

*The Data Quality Act*

# A New Weapon to Defeat Junk Science

by Bruce R. Parker and Michele R. Kendus

Imagine yourself in a courtroom listening to the plaintiff's expert testify that a causal relationship exists between your client's product and the plaintiff's injury. The expert's opinion is largely based on an FDA risk assessment. The jury listens carefully to the expert describe the FDA's "thorough" analysis of the risks associated with your product. Among the risks identified by the FDA is a "probable" causal nexus between your client's product and the plaintiff's injury. Not surprisingly, the expert glosses over the fact that the FDA's "findings" are based on case reports and liberal use of default assumptions. While the testimony hurts your defense, it is not as bad as you had anticipated. Despite having lost a pre-trial *Daubert* challenge, you remain optimistic that your cross-examination will demonstrate the methodological weaknesses in the FDA's risk assessment. You are confident that your expert will offer a convincing explanation why the risk assessment cannot serve as a basis for a

scientific conclusion on general causation.

First slowly, then with increasing velocity, your optimism drains as you hear the expert explain to the jury that federal law required the FDA's "study" to meet high standards of scientific quality. The jury is told that if your client felt that the risk assessment had not met Congressional-mandated levels of quality, procedures exist that would have allowed your client to force the FDA to correct the report. Where optimism once existed, you're now left feeling slightly dizzy as you hear the expert explain that your client made no effort to challenge the risk assessment. You mutter a feeble objection that the court quickly overrules. The expert continues to explain that the absence of a challenge entitled the FDA to conclude that its information met federal standards of high quality. As you stand to begin your cross-examination you first wonder why you ever wanted to be a trial lawyer, then why no one advised your client (or why it failed to listen) of the ability to challenge the report under the Data Quality Act.

## A Means to Weaken the Plaintiffs' Arsenal

The Data Quality Act provides the means by which the defendant in the above scenario

might have successfully challenged the FDA's risk assessment long before the trial began. The DQA was enacted in December 2000 as part of the Treasury and General Government Appropriations Act for Fiscal Year 2001. Pub.L. 106-554, §515 (2000). Occupying a scant 38 lines in the Congressional Record, the DQA's potential impact far exceeds its diminutive size.

The DQA requires the Office of Management and Budget to issue government-wide policy and procedural guidelines for federal agencies to implement the DQA. In turn, the OMB Guidelines require each agency to issue guidelines to ensure compliance. The individual agency guidelines became effective October 1, 2002. See "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," 66 Fed.Reg. 49718 (Sept. 28, 2001), *revised by* 67 Fed.Reg. 8452, 8458-60 (Feb. 22, 2002).

In the Fall 2002 issue of the DRI Drug and Medical Device Committee newsletter, available on DRI's Web site, the present authors provided a detailed analysis of the DQA and the OMB's Guidelines in "The Data Quality Act: Will it *Daubertize* Federal Agencies?" In the article, we raised several questions that emanate from ambiguities in the OMB Guidelines. We begin this article with a brief overview of the OMB Guidelines, but encourage the reader to refer to the earlier article for a more detailed discussion. The current article focuses on the FDA Guidelines and the procedural mechanisms for challenging information released by the FDA. Throughout our analysis, we comment on how defense counsel and their clients can use the DQA and FDA Guidelines to weaken plaintiffs' expert evidence and to strengthen a *Daubert* challenge at trial.

## Overview of the OMB Guidelines on Information Dissemination

The OMB Guidelines require federal agencies to: 1) "ensure and maximize the quality, objectivity, utility, and integrity of information" that agencies disseminate; 2) provide administrative mechanisms to allow "affected persons" to seek and obtain correction of information that does not comply with the OMB Guidelines; and 3) report annually to the OMB Director regarding the number and nature of complaints received, and how they were handled. Pub.L. 106-554, §515; 67 Fed.Reg. at 8459.

Each agency must adopt a basic standard of quality that it integrates in every step of in-



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