Journal of Pharmaceutical Sciences

MAY 1975

VOLUME 64 NUMBER 5

The *Journal of Pharmaceutical Sciences* is published monthly by the American Pharmaceutical Association at 2215 Constitution Ave., N.W., Washington, DC 20037. Second-class postage paid at Washington, D.C., and at additional mailing office.

All expressions of opinion and statements of supposed fact appearing in articles or editorials carried in this journal are published on the authority of the writer over whose name they appear and are not to be regarded as necessarily expressing the policies or views of the American Pharmaceutical Association.

Offices—Editorial, Advertising, and Subscription Offices: 2215 Constitution Ave., N.W., Washington, DC 20037. Printing Offices: 20th & Northampton Streets, Easton, PA 18042

Annual Subscriptions—United States and foreign, industrial and government institutions $50, educational institutions $50, individuals *for personal use only* $30; single copies $5. All foreign subscriptions add $5 for postage. Subscription rates are subject to change without notice. Members of the American Pharmaceutical Association may elect to receive the *Journal of Pharmaceutical Sciences* as a part of their annual $55 (foreign $60) APhA membership dues.

Claims—Missing numbers will not be supplied if dues or subscriptions are in arrears for more than 60 days or if claims are received more than 60 days after the date of the issue, or if loss was due to failure to give notice of change of address. The Association cannot accept responsibility for foreign delivery when its records indicate shipment has been made.

Change of Address—Members and subscribers should notify at once both the Post Office and the American Pharmaceutical Association, 2215 Constitution Ave., N.W., Washington, DC 20037, of any change of address.

"THE BUCK STOPS HERE!"

The so-called crisis in medical malpractice insurance has been very much in the news, both in the lay press and in the medical press. All of this, of course, has grown out of a rather recent inclination on the part of the public to hold individual medical practitioners personally responsible for performance at a certain accepted level or standard.

Many feel that the pendulum has swung much too far, with the result that damages awarded are excessive, liability findings in some cases are unjustified, and many physicians have resorted to practicing "defensive medicine" in an effort to protect themselves. Be this as it may, the fact remains that medical malpractice lawsuits have become a major concern in the medical field.

Except perhaps for attorneys who specialize in food and drug law, relatively few people in the area of pharmaceutical production and distribution are even aware that a somewhat comparable situation potentially exists with respect to liability relative to the manufacture and distribution of pharmaceutical products.

To date, most action on the part of regulatory agencies is directed either at a specific product or a corporation. That is to say, a particular product is alleged to be adulterated or misbranded and is condemned or seized; or in other cases, a specific corporation is found to be in violation of good manufacturing practices and may be forced to close down.

For some time, however, questions have been asked as to whether this line of enforcement is either adequate or effective. Comments have been made to the effect that a certain major corporation when found guilty pays its $1000 fine and the next day resumes its multimillion dollar business with no real effort to correct the situation about which court action was initiated. In other instances, it has been felt that those responsible for supplying the public with pure food and with safe and effective drugs have not exercised sufficient concern, with the result that substantial injury—and at times, even death—have directly resulted. This experience has prompted thoughtful observers to suggest that enforcement-related action in more cases should be against *persons* within the corporation, and that such court action might even take the form of prosecution on the basis of criminal liability.

A case is now before the United States Supreme Court, *United States v. Park*, in which the president of a major food company has been held to be criminally responsible for not seeing that necessary steps were taken to prevent rodents from contaminating food stored in one of his corporation's warehouses. The outcome of this test case will undoubtedly have a significant impact on the degree of personal liability individuals may be held to have in the case of pharmaceutical manufacturing and distribution.

Indeed, it is reported that proposed revisions in good manufacturing practice (GMP) regulations for large-volume parenterals will place direct and specific responsibility on the designated quality assurance officer for certifying as to the qualifications of the manufacturing plant, all processes and procedures in the production of the article, and the suitability of the container and its enclosure before the product is released. Undoubtedly, many questions can be raised as to who *specifically* should bear the responsibility if criminal liability action is brought as the result of some defective product.

Although he did not originate it, Harry Truman made famous the comment "the buck stops here!" But again, where is "here"? Is it the person or persons who work out the formulation, or is it those who prepare the formulation, or is it those who are responsible for assuring the quality of the formulation, or is it those in some high strata of company management? These are questions which eventually the courts will decide.

In the meantime, it appears to us that the only prudent course of action for everyone involved in drug production is to perform in a manner as if such liability does rest directly on one's personal shoulders.

But, even putting the issue of personal liability aside, isn't such an attitude what we ought to expect from those who have assumed responsibility for producing and supplying our drug products? At times, it seems that a good deal of lip service is given to the term "a reputable manufacturer." Saying "we are sorry" after having a recall for a defective drug product really is not sufficient. A reputable drug manufacturer, in the true sense, is one which, to the extent possible, takes the necessary actions to anticipate and prevent the defect from occurring. It seems to us that companies as well as individual employees and corporation executives who perform with this philosophy will have little cause for concern in the event that criminal liability does indeed become a strategy of drug quality enforcement.