Journal of Pharmaceutical Sciences

DECEMBER 1976

VOLUME 65 NUMBER 12

MARY H. FERGUSON
Editor

L. LUAN CORRIGAN
Assistant Editor

SHELLY ELLIOTT
Production Editor

JANET D. SHOFF
Copy Editor

EDWARD G. FELDMANN
Contributing Editor

SAMUEL W. GOLDSTEIN
Contributing Editor

LELAND J. ARNEY
Director of Publications

EDITORIAL ADVISORY BOARD

JOHN AUTIAN	HARRY B. KOSTENBAUDER
LYNN R. BRADY	CARL J. LINTNER, JR.
WILLIAM O. FOYE	DAVID E. MANN, JR.
WILLIAM J. JUSKO	GERALD J. PAPARIELLO

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 $60 (foreign $65) 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.

© Copyright 1976, American Pharmaceutical Association, 2215 Constitution Ave., N.W., Washington, DC 20037; all rights reserved.

SCIENTIFIC RESEARCH FREEDOM

In November 1969, the APhA House of Delegates held a special meeting during which George E. Schreiner, M.D., Professor of Medicine at Georgetown University School of Medicine, delivered the luncheon address on the subject of "Scientific Freedom."

In his opening remarks, Dr. Schreiner observed that *"Research scientists have been recognized by society as being creative persons, very analogous to the artist and poet, and they, therefore, have been accorded considerable latitude in expressions of freedom in an open society which recognizes innovation and imagination."* He then went on to list seven specific scientific freedoms, ranging from choosing the research area, through conducting the project and communicating the results, to drawing conclusions from the data developed.

Having made these points, the speaker devoted the balance of his presentation to emphasizing that *"such extreme degrees of freedom carry with them quite definite responsibilities"*—namely, that the researcher must develop a personal code of professional conduct. He spoke of general codes, such as those of Nuremberg and Helsinki, as well as the traditional obligation of the scientist to strive for accuracy, integrity, and honesty in the work conducted and reported.

He then went on to point out that the scientific and moral criteria used by society as a benchmark for arriving at an attitude of general "approval" were becoming more and more specific—largely as a cause and effect result of omissions or errors in judgment by scientific investigators. For example, he attributed the series of New York State trials involving the injection of cancer cells into elderly patients at the Jewish Chronic Disease Hospital as the prime stimulus leading to adoption of the requirement for written informed consent.

In the ensuing seven years, we have heard of a number of other disturbing incidents—such as the careless use of prisoners in a poorly planned and inadequately supervised syphilis study. In turn, this revelation has led to severe restrictions being applied to the use of prisoners for any kind of medically related research, irrespective of how well controlled, conducted, and supervised.

Currently, the National Institutes of Health is attempting to anticipate the potential risk and hazard which might ensue from any slip or careless step in the conduct of recombinant DNA research. These are the so-called "creation of life" experiments which involve combining gene-containing fragments of DNA (deoxyribonucleic acid), the molecule that transmits heredity, with chromosomes of another sort of organism to produce an entirely new or different type of organism.

The NIH has set forth proposed guidelines and published these for public comment. In part, the preamble cryptically states: *"The promise of recombinant DNA research for better understanding and improved treatment of human disease is great. There is also a possible risk that microorganisms with foreign genes might cause disease or alter the environment should they escape from the laboratory and infect human beings, animals, or plants."*

World history is replete with examples of such "escapes from the laboratory" and elsewhere of microorganisms, insects, rodents, and other animal pests which previously were unknown to a certain part of the world and which then rapidly proliferated to produce a wave of destruction. Current laws restricting the import of agricultural products are one means now used to control such problems.

During the past fifteen years, space science turned into reality the Buck Rogers-type fantasies of the 1930's. Recombinant DNA research has the potential of turning the present day horror films depicting seven-foot long rats and man-eating spiders into tomorrow's realities. Consequently, we believe that NIH is acting prudently, wisely, and timely in its effort to establish guidelines designed to ensure proper safeguard and controls in conducting this research.

Moreover, the seriousness of this subject would lead us to expect that all other responsible parties would share this view. And it appears that most do.

For a while it appeared that there would be one sour note. It seems that one special interest group was reluctant to support or embrace these guidelines out of fear that the guidelines for voluntary compliance would eventually become obligatory and thereby be enforced. Frankly, we were stunned by this attitude.

Since there is ample precedent to believe that a real danger does exist if this kind of research is not properly monitored, it strikes us that—rather than be concerned that the guidelines *might* become mandatory—we should ask why they were not proposed in a fashion that would definitely provide for them to become mandatory after appropriate review, comment, and possible revision.

Dr. Schreiner put this proposition very well in his scientific freedom speech of seven years ago when he quoted Teddy Roosevelt: *"Your right to swing ends where my chin begins!"*

Edward G. Feldmann