Is Overreporting Adverse Event Information Always In A Company's Best Interest?

Alan G. Minsk

Recently, we moderated a panel at the Food and Drug Law Institute's Annual Conference, where a senior Food and Drug Administration official participated. The individual from the Center for Drug Evaluation and Research made an interesting comment that many pharmaceutical companies, in his opinion, oversubmit adverse event information they receive during clinical trials. While he recognized the legal obligation to report, when required, he noted that overreporting may be unnecessary and, in fact, counterproductive, as these reports inundate FDA officials, who have to collect and review the data.

In a time when companies believe FDA expects more reporting, rather than less, the official's comments raised an interesting point. It is important to note that he was speaking for himself, and not stating an agency position.

We will not describe here the Food and Drug Administration's adverse event reporting requirements for clinical trials, which are detailed in 21 C.F.R. Part 312 and in agency written guidance. However, we see all the time how companies try to balance their regulatory obligations to report with concerns about either negatively affecting the clinical trial and the product's likelihood of success in obtaining FDA approval (e.g., FDA may raise concerns, initiate a clinical hold, or impose label restrictions) or exposing themselves to liability lawsuits, or both. While well-drafted informed consent forms help minimize such risks, and investigational products are, by definition, not approved for general use, companies continue to struggle with when and how to report.

Let's be clear. If a particular situation dictates that adverse event reporting is required, whether during clinical trials or post-approval, report. However, overreporting may not necessarily garner brownie points with FDA and, in fact, might have the opposite effect. In addition, reporting an adverse event, when not required, may increase liability exposure. Therefore, companies must carefully review FDA's regulations, the preambles to these regulations (found in the Federal Register) to understand FDA's thinking, and agency written guidance to ensure they comply with FDA rules but don't unnecessarily overdo it, thinking more is better.

Companies' standard operating procedures, and training on these SOPs, should describe FDA's requirements, using FDA's definitions (not summaries or generalizations), and be well understood by those at the company who will be part of the decision-making process. The SOPs should include how to investigate, resolve, and close out a complaint or report. And, documentation is equally important. Proper documentation, particularly if a decision is made not to report, can help preempt regulatory investigation or challenge. While people can agree to disagree on any decision made, a well-reasoned, researched, and documented rationale, based on a review of the law and FDA guidance, may help minimize regulatory and liability exposure.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

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