IADC Committee Newsletter

DRUG, DEVICE AND BIOTECHNOLOGY

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IN THIS ISSUE

In this month's article, the authors explain how to map a regulatory work plan and build the work product your trial team needs, early and efficiently.

Developing a Regulatory Story That Counts

ABOUT THE AUTHORS



Mollie F. Benedict is a Partner in the Los Angeles office of Tucker Ellis LLP and Chair of the Medical & Pharmaceutical Liability Group. The focus of her practice is defending pharmaceutical and medical device companies in product cases, especially in coordinated proceedings and nationwide litigation. She may be reached at mollie.benedict@tuckerellis.com.

Andrea Przybysz focuses on pharmaceutical manufacturer liability—specifically regulatory and post-market surveillance issues. She has served on several national counsel teams for three top 20 drug and device manufacturers in litigation involving sulfonamide and glitazone drugs as well as metal on metal implants. She may be reached at andrea.przybysz@tuckerellis.com.

Corena Larimer's practice targets the legal and regulatory issues surrounding medical devices and pharmaceutical products, with a focus on complex briefing in both trial and appellate courts. She serves on national and regulatory counsel teams for drug and device manufacturers, including at trial and in national and statewide coordinated proceedings. She may be reached at corena.larimer@tuckerellis.com.

ABOUT THE COMMITTEE

The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. In the future, the Drug, Device and Biotechnology Committee will be focusing on increasing its use of technology to make it an even more valuable resource for its members.

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Brigid M. Carpenter
Vice Chair of Newsletters
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
bcarpenter@bakerdonelson.com

Your client has just asked you to defend it in new pharmaceutical products liability litigation. You and your colleagues begin sorting through the issues at play. The science. The epidemiology. Someone mentions the word "regulatory" and . . . everyone's eyes glaze over.

But ignoring the regulatory piece of the puzzle is simply not an option. In modern drug litigation, the FDA's statements about your client's product are critical —its benefits, its risks, and how both should be presented in the label. Those statements may drive the litigation.

Piecing together a drug's regulatory story can be daunting and, if not tightly managed, can become a black hole for your client's money and your time. If you find yourself in the driver's seat, keep the project under control with a few questions to help you begin working through a complicated and lengthy history efficiently.

What are the initial steps in working up the regulatory story in a cost-effective manner?

Understand the drug's label. Many issues at trial will come down to the label. The label represents what the company told the public about this drug at different points in time, so it is an important starting point for efficiently and effectively building your client's story. This story will be important not only to those at counsel table during trial, but to everyone building case themes and strategy, taking depositions, and working with experts. Failing to start here may result in case themes and strategy that are inconsistent with your label and its evolution. So gain a concrete understanding of the label's content at the outset—it'll serve you and your client well.

Talk with the company's regulatory employees. Consider conducting general interviews with regulatory employees at the beginning of the litigation, before you begin document review. Doing so can give you an early understanding of the big-picture story, the regulatory group's perspective of the drug, their interactions with the FDA, and who the key players are. For example, is the company organized with both regulatory and pharmacovigilance in one group?

Then, share what you learned in those early meetings with the regulatory and other document reviewers. Information learned with witnesses becomes a framework for the entire review team, and allows them to place documents into context early in the litigation.

Identify what you need to try your case. Ask yourself at the outset what you need to try this case, and design your work product with that end-point in mind. Identifying and beginning to assemble support for key themes at the outset will allow you to work through the regulatory documents more efficiently, rather than collecting large amounts of information that you need to sort through later.

Be careful to create a flexible work plan and product that will allow you to expand the regulatory story if and when the litigation morphs. While one adverse event or type of injury may have triggered the litigation, new issues often move to the forefront as plaintiffs' attorneys sift through millions of documents and pull out a handful of "bad documents" they want to emphasize at trial.

One way to keep your work plan flexible is to divide the regulatory story into themes or modules and have certain individuals take charge of related themes. Then, when new

issues arise, someone may have pre-existing institutional knowledge on a related topic. Themes could include:

- The scope of information the company submitted to the FDA during the approval process was broad and demonstrates how much the agency knew about the risks and benefits;
- The company continued to collect safety data after approval and shared that data and related concerns with the FDA;
- The company communicated the drug's risks to doctors and the public, primarily through the label;
- The labeling reflected the evidence available *at the relevant times*, and the company addressed those issues in appropriate sections of the label;
- The drug is safe and effective—the FDA approved it, continues to permit its use in various forms (i.e. fixed drug combinations and generics), and has approved similar drugs; and
- There is an important patient need for this drug, including treating the condition for which the plaintiff used it.

And be mindful of the need to educate the judge before trial on the FDA's role in regulating drug safety. FDA-related issues often arise during pre-trial motion practice, and the trial team will be in a much better position to present your client's story if the judge understands the FDA's role in drug approval and marketing.

How can I collect additional, targeted information to support the trial team's themes?

Develop a basic understanding of key labeling regulations. The FDA's regulations outline standards for including information in a label, both when inclusion is warranted and where information belongs.[1] The regulations also provide direction on the types of label changes that require the FDA's prior approval, as opposed to those a company can implement immediately upon receiving information triggering a change.[2]

Those regulations are important on multiple fronts. First, they provide context for communications between the FDA and the company—particularly in those scenarios that implicate but do not cite to a specific regulation. Familiarizing yourself with a few key regulations allows you to recognize those references and understand the meaning and consequences of the FDA's statements.

Second, those regulations could provide the basis for dispositive or evidentiary motions. Where, for example, federal regulations prevented the company from changing certain aspects of its label, your client has a strong argument that any claim requiring such a change is preempted by federal law.[3] Even where that argument does not dispose of all claims, it may narrow the issues for trial.

Pay close attention to all communications with the FDA. Communications between the company and the FDA, including letters, meeting minutes, and contact reports can demonstrate that the FDA reviewed, appreciated, and commented on data or events

[1] *See* 21 C.F.R. § 201.57 (requirements for various label sections under the Physician Labeling Rule); 21 C.F.R. § 201.80 (requirements for various label sections under the older label format).
[2] *Compare* 21 C.F.R. § 314.70(b) (changes requiring prior FDA approval) *with* 21 C.F.R. § 314.70(c) (changes a manufacturer may put into place without prior FDA approval).
[3] *See, e.g., PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (claims preempted where manufacturer could not change warning label without FDA permission).

the company submitted. That evidence presents an opportunity to demonstrate that: 1) the company did not withhold relevant safety information; 2) the FDA had the time, resources, and wherewithal to review the company's submissions; and 3) the FDA understood the information and independently determined what label changes, if any, were warranted.

In addition to its usefulness as a trial theme, the FDA's involvement with labeling can be relevant to a dispositive motion on preemption or related grounds. Look for interactions in which the FDA signaled that the company was required to use certain language in the label or that certain studies or safety data did not provide sufficient information to support a label change under the regulations. Also remember that the FDA's involvement with the label could have a "cumulative" effect. A particularly involved record may lend itself to arguments that FDA was so closely involved with a particular drug or scenario that a unilateral label change by the company would have been at odds with the FDA's authority and decision-making.

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These guideposts are a starting point, and every litigation is different. The fundamental point is that it is critical to map out a work plan and identify the work product your trial team needs at the outset. Doing so will allow you to be efficient and effective as you get to the heart of your client's regulatory story.

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