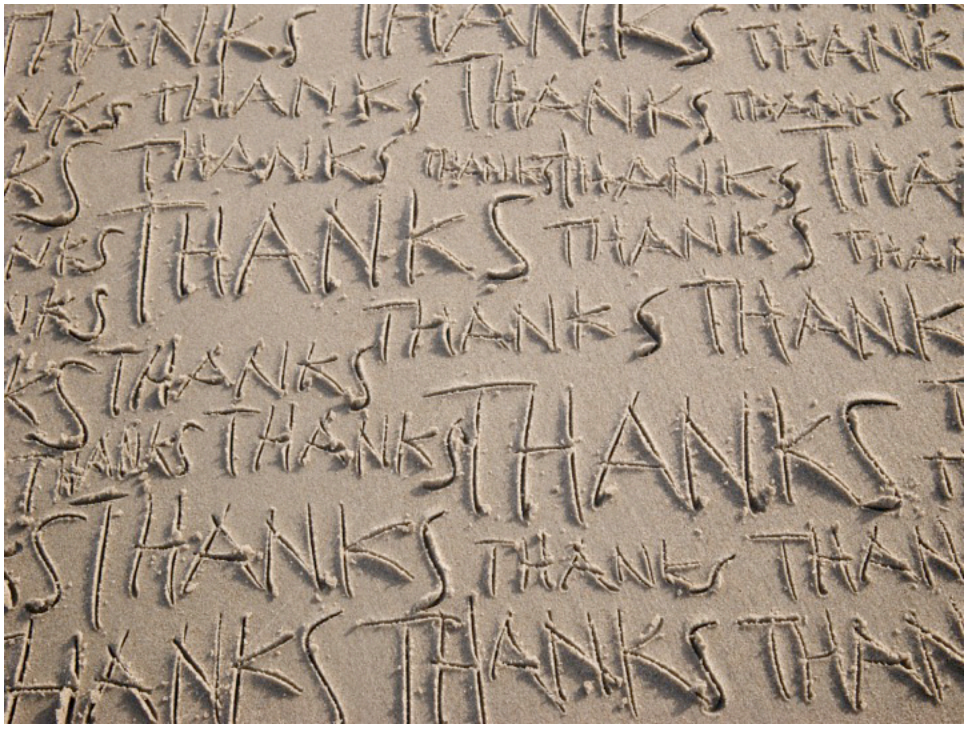
Crisis Checklist

- ☑ **PROTECT PRIVILEGE!**
- ☑ Notify key stakeholders and assemble external litigation team
- ☑ Develop unassailable science-based messaging
- ☑ Determine external and internal communication strategy
- ☑ Assess scope of relevant documents/data and issue litigation hold
- ☑ Monitor crisis communications to check for consistency with science-based messaging
- ☑ Assess need for and scope of any internal investigation
- ☑ Determine self-reporting and notification obligations

Litigation & Regulatory Proceedings

Benefits of Adherence to Crisis Checklist

- ☑ Unassailable scientific and medical themes
- ☑ Consistent and accurate company messaging in all forums based on these themes
- ☑ Response that mutes attempts to portray company as a "bad actor"
- ☑ Out front on expert retention and preparedness
- ☑ Outside team that is fully versed in all the relevant facts and data
- ☑ Relationship of trust & confidence between outside team and key company personnel



How litigation time capsules can help a company minimize legal risk
By: Troy Sympson

Understandably, the company mindset is always to be looking forward. So, when a company hits a milestone with a product it has had in the development pipeline for a lengthy period of time, the natural inclination is to pause (briefly) to celebrate the accomplishment, before turning attention to the next product. This pattern of constantly looking to the next and the newest challenge is essential to continued growth and innovation, but it is also the source of major problems when, after several years have passed since approval, a product becomes the focus of litigation that has the potential to sprawl into hundreds, even thousands, of cases.

This puts the company into "panic mode" as it is confronted with the need to make critical strategic decisions in a highly compressed period of time based on an overwhelming amount of fragmented and incomplete information — often with no reliable guide to explain the company mindset during the approval process and to shed light on why certain actions were taken while others were not. Litigation "time capsules" are a proactive step intended to help address this problem.

"Litigation time capsules are designed to capture relevant information and key documents, and to identify and clarify the mindset of decision-makers at the point when product milestones were achieved," says Kevin M. Zielke, a member and the practice group leader for the Pharmaceutical and Medical Device Litigation practice group at Dykema Gossett PLLC. "All of this information would be captured while memories are fresh and documents are close at hand, and then would be stored away such that, if the product faced litigation down the line, the company would have ready access to it. Armed with this information, the company is in a much better position to make the important strategic decisions necessary so that it has the best prospects for litigation success."

Smart Business spoke with Zielke about litigation time capsules and how they can help a company minimize litigation risk.

Why are litigation time capsules so useful and why don't more companies utilize them?

The problem is that when something good happens — a new product has made it through the development pipeline to approval, for example — no one wants to spoil the party by raising the possibility of future litigation. That, however, is precisely the time when undertaking this effort is imperative. The ounce of prevention that a company gains by taking the additional time and effort necessary to work with its attorneys to develop these time capsules has the potential to provide pounds of cure when, in the event of litigation, the company can avoid being caught flat-footed by the informational disadvantage that often exists at the outset of litigation.

While these time capsules can prove enormously helpful in the products liability context, where the company faces the prospect of many lawsuits being brought relating to a particular issue, they can also be used when significant corporate transactions or real estate deals are concluded. Essentially, they provide a snapshot of the then-existing facts, circumstances, key players and driving forces at the time the product was approved or the deal was done.

AN OUNCE OF PREVENTION

Litigation Preparedness Strategies to Minimize Risk and Maximize Results

I. The Litigation Mindset - Know Your Enemy

Victorious warriors win first and then go to war, while defeated warriors go to war first and then seek to win. (Sun Tzu)

While drug and medical device companies face a wide variety of litigation risks, including qui tam actions, shareholder claims, patent and other intellectual property disputes and cases brought by state attorney generals, an exhaustive review of each of these various types of litigation is beyond the scope of this chapter. Instead, this section will focus on mass tort claims brought by those claiming the product caused them to suffer an injury that the product labeling failed to adequately warn about, or which occurred as a result of the defective design of the product. This litigation variant is often the "tip of the spear," with other forms of litigation premised on similar themes and theories concerning the safety of the product following in its wake.

A foundational step in litigation preparedness that is too often given little or no consideration is an understanding of how plaintiffs' attorneys typically approach mass tort matters. This is how companies and their counsel can come to know their enemy in a way that will allow them to formulate policies and procedures that make the company an undesirable litigation opponent for plaintiffs' attorneys. To develop this understanding of plaintiffs' attorneys, the fundamental inquiry is aimed at identifying the principal focus plaintiffs' attorneys use repeatedly in mass tort litigation. An assessment of the main themes pursued by plaintiffs' attorneys in the overwhelming majority of mass tort matters establishes that they spend most of their time and energy attempting to present the company as a "bad actor," and pay limited attention to the medical and scientific issues surrounding the injury claims. That is, plaintiffs' attorneys treat mass tort matters primarily as company conduct cases, with as little science and medical information as possible. On the other hand, companies and their counsel tend to allocate their efforts in a diametrically opposed fashion by focusing on the scientific and medical issues, with as little discussion of company conduct as possible. In most cases, however, this approach by the defense may be seen as an effort to downplay or dodge the issue. This, of course, is not an effective strategy and, in fact, can provide further support for the effort to cast the company in a bad light.

An effective litigation preparedness strategy begins with the recognition that plaintiffs' attorneys primary objective is to convince the jury that the company is a bad actor that deserves to be punished. With this in mind, company policies and procedures can be fashioned that effectively deprive plaintiffs' attorneys of the evidentiary support they typically rely on to further that objective.

II. Turn, Turn, Turn - The Phases Of Litigation

For everything there is a season, a time for every activity under heaven (Ecclesiastes 3)

Companies tend to adopt a binary mindset toward mass tort litigation – with it either being "on" or "off." During the "off" periods, planning and preparation for the possibility of litigation are either relegated to the bottom of the list of priorities or left off it entirely. True litigation preparedness, however, is fostered by dividing the time into the following three distinct phases:

- Pre-Crisis;
- Signaling Event/Crisis Onset; and
- Litigation/Regulatory Proceedings.

From this perspective, the company and its counsel can consider and implement a set of best practices during the two pre-litigation phases that are designed to mute any attempts by plaintiffs' attorneys to portray the company as a bad actor in need of punishment.

III. The Pre-Crisis Phase – Turning Off The Incubator

'The time to repair the roof is when the sun is shining (John F. Kennedy)

Though questions raised during a crisis concerning a company's conduct typically feel like they rose up suddenly and came out of nowhere, the reality is that the most dangerous of these are not the result of an instantaneous collision of unforeseen forces, but, instead, are due to a culmination of problems that have been ignored and allowed to incubate over time. Preparedness in the pre-crisis period involves identifying existing policies and procedures or gaps in existing policies and procedures that could allow for this type of incubation to occur and aggressively rooting out those areas. Engaging in this effort sharply reduces the ability of plaintiffs' attorneys to offer concrete examples of poor company conduct to the jury. Instead, the company can present itself as a concerned and well-meaning corporate

citizen that, at most, had a rogue employee that failed to adhere to the company's policies and procedures and who was appropriately disciplined for his misconduct. In terms of litigation defense, this scenario is far preferable than having to answer for a corporate culture that, intentionally or unintentionally, impeded the flow of information bearing on the safety of end users of the product.

In furtherance of this objective, company policies and procedures should require that information having any bearing on safety of the product be shared across the various disciplines within the company. This approach militates against each segment (or sub-segment) of the company, developing a "silo mentality" resulting informational bottlenecks that can be portrayed by plaintiffs' attorneys as a knowing decision by the company to put profits over safety. In preparation for litigation, the company should also have clearly defined crisis management and crisis communication plans.

Given the attention plaintiffs' attorneys have dedicated to arguments concerning spoliation of evidence – and the large awards that have been handed down by juries based on their apparent perception that the company destroyed relevant documents or electronically stored information – a critical pre-crisis activity is to establish a sensible and defensible litigation hold policy and process. Due to the risks involved, this policy should err on the side of caution and should be subjected to regular review to determine whether changes in the law require any changes to the policy. To keep this from being a "paper policy" rather than a "practical policy," coordination between the legal and the IT department should be stressed and regular training should be required.

To keep the company's litigation mindset sharp, annual legal risk assessments should be conducted, with the assistance of outside counsel, in an effort to identify, prioritize and proactively address potential risk areas. In furtherance of the same objective, companies should conduct regular "lessons learned" sessions with outside counsel. While these should certainly be derived from the company's own litigation experience, they should also include lessons gleaned from assessing how other companies are handling or have handled litigation. What did they do well? What was done poorly? What other options are available in such a situation? It would be reasonable to expect outside counsel to conduct these sessions without cost to the company in the interest of furthering good client relations. These sessions should include both legal and non-legal personnel at the company who are either on the crisis management team or could, based on their title or responsibilities, could become involved in litigation matters, and should involve running scenarios or working through hypotheticals that would allow the attendees to develop the skills and judgment necessary to properly respond when an actual crisis does arise.

Finally, all of the effort that goes into developing the appropriate litigation mindset and to train company personnel to effectively respond at the onset of a crisis would be of limited utility if the company does not take steps to ensure ready access to key information about its products. This can be accomplished by putting together succinct "in case of emergency" dossiers for all products that receive regulatory approval. These dossiers, which should be put together and retained by outside counsel, would include a list of the key personnel, along with a summary description of their involvement, as well as copies of critical documents, a timeline of events leading to approval and a list of any post-approval commitments made to regulatory authorities.

IV. The Signaling Event & The Onset Of The Crisis Period

"Everybody has a plan until they get punched in the mouth" (Mike Tyson)

What separates the pre-crisis period from the crisis period is a "signaling event." In general terms, a "signaling event" is anything that could be construed as raising a serious questions that could affect the positive risk-benefit profile that was the basis for regulatory approval of the drug or the device. The most common types of signaling events for pharmaceutical products and medical devices are publications in medical or scientific journals – particularly those that are well regarded or have a high impact factor, such as the New England Journal of Medicine, Lancet or the Journal of the American Medical Association – or pre-publication presentations at conferences. In addition, regulatory action, including any regulatory requests for information, are a well-recognized signaling event.

An increase in the number of Adverse Event Reports (AERs) for a particular drug could also be construed as a "signaling event". As data becomes more transparent and available, an area that appears to be growing involves data assessments being performed and, often, self-published without the benefit of peer review by organizations or health care providers purportedly interested in patient safety, but who seem to repeatedly appear as experts for plaintiffs in mass tort matters. As the internet age continues to erode perceptions of a hierarchy of information quality and reliability, these types of analyses present greater risk as either a constituting a standalone signal to the company or information that can trigger regulatory action.

Once the "signaling event" has occurred, it is critical that the company act in accord with a well thought out "to do" list designed to help the company avoid the type of conduct that feeds into the efforts of plaintiffs' counsel to portray the company as a bad actor that deserves to be punished. An essential foundational step in this effort is the development, with the assistance of outside counsel and consulting experts, of unassailable and understandable science-based messaging that can reasonably be expected to endure as

defense themes throughout the life of the matter. These are not the granular points that revolve around discrete data points from individual studies, but, instead, represent "macro level" themes based on an examination of the totality of the evidence then available. The fact that successfully completing this task is difficult and complicated is not an excuse for delay! The messaging that results from this effort is essential to achieving the main objective during the crisis period, which is consistency across all disciplines as the company responds to the crisis. In the absence of this approach, it is highly likely that company personnel will attempt to formulate their own strategy for alleviating the crisis. This scattered approach can lead to areas of disconnect among employees and between the various disciplines within the company. In the hands of a skilled plaintiffs' attorney, these areas of disconnect become evidence of poor company conduct. For this reason, immediate and strict coordination is required to avoid the internal inconsistencies that can result from these scattered efforts.

V. Conclusion

As cases are filed and regulatory proceedings are scheduled, the battle lines begin to come into focus and the tumult of the crisis period takes on a greater sense of process and order. This is when the results of the effort expended in the pre-crisis period and during the crisis manifest. Those results include a set of unassailable scientific and medical themes coupled with consistent and accurate messaging from all segments of the company and in all forums based on these themes In addition, the company will be well positioned to meet any effort by plaintiffs' counsel to portray it as a "bad actor" deserving of punishment.

From a practical standpoint, the outside litigation team will be fully versed in all the relevant facts and data and will, through the process of developing the science-based messaging, have developed a relationship of trust and confidence with key company personnel. The litigation team will also be out front in terms of expert retention and preparedness.

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Kevin M. Zielke is the Leader of the Pharmaceutical Team and a former Practice Group Leader for Dykema's Pharmaceutical and Medical Device Litigation Practice Group. He is a litigator based in the Firm's Detroit office. In his work for pharmaceutical and medical device manufacturers, Mr. Zielke combines a thorough understanding of the medical and scientific issues with his exceptional legal judgment to develop proactive and creative steps to anticipate, avoid and minimize the potential impact of litigation. Should litigation ensue, these skills allow Mr. Zielke to provide clients with the best factual and scientific defense. This experience has put Mr. Zielke at that critical point where the science, the facts, the regulatory environment and the company conduct intersect and the interplay of these elements must be carefully considered in formulating the most effective strategy.

Experience

- Gadolinium Based Contrast Agents Litigation. Represent Bayer in litigation regarding its gadolinium-based contrast agent, Magnevist® (gadopentetate dimeglumine). Member of national science and expert teams.
- Trasylol Litigation. Represent Bayer in litigation regarding its cardiac surgery drug, Trasylol® (aprotinin injection). Member of national science and expert teams.
- Phenylpropanolamine (PPA) Litigation. Represented Bayer in litigation regarding the use of PPA in its over-the-counter cough/cold treatment, Alka Seltzer Plus®. Member of national science and expert teams.
- Imitrex Litigation. Represented GlaxoWellcome in litigation regarding Imitrex® (sumatriptan succinate), a drug indicated for the acute treatment of migraine attacks with or without aura and cluster headache episodes.

Areas of Practice

- Litigation
- Construction Law
- Pharmaceuticals & Medical Products

Industries

- Pharmaceutical and Medical Products Industry Group
- Automotive Industry Group
- Automotive, OEM & Supplier Litigation
- Pharmaceutical National/Regional Litigation Counsel Services
- Pharmaceutical Liability and Related Claims
- Pharmaceutical Commercial Litigation
- Pharmaceutical Consumer Protection, Fraud and Abuse

Education

- University of Michigan, J.D., cum laude
- Central Michigan University, B.S.