



## **Embracing Compliance**

## Monday, June 27, 2011

When we began practicing law, we worked for a partner who believed in scorched-earth research. Every time we'd go to his office with our findings, he'd begin by asking what we had looked at: "Did you look at X? Did you look at Y? Did you look at Z?" As soon as we admitted we hadn't looked at something (it was all too often X) he bellowed and chased us out of his office. One thing he always told us to look at were law review articles. But he insisted that we look only at the first half of an article, where the problem was laid out and cases were discussed. He said we needn't bother with the last part, where some smug law student arrived at a 'solution' that was invariably at odds with reality and common sense.

We're afraid that we recently acted the part of smug law student when we authored a half-useful piece called "<a href="Anger Management">Anger Management</a>." In it, we argued that jury anger, even when created by an obnoxious plaintiff lawyer, was harmful to a corporate defendant. A jury that is sympathetic to a plaintiff is tough, but you can still talk to them. If a jury is mad at you, they won't even listen.

Anyway, we went on to offer suggestions for diffusing the anger in the courtroom, including talking to the jurors about what standard the company was required to meet and how the company in fact met that standard. Here was our proposed solution: "The sad truth is that jurors tend to hold companies to a higher standard. Why not embrace that, and show that the defendant even exceeded that standard?"





Remember how in our original post we confessed to pilfering from a clever in-house lawyer the idea that jury anger, no matter the source, was bad for defendants? That same in-house lawyer (who is, by the way, brilliant and exceedingly well-dressed) recently told us that she thinks our suggestion is interesting, but potentially fraught with peril in practice. First of all, how often does one have the pleasure of representing a company that exceeded some standard it was required to meet? And even if a company exceeds one standard it is held to, it might be barely meeting other standards equally relevant to the issue at hand. Or maybe the company started exceeding standards only a year ago, and was simply meeting them for the previous five years that the product was on the market. There is a danger that even suggesting to a jury that a company did more than it was required to on some issues validates the notion that many of the jurors may have that the regulations currently in place are not enough, that manufacturers can and should do more, and that it's up to the jury to superimpose their judgment of what the right regulations should be onto this landscape via a stratospheric plaintiff verdict.

Is this scenario likely? We do vaguely recall wrongful termination cases where companies got hosed for failing to live up to their own higher standards. Or are self-imposed standards more like Good Samaritan cases? We'd like to think that if plaintiffs try to assert that the voluntary standard creates an automatic legal duty, like negligence *per se*, plaintiffs will lose, because these self-imposed standards have no force of law. Then again, maybe plaintiffs can phrase their claim in terms of a voluntarily assumed duty under Restatement §323/324A. In any event, the concern isn't so much about the legal issue of cognizable claim as it is about jury atmospherics. How comfortable are you trying to predict how that will play out?

And it gets worse -- which is to say that there's more annoying reality out there that we hadn't considered. In the brave new world of innovator and generic (or multiple generics) sitting as co-defendants at the same table, it's a dangerous practice to engage in the functional equivalent of what happens on many nights at the dinner table where Drug and Device Law Child Number 1 gets yelled at for not eating her dinner or playing with her food and Drug and Device Child Number 2 looks lovingly into his parents' eyes, smiles sweetly and says, "I'm being a good boy, aren't I?" Want to guess how well that goes over with his sister?





According to our in-house friend (did we mention how gosh-darned smart and eloquent she is?) the goal has got to be to show the jury that the defendant did everything it was supposed to do and that's okay. Compliance is enough. As we've written many times in the past (for example, <a href="here">here</a>, and <a href="here">here</a>, and <a href="here">here</a>), compliance with FDA regulations can be a complete defense. In some jurisdictions, compliance can at least help <a href="fend">fend</a> off punitive damages.

"Mere" compliance might not always be the easiest concept to sell to a jury. Too many jurors think corporations are omniscient and omnipotent. The concept might be even harder to sell to most corporate witnesses because, generally, those people think that their company is the best and they personally have made a career out of doing more and going beyond, so it's their natural inclination to embrace those concepts in front of the jury. But once you show a jury that more could be done or in fact has been done in some situations, you have given the jury permission to set a new standard of behavior. Compliance with that new standard is bound to be imperfect and your client might even be — dare we say it? — punished. That punishment is likely to be somewhat worse than what Drug and Device Child Number 1 gets for flinging lima beans under the table.

Let's go back to that partner-ogre we mentioned in the first paragraph. Another thing he used to say to (scream at) us was that "It's all in the drafting!" That is, there's probably a way to say what you want to say and make it work. So despite our in-house friend's concerns (and let's put our cards on the table right here and right now: she is always, always right), we still think there are ways we can take advantage of those times when a corporation goes the extra mile to assure patient safety. Maybe we can simply lay out the facts and let the jurors conclude that the company should get credit for doing more than was strictly called for by laws or regulations. Then the jurors, rather than seek to argue against our position, would arrive at the position themselves and come to own it.

Or have we yet again proposed a 'solution' that is pure bunk?. Don't be shy to tell us. You don't have to be a client or plaintiff lawyer or corner office codger to call us crazy.