Adverse Drug Reaction Reporting

After reading your comments in the June 10th issue of *Apharmacy Weekly*[1], regarding the adverse drug reaction reporting system, I felt that it was necessary to write you regarding this matter. Our company has been greatly concerned with this problem for many years. We have been constantly trying to find an effective system for reporting adverse drug reactions to the pharmacy department and participating in a national data collection program.

It has been our experience that the principal obstacle to the adverse drug reaction program is the physician. In the hospital setting, no physician wants to have an entry on a patient's chart stating that the patient experienced an adverse drug reaction. This is due to the fear of civil liability. In our efforts to have this information placed on the chart by a nurse, both pharmacy and nursing have been criticized for "diagnosing" or "practicing medicine."

I believe our experience is directly related to the surprising fact that Johnson and Johnson knew of nearly twice as many instances of adverse drug reactions from the prescription medication, Zomax, as the FDA had known. I would not be surprised to discover that this information, which the company had acquired, was verbal feedback from the physicians to the sales representatives, rather than a written report directly from the physicians. It appears that the fear of legal liability is having a very strong impact on the practice of medicine and our ADR reporting system problem is just one symptom of this.

Until this problem is resolved, it is my belief that it will be a continuing problem and present great difficulties in developing an effective reporting system. This situation will continue in spite of the efforts of JCAH surveyors, who constantly stress the necessity of accurate charting the patient's history and the response to therapy, and our own efforts in trying to have this information placed in the chart within the nursing notes, as a nursing diagnosis of a "suspected" adverse drug reaction. In addition to this, we are informing the medical staff through the pharmacy and therapeutics committee of their potential liability for failure to report adverse drug reactions in the patient's medical history and chart. This legal liability would result if the patient suffers a repeat adverse drug reaction with possible injury and mortality during subsequent hospitalization.

In summary, we continue to search for and would greatly enjoy your support in finding a system for reporting adverse drug reactions which could achieve the necessary physician support to ensure it's success.

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[1] *Apharmacy Weekly*, **22**, 91 (1983). See also E. G. Feldmann, *J. Pharm. Sci.*, **72**, 585 (1983).

Postscript:

Since I am in agreement with your concern with the problem of adverse drug reaction reporting, I am agreeable to using my letter in the "Open Forum Page" of the *Journal*. I hope it will stimulate more thought and discussion toward an effective method for reporting in our clinical settings. Hopefully, each pharmacy practitioner will begin to view themselves as members of the research and development process and communicate this attitude to physicians in such a manner that it becomes contagious within their ranks also.