Drug and Device Law

Thursday, January 21, 2010

Wajert-Bexis Published On FDA Shift Away From Internal Oversight

Proving they can do more than just blog, Dechert’s two longest-running bloggers, Bexis and Sean Wajert (who writes the Mass Tort Defense Blog), along with associate Vince Gallo, recently wrote a “Legal Backgrounder” for the Washington Legal Foundation analyzing the FDA’s decision to do away with the vetting of its Warning Letters by actual lawyers before such letters are issued.

The predictions: (1) more warning letters about less important things; (2) poorer quality and more mistakes as FDA employees apply their own subjective standards concerning what’s a violation and what isn’t; (3) increased liability risks as the folks on the other side of the “v.” pick up on letters suffering from defects (1) and (2); and (4) a greater likelihood of warning letters that improperly curtail the First Amendment rights of regulated entities.

If that kind of stuff interests you, take a look.

Posted by Beck, et al. at 7:30 AM
Labels: FDA

About

This blog contains JIM BECK’s personal views (and those of several other Dechert attorneys) of various topics that arise in the defense of pharmaceutical and medical device product liability litigation. Please read the DISCLAIMER about the nature of this blog, and understand that you are accepting its terms, before reading any of our posts.

About Me

Beck, et al.
MARK HERRMANN Blogger Emeritus.
JAMES M. BECK is a Counsel resident in the Philadelphia office of Dechert LLP. He is the author of, among other things, Drug and Medical Device Product Liability Handbook (2004) (with Anthony Vale). He can be reached at james.beck@dechert.com.

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