I think what we need is a consortium of universities, certain practicing physicians who are knowledgeable and have carried out adequate controlled clinical trials along with the FDA and possibly NAS–NRC in order to obtain the best kind of drug knowledge available in the country. I do not believe a single Federal organization has within it all the necessary knowledge or expertise to make the kind of judgments that I think we would want to have made for drug prescribing. So we will have to develop this expertise through a continuing interaction such as with the NAS–NRC with its academic physicians and the FDA in carrying out the second role which you described.

This Department and the Congress are providing financial support to FDA for necessary educational and inspection operations. Within this level of support significant improvements in quality control are being instituted and maintained in drug manufacturing and packaging establishments. The following are among the initiatives being taken by FDA:

(1) An Intensified Drug Inspection Program (IDIP) has been quite effective in bringing the need for quality control to the attention of drug industry management. This program involved the assignment of inspectors to selected drug manufacturing establishments on an extended basis to detect and assist in the correction of manufacturing defects. This inspectional surveillance covered all manufacturing steps; that is, the examination of raw materials, formulation mixing, production of dosage forms, and quality control procedures.

(2) Revised good manufacturing practice regulations for the drug industry were published in the Federal Register on January 15, 1971. I have a copy here for the committee's information.[1]

(3) The development and dissemination to the drug industry of drug recall case histories has been begun. These cases analyze the causes of drug manufacturing defects and describe the remedial actions taken. They serve as a useful industry information and educational device.

(4) Drug manufacturing and quality control workshops have been held in various sections of the Nation in which over 1,900 drug industry employees participated. Approximately 7,000 key drug industry personnel have also attended showings of the FDA film, "Good Manufacturing Practices."

Recommendation 17 asked for a test of the proposed drug classification system. The system is being tested in a drug utilization review study now underway. A report is due next month.

The Department has developed an appropriate drug coding system as proposed in recommendation 18. It is designed to meet the need for a single, comprehensive nomenclature, and coding system for identifying drug products covered by departmental drug-financing programs and private third-party programs. Use of the code can enable high-speed data handling equipment to process millions of claims and other pieces of drug information with tremendous speed, accuracy, and economy.

[1] See pp. 8339–8347.