

Risk reduction

How litigation time capsules can help a company minimize legal risk **Interviewed 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 pipe-



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line 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.

Why are litigation time capsules so important for businesses to have now?

Today, the need for ready access to key information years after the milestone

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has been achieved is made all the more critical by two fairly recent developments. First, the ready availability of inexpensive and potentially limitless electronic storage means that those tasked with responding when litigation has been brought are confronted with a veritable ocean of potentially relevant materials that may be stored on hard drives, servers, backup discs, external drives, flash drives, cloud storage and the like. Second, the increasingly rootless nature of company personnel frequently means that those who were responsible for key decisions or who possess information necessary to effectively respond to the litigation are no longer with the company and not readily available to discuss these issues. As a result, capturing the most relevant materials and having immediate insight into the thinking at the time are essential.

What are the consequences of not appreciating these risks?

Now, perhaps more than ever, successful companies have to confront the fact that the litigation target is on their backs at all times, and have to build this sensibility into their culture by making it part of standard operating procedure. The failure to do so means the company will find itself forced to make key strategic decisions based on whatever information those charged with formulating the response were able to cobble together in the often highly compressed time frames found in the litigation context — after that the company will be largely locked into those early strategic decisions. That's why litigation time capsules work so well: you can wrap your head around lawsuits and respond to them as quickly and efficiently as possible. <<