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Clinical Investigator, Patient, Pharmaceutical Industry, and Federal Agencies

There has always been need for a responsible relation among clinical investigators, patients, federal government, and the pharmaceutical industry.

Two questions of special concern are, (i) how the environment can be improved to provide better clinical evaluation of drugs, and (ii) how the patient and investigator can be protected against the many hazards inherent in such experiments. These questions were the concern of a conference held in Bethesda, Maryland, on 27 August 1966 and reported in the June 1967 issue of the *American Journal of Cardiology*. Some highlights follow.

Where feasible, the research project should be approved by an appropriate panel of peers before it begins, but such approval does not lessen or limit the responsibility of the investigator, or the rights of the participants. Consent is not implied and, therefore, must be explicit and specific if (i) the physican employs original, untested, or experimental substances, procedures or dosages; (ii) new substances or procedures are being investigated; or (iii) there is no obvious or justifiable benefit to the patient.

The investigator must keep adequate records, with safeguards such as coding of names, to protect the privacy of the patient. Timely submission of adequate reports to sponsors is mandatory. Records should be retained for the period required by law and should be available for review by legally authorized agents.

For mutual protection, the pharmaceutical manufacturers should provide either the cost of liability insurance or indemnification of the investigator for any damages incurred from alleged claims of injury due to the investigation.

For its part, industry must continue to move beyond the present standards of demonstrated "safety" and "efficiency" toward a basic understanding of drug interactions in human beings. Animal testing procedures should be improved so that they become more predictive of safety and effectiveness in man, to cut down on extensive, costly studies of dubious value.

The Food and Drug Administration is urged to continue to allow close association by industry and FDA technical people on specific drug problems, because only in this manner will new therapeutic agents be rapidly and efficiently evaluated. The FDA should keep the public informed through the usual news media, but should explore the possibility that some statements of policy or actions be released initially only to the medical and scientific press. This would avoid public condemnation of drugs, too often based on ignorance fostered by sensational news reporting. The FDA should try to keep the public aware that progress in medicine requires that some inherent risks be taken.

Responsible individuals should work actively toward broad understanding of the importance of preserving the present overall patent system in the drug field. It has been a major stimulus to the drug-research effort. There needs to be liberalization of the government patent policy on developments occurring in projects financed, in part, by government grants, and active encouragement of scientific collaboration among pharmaceutical company, government, and academic scientists toward a speedup of drug development. A great industry must not be allowed to languish because of past mistakes and their correction by punitive actions.—IRVINE H. PAGE, *Cleveland Clinic*

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