A STUDY OF THE ROLE OF
THE CLINICAL PHARMACOLOGIST
IN DIRECT PATIENT CARE

DECEMBER 1972

Prepared for
THE NATIONAL CENTER FOR HEALTH SERVICES
RESEARCH AND DEVELOPMENT
U.S. DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE
WASHINGTON, D.C. 20310

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and Welfare. The views expressed in this report are those of the author and do not necessarily reflect the
official views of the National Center for Health Services Research and Development, DHHS.

LIFE SCIENCES RESEARCH OFFICE
FEDERATION OF AMERICAN SOCIETIES
FOR EXPERIMENTAL BIOLOGY
9650 Rockville Pike
Bethesda, Maryland 20014
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By

C. Jelleff Carr, Ph.D.

LIFE SCIENCES RESEARCH OFFICE
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FOREWORD

The Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB), provides scientific assessments of topics in the biomedical sciences. These reports are based upon comprehensive literature reviews and the opinions of knowledgeable scientists engaged in work in the field. Although LSRO reports are recognized by FASEB as contributions to societal needs and most LSRO consultants are members of FASEB constituent societies, the reports do not necessarily reflect the views of the Federation as a corporate body or carry the endorsement of the members of its six constituent societies. However, the report has been reviewed for policy considerations by the LSRO Advisory Committee, which includes representatives of each constituent society.

This technical report was prepared for the National Center for Health Services Research and Development, Health Services and Mental Health Administration, Washington, D.C., in accordance with the provisions of contract number HSM110-72-112.

The report reflects many of the opinions expressed by the participants in an ad hoc review group that met at Beaumont House, FASEB, June 27-28, 1972, and other consultants. The author gratefully acknowledges the contribution of the time and talents of these experts in reviewing a draft of the report. The final report includes most of their suggestions; however, the author accepts the full responsibility for the contents of the report. The listing of the consultants' names in Section X must not be construed as indicating that they are authors of the report or that they endorse the study conclusions.

Special acknowledgment is made to Dr. Kenneth D. Fisher and Dr. Humphrey F. Sassoon, Research Associates, LSRO, for their assistance in the conduct of the study and the preparation of the report.

C. Jelleff Carr, Ph.D.
Director
Life Sciences Research Office
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SUMMARY

This study examines the present medical care systems that utilize the skills of the clinical pharmacologist in providing rational drug therapy. It reviews and analyzes the professional contributions and responsibilities of the clinical pharmacologist and factors of drug therapy that influence the quality of drug therapy, adverse drug reactions and interactions, and costs of health care delivery.

The current and proposed training programs in clinical pharmacology are reviewed. Manpower studies illustrate that although the demands for clinical pharmacologists are recognized, there is no national program that is training these medical specialists to meet the anticipated needs.

The relationships of the clinical pharmacologist to the nurse specialist and the clinical pharmacist are noted as these health care personnel are involved in drug therapy for patients. The role of the hospital administrator in controlling hospital care costs as related to drug therapy is discussed.

The study illustrates that while recommendations to improve the quality of drug therapy in patient care by the increased use of medical specialists, such as the clinical pharmacologist, may prove successful the cost may be excessive. Wisely conceived and skillfully consummated research ideas can lead to the desired goals; however, there are economic constraints that may prohibit the achievement of these ideals.

In addition, it does not appear that there will be enough clinical pharmacologists to meet the anticipated future needs in direct patient care as described in this study.

Future opportunities are reviewed and studies proposed related to the program interests of the Health Services and Mental Health Administration and the societal needs and expectations of the American people.
I. BACKGROUND

A. PROGRAM INTERESTS OF THE HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

The Health Services and Mental Health Administration (HSMHA) is the agency of the Department of Health, Education, and Welfare (DHEW) primarily concerned with the organization and delivery of health services to the American people. Its mission is to help make better health care readily accessible to individuals and families (Wilson, 1970). To attain these broad objectives, HSMHA includes a number of programs responsible for delivery of health services. The National Center for Health Services Research and Development of HSMHA promotes and supports research leading to improvement in the organization, delivery, and financing of health services. The broad goals of the innovative programs of the Center are to improve the quality and efficiency of health care for more people at a cost they can afford.

An essential part of the research effort of HSMHA is to develop an appropriate data base on which to build improved therapy for disease, including drug therapy. The Pharmacy-Related Programs Branch of the National Center for Health Services Research and Development (1971) is evolving and implementing programs to enhance the quality, safety, and effectiveness of all aspects of drug therapy. The Branch is concerned with the present quality of drug therapy provided for patients of private practitioners, hospitalized patients, and hospital clinic outpatients. Therefore, before plans can be organized for future programs, it is necessary to review the existing facilities and their effectiveness. This study was undertaken to examine one facet of this broad subject of delivery of adequate drug therapy.

The character of drug therapy is influenced by the clinical acumen of the clinical pharmacologist. His role is significant in planning and developing any future programs that stress innovative procedures, more efficient use of manpower, and improved availability of medical services. Special emphasis will be given to these factors in seeking new avenues to improve drug therapy. However, an evaluation must be made first of the quality of present services in health care.
Although the role of the clinical pharmacologist in research is well established, his involvement in direct patient care is less well defined. The clinical pharmacologist, as a physician, is in a unique position to improve health care delivery by efficient implementation of drug therapy in patient management. In general, hospital and outpatient clinical practice usually is conducted without continuous involvement of the clinical pharmacologist. An expanded role for clinical pharmacology in health care delivery represents one of several concepts being explored in the evolution of more efficient health care delivery systems. This study is based on the assumption that future medical care systems will place greater emphasis on the discipline of clinical pharmacology in the delivery of primary health care and direct patient care of hospitalized patients. Ultimately, the question of payment for these increased services must be considered.

B. DEVELOPMENT OF THE STUDY

Planning meetings were organized to identify relevant facets of the subject and to establish priorities for the numerous suggested topics for review. These meetings were attended by clinical pharmacologists and representatives of Federal regulatory agencies, Departments of Pharmacology in Schools of Medicine and Pharmacy, and the professional organizations of pharmacology and pharmacy. In addition, advice and suggestions were provided by hospital administrators, social scientists, and directors of pharmacology research and research training programs in the National Institute of General Medical Sciences, National Institutes of Health, and representatives of HSMHA.

In keeping with the general requirements of the study the suggested topics included:

- An analysis of the activities of clinical pharmacologists in providing drug therapy for hospitalized patients at the present time;
- An examination of the teaching requirements of clinical pharmacologists;
- Aspects of medical record keeping for drug therapy, adverse drug reaction reporting, and poison control centers that are the concern of the clinical pharmacologist;
An analysis of the present and future estimated manpower needs in clinical pharmacology;

The present accepted responsibility of the clinical pharmacologist in monitoring hospital formularies and drug therapy compendia;

An examination of the relationships of clinical pharmacologists to other health care personnel;

Possible future contributions of the clinical pharmacologist for drug therapy in primary patient care;

A review of the clinical pharmacologist's ability to improve drug therapy for nonhospitalized private patients, pediatric patients, and outpatient residents of urban inner city areas; and,

An analysis of the effectiveness of the clinical pharmacologist as a medical specialist as viewed by his medical colleagues and hospital administrators.

Additional broad topics of secondary consideration were suggested for review as related to the general subject. These were:

A study of all factors that influence optimal drug therapy in patient care;

An estimate of the potential costs for drug therapy that may follow any significant increase in the number of specialized medical personnel required to meet the proposed needs;

Hospital administration problems related to the increased costs for improved drug therapy, e.g., drug costs, personnel costs, and operation costs;

A review of established programs in those few hospitals that have developed successful collaborating clinical pharmacology and clinical pharmacy programs for patient drug therapy;
• Plans of the Division of Clinical Pharmacology, American Society for Pharmacology and Experimental Therapeutics for assessing and meeting future manpower needs or licensure; and,

• Societal attitudes toward improving drug therapy and the related costs.

These guidelines served as a basis for the agenda of the ad hoc review group meeting at Beaumont House, June 27-28, 1972 (Section X). The dialogue of the 21 consultants at this meeting, in part, provided the background for this staff report. In addition, a number of other specialists have been consulted and their views and an analysis of the pertinent literature have assisted in the preparation of this study. The counsel of all these specialists is gratefully acknowledged.

C. PRIOR REPORTS ON CLINICAL PHARMACOLOGY

Several significant reports have been prepared in recent years that are concerned with the current status of clinical pharmacology (Goldberg, 1965; National Academy of Sciences, 1971a; World Health Organ., 1966 and 1970). These reports include discussions of:

• The increasing demand for clinical pharmacologists to make rigorous evaluations of new drugs for industry and government regulatory agencies;

• The need for clinical pharmacologists in many government research laboratories;

• Academic programs for clinical pharmacology; and,

• The need for these medical experts in schools of medicine and the associated teaching hospitals.

These reports reflect the views of clinical pharmacologists, educators, industrial representatives and government officials. However, none of these reports has addressed the question of the clinical pharmacologist's role in direct patient care as described in Section II of this document. This is understandable because the traditional responsibilities of the clinical pharmacologist have not embraced this concept.
II. DIRECT PATIENT CARE AS DEFINED FOR THIS REPORT

Within the context of this report, it is necessary to define direct patient care because the study does not address such questions as the shortcomings in health care, the proposed health maintenance organizations (HMO's), or the costs of health care in general. On a reimbursable cost basis, hospital administrators and health insurance programs define direct patient care as any identifiable service rendered to a person or category of patients for health purposes.

The physician is directly involved in patient care at all important stages of health care delivery. However, the complexities of modern medical practice, unusual hospital care facilities, new technology, and especially the bewildering fund of pharmacologic knowledge demand a degree of sophistication of the physician unparalleled in history. To meet this formidable task, a corps of attendants provide multiple specialized services to assist the physician in the full context of patient care. These facilities are available in the United States at large urban hospital centers. The Kaiser Foundation hospitals and clinics (Somers, 1971) and The Foundation for Medical Care of San Joaquin County (Saluly and Hopkins, 1967) are often cited as models of implementation of technology in all facets of patient care.

Primary medical care has been called "front-line medical care" and is generally described as care by physicians who provide access to the health care system, health maintenance, treatment for common illnesses, and overall medical care including referral of patients for care by medical specialists (Garrison, 1971). As discussed in Section VII of this report there is no formal provision at the present time for primary care physicians to call upon the clinical pharmacologist for advice on problems of drug therapy.

Direct patient care also includes nonhospitalized patients of physicians and large numbers of outpatient clinic attendees. The clinical pharmacologist rarely is involved in the care of these patients.

As pointed out by Brodie (1971), most drug utilization data are available from hospitalized patients because of more readily accessible records. There is a need for reliable information on drug utilization in direct patient care from other health care facilities including nursing
homes, extended care facilities, neighborhood clinics and practicing physicians. The present incomplete records and nonuniform reporting systems of providers of health services seriously inhibit an organized review of drug utilization.

The emphasis that the term "direct patient care" implies in this report is on all kinds of patients. The study might have been entitled: How Can the Clinical Pharmacologist Contribute to Improving the Quality of Drug Therapy for a Larger Number of Patients? In these terms at the present moment there seems to be no organized plan to involve the clinical pharmacologist in primary or direct patient care as described in the terms of this report.

It should be noted that in this study the clinical pharmacologist is considered a specially trained physician as described in Section IV. The definition as developed by the American Society for Pharmacology and Experimental Therapeutics' Committee on Manpower and Goals is broad and includes doctoral level training in other disciplines.
III. SCOPE OF THE STUDY

Direct patient care as defined in Section II includes a consideration of safe, efficacious, and rational drug therapy for patients in hospitals, clinics, and other institutional environments. As physicians with special training in pharmacology, qualified to make discriminating judgments in the selection and use of drugs, clinical pharmacologists have a unique responsibility for drug therapy and patient care. This study embraces a current analysis of these activities.

The emphasis in this review has been placed on assembling expert opinions and examining existing programs. The title of the report raises questions that cannot be answered in this type of study. It may be possible to develop future programs in the fields of clinical pharmacology, hospital administration, academic teaching, and public health that will address these questions.

Because this study specifically examines the role of the clinical pharmacologist in terms of drug therapy for many patients, emphasis is placed on an analysis of his present activities and how these might be enlarged to improve drug therapy for more patients. In contrast to his major responsibilities as a medical drug specialist available to staff physicians for advice and consultation on drug therapy problems, there is need to determine whether he can extend his expertise to bring him in direct relationship with a larger number of patients. As an acknowledged drug expert, the clinical pharmacologist is in a position to influence favorably the quality of drug therapy for more institutional patients. At present he contributes indirectly to care of these patients through teaching, research, hospital formulary guidance and related roles in the medical complex of academic centers. While these activities are forms of patient care, it appears desirable to extend the influence and number of these physicians to a more substantive impact on direct health care delivery; however, there are no formal plans to develop these concepts.

The study does not include a discussion of the research activities of clinical pharmacologists in the evaluation of new drugs. This facet of clinical pharmacology is widely recognized as a traditional role of these medical specialists; however, it is tangential to the subject of direct patient care as a medical service.
In developing the scope of the study it was agreed that projections would be made only on the basis of the next five years. This seems appropriate in the rapidly changing economic and professional milieu.
IV. THE CLINICAL PHARMACOLOGIST

A. PROFESSIONAL CONTRIBUTIONS AND RESPONSIBILITIES

The importance of the work and the sphere of influence of the clinical pharmacologist in medical practice has enlarged in recent years. As a special medical and scientific discipline the "guild" has gathered the respect and approbation of many facets of the community concerned with medical care. For these reasons it is germane to document the numerous activities and responsibilities of the clinical pharmacologist in patient care to clearly illustrate the contributions of this discipline to modern medical practice.

The expert groups who prepared the prior reports on clinical pharmacology and the Division of Clinical Pharmacology of the American Society for Pharmacology and Experimental Therapeutics (ASPET) have not developed a universally acceptable definition of clinical pharmacology (National Academy of Sciences, 1971a; Pelikan, 1969). However, in the ASPET recruiting brochure, the Committee on Education and Professional Affairs offers this description of clinical pharmacology:

"Clinical pharmacology tests the products of general pharmacology on the human animal. How do drugs work? How do they interact with other drugs? Do they produce serious toxicity, or do they increase each other's beneficial effects?

"Only in man can laboratory judgments be tested on the efficacy of new chemicals. Only then can the full spectrum of a drug's activity be revealed. This is the realm of clinical pharmacology.

"As a clinical pharmacologist you help define therapeutic regimes, determine valid methods of observation of drug effect, draw scientific conclusions from testing, employ drugs as diagnostic agents and create new purposes for old drugs. In the process you may make new discoveries in pathology and physiology."
"Finally you disseminate the results of your patient-oriented research. You help medical therapists recognize the shortcomings and dangers of drugs and how to monitor their effects so as to minimize risks and maximize benefits.

"You are the therapeutic consultant to guide developing doctors in what they can expect from drugs and how disease can alter the disposition and effects of drugs.

"It is the clinical pharmacologist who puts the imprimatur on the products of pharmacology for man."

ASPET, through the Committee on Manpower and Goals developed an operational definition of a clinical pharmacologist (Pelikan, 1969). This definition is broad and is presented to show the relationships between the several subdisciplines. It embodies the definitions employed in the manpower surveys of this committee as reported in Section V.

"Pharmacologists, toxicologists, and clinical pharmacologists are health-scientists engaged in the systematic study of the interactions of chemicals and living systems: the nature of the interactions, their causes and consequences.

"Pharmacologists, toxicologists, and clinical pharmacologists differ in training, research methodologies and in the kinds of chemical agents and the kinds of chemical and biological effects which are objects of investigation.

"In general a person in the job category of pharmacologist, toxicologist or clinical pharmacologist is considered to have "professional" status only when he holds an appropriate academic degree at the doctoral level and has published scientific papers in an edited journal pertinent to his discipline or job category. Direct participation in research, per se may be only a small part of the professional person's total effort, but involvement with problems of pharmacology, toxicology or clinical pharmacology is a primary job responsibility and represents a long-term career interest.
"The Pharmacologist holds a doctoral degree in pharmacology or closely-allied health-oriented field, including the fields of medicine, dentistry, or veterinary medicine. He studies the actions of chemical agents which may or may not have immediate relevance to maintaining or restoring health. His experimental preparations are chosen as models, as of situations in which the agents might have use.

"The Toxicologist has received training like that of the pharmacologist, and they hold similar academic degrees. The toxicologist studies chemical agents which may cause disease or present a hazard to life. His experimental preparations are usually those which permit establishing conditions of safe, or hazardous, exposure to the agents.

"The Clinical Pharmacologist holds a doctoral degree in medicine, dentistry, veterinary medicine or pharmaceutical science. He studies, systematically, agents which have immediate relevance to maintenance or restoration of health. His studies are carried out in species in which the agents are, or may be, used; his studies are carried out under conditions which are, or approximate, the conditions of use." (Pelikan, 1969, 1972).

Riker has observed that the hallmarks of a clinical pharmacologist are his specialized training in medicine and pharmacology and his liberal experience in scientific research methodology (Riker, 1968). In addition, he emphasized that physicians with only limited experience in pharmacology cannot truly be labeled clinical pharmacologists. To paraphrase Riker, we would be able to recognize the physician and the pharmacologist in the clinical pharmacologist.

Melmon and Morelli (1972) described clinical pharmacology as an independent academic discipline concerned with the effectiveness of drugs in man. They emphasize that basic pharmacology and the study of mechanisms of drug action in man are the chief concerns of clinical pharmacology. These writers note that most clinicians are concerned with the pathophysiology of disease in a particular organ system and very likely will not have a primary interest in evaluating
the efficacy of a drug in a patient with a given disease. This latter
interest is the unique characteristic of the clinical pharmacologist.
Melmon and Morrelli (1972) conclude their description of the discipline
by noting:

"The clinical pharmacologist is concerned with the inter-
digitation of therapeutics with basic pharmacologic
principles, research methodology, biostatistics, and
clinical acumen. An essential product of these relation-
ships is the clinical trial, a prerequisite to rational
therapeutics."

Other descriptions of clinical pharmacology have been prepared.
Goldberg (1965) observed that the teaching of clinical pharmacology in
part described the practitioner. By insisting on a critical attitude
toward the use of any drug and with a scientific approach to the demon-
stration of effectiveness, the clinical pharmacologist requires his
colleagues to appraise their own drug therapy regimens. The results
are desirable because they lead to more refined clinical examination
and evaluation of all aspects of drug therapy (Goldberg, 1965; Lasagna,
1966).

Palmer (1969) described the clinical pharmacologist as a
teacher "anchored" in basic pharmacology but a "translator" of
effective information on the use of drugs in patients via his clinical
background as a physician.

Lasagna (1966) placed great emphasis on the training of the
clinical pharmacologist as indications of his skills and hence served
to define the discipline. For example, in addition to a knowledge of
the fundamentals of pharmacology, he is trained in understanding and
using the "pharmacologic hallmarks," e.g., the dose response curve,
structure activity relationships among drugs, techniques for measuring
absorption, distribution, biotransformation and excretion of drugs in
man, and extrapolation of animal data to man. Lasagna (1966) observed
that while the clinical pharmacologist might be considered as responsible
for all aspects of drug therapy in a hospital, his functions would be
super-departmental, cutting across department boundaries, teaching
many things to his colleagues; however, he should not be considered a
renaissance figure, expected to know everything about everything.

The inability of the practicing physician to keep abreast of the
demands of modern drug therapy and to make informed judgments on
the uses and hazards of the multiplicity of drugs has been documented by many authors and review groups (Barber, 1967; Brodie, 1971; Cluff, 1969; Lasagna, 1962; National Academy of Sciences, 1971a; Palmer, 1969; Schimmel, 1964; Talalay, 1964). Indeed, trained clinical pharmacologists admit that it is difficult to be informed about the new knowledge on the various facets of drug bioavailability, metabolism, interactions, and hazards. These facts illustrate the need for and responsibilities of a clinical pharmacist as an essential part of health care delivery for rational drug therapy.

Studies have revealed documented examples of poor prescribing by physicians of antibiotics for the common cold, chloramphenicol for trivial infections, and vitamin preparations for a wide variety of conditions (Stolley et al., 1972; Stolley and Lasagna, 1969).

In reviewing the problems of the physician to provide rational prescribing, the Task Force on Prescription Drugs (1969) observed that although few physicians are inclined to question their competency in this field of therapeutic judgment, many medical educators, clinicians and scientists do not agree. It was noted that observers had reported a lack of knowledge and sophistication in the proper use of drugs as perhaps the greatest deficiency of the average physician today. There is need for the kind of postgraduate education in pharmacology that the clinical pharmacist can provide. The Task Force members emphasized a number of factors that interdict in rational drug prescribing, including inadequate training, poor information sources on drugs and drug costs, rapid drug obsolescence, and the limited time of the physician to examine, evaluate and document current drug uses and hazards. Finally, the report concluded that the difficulty in part is related to "The constant insistence on the idea that the average physician, without guidance from expert colleagues, does in fact possess the necessary ability to make scientifically sound judgments in this complicated field." The facts speak otherwise. Unfortunately, the report made no effective, forceful recommendations for correcting this obvious deficiency in the health care system.

Physician characteristics and prescribing appropriateness were assessed in a study of the prescribing behavior of primary care physicians in private practice (Stolley and Lasagna, 1969). Again, no attempt was made to investigate the contributions a clinical pharmacist could make to improve the prescribing habits of these primary care physicians.
Palmer (1969) has cited the lack of teaching by clinical pharmacologists in the medical school education of physicians as the major cause of drug misuse by physicians. Clinical experience is essential in imparting the proper understanding of the use of drugs in therapy according to this author. Unfortunately, he offered no suggestions to increase the number of these highly trained physicians.
B. ACTIVITIES OF CLINICAL PHARMACOLOGISTS

The clinical pharmacologist is primarily concerned with the scientific study of drugs in man. He constantly seeks rational and economic ways to make decisions about drug utilization - has the drug been used correctly or indeed should it have been used at all? As a drug expert he works most often with a relatively few patients. However, efficacy of drug utilization in the entire hospital falls within the scope of the responsibility of the clinical pharmacologist.

In describing the proposed aims, organization, and activities of a division of clinical pharmacology, Carr (1963) suggested that the clinical pharmacologist(s) be assigned about one-third of the duties carried out by other staff of similar rank in the two departments of medicine and pharmacology. This would permit the clinical pharmacologist the time for special services and research. The department duties normally would include ward rounds, medical clinics, and teaching basic pharmacology at the clinical level in the third and fourth years of the medical course in most schools. Obviously such a program requires tact and diplomacy on the part of the participants because the idea runs counter to the rigid departmental concepts deeply entrenched in most medical school hierarchies.

The activities of academic clinical pharmacologists have been described by several successful program organizers (Carr, 1963; Crout, 1965; Goldberg, 1965; Lasagna, 1966; Tilghman, 1971).

The clinical pharmacologist may serve on a review committee to assess the hazards of radiation exposure from radio-labeled drugs used in the study of metabolism of drugs in man or for therapy.

The teaching responsibilities of the clinical pharmacologist are numerous. They include teaching medical students as a member of the staff of the department of pharmacology. In some institutions, these teaching requirements include nursing, pharmacy, and dental students. Unquestionably, the most fruitful instructional role for the clinical pharmacologist is his contact with the medical student and his influence on the drug therapy practices of the hospital house staff.

When students and house officers prescribe with inadequate knowledge of the basic pharmacologic action of drugs,
the therapeutic results may be expected to be poor. The major effort of clinical pharmacologists is in the field of pharmacology and they are able to keep abreast of the rapidly changing pharmacologic picture. They are trying to change the attitude of students about drugs. They want students to feel as they do - that drugs are important and potentially dangerous and that clinical research on drugs is necessary and often exciting.

It is difficult to assess the impact of the academic clinical pharmacologist on his fellow practicing physicians. Only a few studies have been conducted on education influences on the prescribing patterns of physicians (Becker et al., 1972; Stolley et al., 1972). There is need to know if the prescribing habits and the general level of prescribing quality have not been substantially influenced by postgraduate training programs for practicing physicians. On the other hand, physicians may seek the aid of the clinical pharmacologist if he is available in cases of adverse drug reactions, ineffective therapeutic response, or when confronted with a therapeutic drug dilemma.

While the clinical evaluation of new drugs is a recognized part of clinical pharmacology, it is obvious that guidance for rational drug therapy with any drug is the major contribution that clinical pharmacologists make to medical practice. The complex techniques that have evolved in the clinical evaluation of drugs within the past 25 years emphasize the important role of controlled clinical investigations in objectively documenting the therapeutic efficacy of a drug product. The control of bias and the utilization of double-blind techniques in clinical drug evaluations are important aspects of this work. In addition, the design of the experimental trial and statistical treatment of the results, as well as traditional pharmacologic principles of drug therapy, are major contributions that clinical pharmacologists make to medical practice (Feinstein, 1968, 1970, 1972a, 1972b).

All of these factors culminate in what is recognized today as rational prescribing of drugs. This depends upon the exercise of good clinical judgment, consideration for the safety of the patient, the efficacy of the drug, the advantages and disadvantages of various dosage forms, the duration of therapy, and possible drug interactions. As has been described elsewhere (Task Force for Prescription Drugs, 1968) rational therapeutics consist of selection of the right drug for the right patient, in the right amounts, at the right times. It may be said that this definition of therapeutics represents the ideal goals of the clinical pharmacologist, reflects his specialized training, and assists in arriving at a definition of the discipline. However remote
this idealized concept of drug utilization seems at present, it is supported by all members of the health care team, physicians, pharmacists, and nurses, each within the context of their own professional skills.

One of the major contributions of pharmacology in recent years has been the introduction of analytical chemical methodology to determine the levels of therapeutic drugs and their metabolites in animals and man. The clinical pharmacist has played a noteworthy role in investigations to determine whether accurate analysis of the drug of its metabolic transformation products in biological fluids can be used as a rational basis for drug therapy. Monitoring blood drug levels provides objective data for the physician that undergirds his clinical appraisal of the status of therapy. The clinical pharmacist has been and continues to be at the forefront in this field in assisting in developing the factual basis for dosage regimens for old as well as new drugs. There is every reason to believe that even greater therapeutic rewards will come in the future as our understanding of the pharmacokinetic aspects of drug action continues to enlarge. The fundamental information for man will be provided by the clinical pharmacist.

The clinical pharmacist renders an important service to society by his clinical research investigations on new and currently used drugs. Indeed, research is a major distinguishing characteristic of the clinical pharmacist and the National Institute of General Medical Science places emphasis on research facilities and research training in their programs that support the training of clinical pharmacologists. These clinical studies determine whether a drug has a potentially beneficial effect and its toxicity hazards. This work requires special expertise to minimize the risk to the patient and to secure the greatest amount of information. These activities have been discussed in prior reports (Goldberg, 1965; National Academy of Sciences, 1971a; World Health Organization, 1966 and 1970).
C. DRUG THERAPY AND PATIENT CARE

There is concern about the misuse of drugs prescribed for health-related needs and the clinical pharmacologist has an increasingly important responsibility for preventing and correcting the mis-utilization of therapeutic agents. In addition, it is assumed that unnecessary costs are incurred by inappropriate or unneeded drugs prescribed for patients (Talalay, 1964). Self-medication is often ineffective and may lead to drug interactions unrecognized by the physician or the patient. While more efficient drug utilization at all levels is a fundamental public health problem and entails responsibilities for many professionals, the clinical pharmacologist is the single medical expert who, by training, is most expert in drug therapy.

By definition, adverse drug reactions are unintended, undesired, and unexpected responses to drugs (Cluff et al., 1965). Studies of hospitalized patients have shown that they receive a large number of drugs. One study revealed that the frequency of different drugs prescribed for a single patient ranged from 6 to 32 and that the average was 14 medications (Cluff et al., 1965). These workers made the observation that the increasing number of drugs given patients increases the risk of adverse reactions. They call for a critical evaluation of present day drug therapy to reduce the number of drugs given to patients and thus eliminate all but essential medications. They further point out that drug reactions prolong hospitalization and increase the cost of medical care (Cluff et al., 1965). It has been stated that about five percent of all medical hospital admissions are due to drug reactions and that about 15 percent of hospitalized patients experience adverse drug reactions (National Academy of Sciences, 1971b).

In general, other reports have supported these findings (MacDonald and MacKay, 1964; Cluff et al., 1964; Seidl et al., 1966; Hoddinott et al., 1967; Hurwitz, 1969; and Learoyd, 1972). However, observers have pointed out that the data in these studies are based on patients admitted to the medical service of the hospital and therefore represent a skewed sample of the population. It is unwise to draw conclusions on this basis alone because many patients admitted to other services, e.g., orthopedic, are not likely admitted as a result of an adverse drug reaction. Therefore, figures based on projections of these findings for all hospital admissions are not accurate.
The cost of hospitalization from adverse drug reactions has been estimated as approximately $900 million a year (Brodie, 1971). There are no estimates of the cost to hospitalized patients who develop adverse drug reactions during hospitalization. Obviously, the untoward effects of rationally prescribed drugs - the right drug in the correct dosage for the right patient, or on the other hand, improperly prescribed drugs - are serious clinical pharmacologic problems.

One study of hospital-induced complications included over 1000 patients in a university medical service (Schimmel, 1964). Most were related to reactions from diagnostic procedures or therapeutic drugs. The average length of hospitalization of the patients who experienced drug reaction episodes was more than double the hospital stay of other patients. No attempt was made to assess the impact of critical review of therapy prior to administration of drugs and no mention was made of a clinical pharmacologist in the study. The report notes that reactions were excluded if they arose from inadvertent errors by physicians or nurses, and patients hospitalized as a result of adverse effects of prior treatment were omitted from the study.

The complexities of modern drug therapy are now becoming more widely recognized by the health care professionals. Unfortunately, there is decreased training in pharmacology and drug therapy in most medical schools in the United States. Therefore, the speciality of clinical pharmacology is required more urgently than in past years to advise physicians in regard to all aspects of drug administration and adverse reaction prevention and treatment. For example, there are fundamental differences in drug reactions that cause minor dermatologic manifestations or constipation, and the serious life threatening episodes caused by unexpected interactions from multiple drug administration. It requires a well trained pharmacologist to comprehend and interpret the voluminous and ever changing information on efficacy, safety, and interactions of drugs, especially as these relate to discoveries of their metabolism, protein binding affinities, or enzyme inducing and inhibiting properties (National Academy of Sciences, 1969).

Some observers have pointed out that efficacious drug therapy is based on the fundamental knowledge of the disciplines of human physiology, biochemistry and pharmacology. Therefore basic scientists in these fields make important contributions to clinical pharmacology and health care. It is unfortunate that the changing curricula of medical schools is reducing the amount of instruction in the basic biomedical sciences.
D. RELATIONSHIPS OF CLINICAL PHARMACOLOGISTS TO PARAMEDICAL PERSONNEL

The clinical pharmacologist works intimately with many paramedical people - hospital administrators, pharmacists, sociologists, and nurses. These individuals as a group make their contributions to patient care. However, for drug therapy the nurse specialist and most recently the clinical pharmacist have received training that enables them to collaborate with the clinical pharmacologist in many ways.

Important contributions have been made by men and women trained in pharmacy who establish and monitor drug distribution systems in the hospital, take complete drug histories, inform patients prior to discharge of the hazards of medication, and reinforce the physicians instructions for following medication directions (American Pharmaceutical Association, 1971). A number of successful programs of this type have been in operation in several hospitals for a number of years (American Association of Colleges of Pharmacy, 1972; Kinnard, 1972). A clinical pharmacy service in a community hospital has been reported by Smith (1972). Palmer (1969) suggested that the practicing physician can utilize the knowledge and talents of the pharmaceutical graduate by providing postgraduate education and some clinical training for the pharmacist.

The pharmacist's role is changing from drug product orientation to one of more patient oriented service. To this end, he now receives education that brings him in direct contact with the hospital house staff on a day-to-day basis (American Association of Colleges of Pharmacy, 1972; Kinnard, 1972). His clinical instruction is provided by physicians to augment his expanded basic training in pharmacology in the school of pharmacy. The specific aim is to educate a well trained person with a fundamental knowledge of the physical and chemical characteristics of drugs, problems of drug metabolism, excretion and dosage, drug interactions, and many of the concerns of the physician in treating disease states. In this manner, the clinical pharmacist is prepared to accept many of the responsibilities for effective collaboration with the clinical pharmacologist or the practicing physician in drug therapy programs for hospitalized patients and outpatient clinics. The recently proposed Health Maintenance Organizations (HMO) for the United States include a "-requirement that a clinical pharmacist survey, evaluate,
and review patterns of patient drug utilization (including drug regimens and therapies) and maintain a drug use profile for each enrollee of an HMO . . . ." These pharmacists are specifically designated as those who have had substantial training and experience in designing and monitoring patient drug therapy programs (U.S. Senate, 1972). Pharmacy schools now train students with the Pharm. D. degree, which is one year beyond the baccalaureate, and clinical pharmacists serve a residency period in a hospital.

The pharmacists knowledge contributes to drug therapy by making information on dosage forms, bioavailability, and related issues available to the physician. Thus the success of drug therapy can be enhanced by the pharmacists contributions to the physician in patient care - a point frequently misunderstood.

In exploring the causes of success and the difficulties in collaborative programs, it is obvious that a great deal of diplomacy has been required on the part of both the medical practitioners and the pharmacist to work out successfully their legal involvement, prerogatives, and contributions. It appears that when these issues have been approached by both parties in a spirit of good faith, the results have proven productive. Not all medical staff agree with the philosophy of programs of this character and are outspoken in their opposition. In general though, the concept has proved its worth in terms of enhancing the health care facilities of busy university associated hospitals in providing better drug therapy (Herfindal and Levin, 1972; Levin, 1972).

Barber (1967) has observed that no social research has been done on the contributions pharmacists make to effective drug utilization other than as community pharmacists. The pharmacist's status is enhanced by his new responsibilities, and accordingly the profession is attracting better educated and more highly motivated young people.

The nurse specialist trained at the graduate level, e.g., the cardiac, psychiatric and pediatric nurse, is recognized as a competent assistant in drug therapy for direct patient care (Little, 1967; Pellegrino, 1961; Silver et al., 1968). By experience and education, the clinical nurse specialist contributes to the use of drugs in patients under the specific requirements of her field of specialization. As such, the nurse specialist can facilitate the delivery of drug therapy of high quality under the supervision of the physician. In unusual drug therapy programs,
for example with new drugs, the clinical nurse specialist provides a unique service. Less highly trained nurses are most often involved in general drug therapy for institutionalized patients. However, they can be trained to be excellent monitors of patients reactions to drugs. The studies of Slone, Jick and their colleagues (1966) have demonstrated how effective nurse monitors can be.

It is of interest that studies have been made of the expanded roles for nurses in health care delivery in keeping with their advanced training (Department of Health, Education, and Welfare, 1971). These studies document the nature of the increased responsibilities of nurses, the absence of legal obstacles because of their significantly enhanced training, and cost-benefit analyses that are proposed in medical centers where the new programs are operating. These extended roles for nurses with specialized training include a more appropriate place in monitoring drug therapy.

The emergence of organized systems of health care delivery will increase the need for and encourage the development of many new types of health care professionals. These new workers are just beginning to take their places on the health care team and as such there must be uniform standards of proficiency as have been established for nurses and pharmacists on a national scale, to insure competence (Todd, 1972). The certification of medical technologists is a more recent development (American Society of Clinical Pathologists, 1970). The medical technologists, nurses and clinical pharmacists are most intimately involved with the clinical pharmacologist in drug therapy. There is a need to study the interrelationships of these specialists in developing plans for future health care delivery programs to define their several legal responsibilities.
V. TRAINING PROGRAMS IN CLINICAL PHARMACOLOGY
PRESENT AND PROPOSED

A. MANPOWER NEEDS

The specialized training of physicians required for an adequate background in clinical medicine and pharmacology has limited the number of clinical pharmacologists. In addition, many trainees after completing the necessary training in the basic medical sciences, and the major medical specialties have elected other areas for emphasis in their medical careers. Although as highly trained as other medical specialists, the clinical pharmacologist is often not regarded by his medical colleagues as a specialist in therapeutics and he may not be accorded a place in the medical hierarchy equivalent to specialists in categorical areas of medicine, e.g., cardiologists or radiologists. For these and other reasons, a young physician may contemplate a career in clinical pharmacology and then turn to the better recognized medical traineeships.

In his broad perspective of the use of drugs to meet societal needs, Barber (1967) observed that two general problems confront the contemporary drug therapist, "inadequate medical training that is often shallow, erroneous or distorted; and the confusion caused by many and often conflicting sources of drug information." The practicing physician needs the advice that can be provided by a clinical pharmacologist. This view is amply supported by numerous reports of special groups appointed to study the national requirements (National Academy of Sciences, 1971a; World Health Organization, 1966, 1970). However, as it now prevails, the system of medical education, training, and experience may not produce enough medically trained clinical pharmacologists to meet these demands. A proper understanding is required of the scientific basis for drug therapy for all patients receiving drugs in medical practice. This facet of the role of the clinical pharmacologist in direct patient care calls for a careful analysis if adequate predictions are to be made. Unfortunately, there are few criteria to assess the quality of patient care or health care delivery in general (See Section VII).

Recognizing the acute need for clinical pharmacology units in the United Kingdom, the Medico-Pharmaceutical Forum (1970) proposed
that financial support be provided to develop 25 to 30 centers in medical schools in that country. It was estimated that in 1970 there were less than ten small units in existence. The Forum consists of representatives of medical institutions and the pharmaceutical industry with membership from the major medical and pharmaceutical societies. The report of the Forum's Committee on Clinical Pharmacology on Facilities for the Early Clinical Studies of New Medicines stressed the urgent need to create a number of clinical pharmacology units with a professional staff of at least three medical scientists.

It has been stated repeatedly that the needs for qualified clinical pharmacologists are not met although the requirements for these medical experts are recognized by teaching institutions, government, and industry. The number of trainees is lagging despite the availability of excellent programs in outstanding medical schools. This lag may be related to the emphasis placed on specialization in categorical areas of medicine with research as a prominent aspect of a specialists' career.

The pharmaceutical industry in the United States, through the Pharmaceutical Manufacturers Association Foundation, Inc., has made significant contributions to the training of clinical pharmacologists since 1967 (Pharmaceutical Manufacturers Association Foundation, 1971). As of July 1972, 24 faculty development awards in clinical pharmacology have been made. These are substantial sums for salary support for training in clinical pharmacology for young physicians who plan a career in this field. In addition, 114 medical student traineeships in clinical pharmacology have been awarded to encourage medical students to consider the future opportunities of a career of research and practice in clinical pharmacology. Support has also been provided for medical school faculties to pursue active programs in clinical pharmacology.

The accomplishments of these support programs in clinical pharmacology are difficult to assess. Some medical students have elected to follow specialty training or medical residency opportunities in clinical pharmacology. Most of the faculty development awardees have continued to pursue research and practice in clinical pharmacology and have made contributions to the training of other young physicians in pharmacology. Thus, a well recognized group of clinical pharmacologists has received critical support in their training years that has fostered their careers in this medical specialty.
The Burroughs Wellcome Fund (Creasy, 1966) has awarded grants to support 22 clinical pharmacology units in medical schools as of 1972. This pioneering program was created in 1959 to establish new clinical pharmacology units in schools of medicine. At present, these are substantial grants of $125,000 payable over 5 years, that have assisted academic clinical pharmacology units to recruit staff and conduct research in the science of therapeutics. By 1972 a total of $2.5 million had been awarded in this program.

In 1971 the Burroughs Wellcome Fund endowed a chair in clinical pharmacology at the Johns Hopkins University School of Medicine (Burroughs Wellcome Fund, 1971). This continuing support for teaching, research, and training in clinical pharmacology should assist materially in establishing prestige for the discipline. However, sustained financial assistance must also be provided from other sources if the immediate future needs for clinical pharmacology units are to be met.

The National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH) has provided major support for training of clinical pharmacologists. Other institutes of NIH have also contributed to training of clinical pharmacologists, indirectly or directly. Training grants in clinical pharmacology from NIGMS have supported 33 individuals, and approximately one-half of the training funds of the National Cancer Institute and the National Heart and Lung Institute might be considered in the field of clinical pharmacology. It is generally agreed by experts closely associated with manpower requirements, that only 15 to 20 of the 100 medical schools in the United States have strong programs in clinical pharmacology (Tuve, 1972). About 20 postgraduate trainees supported by NIGMS are in the field of clinical pharmacology. According to the estimates by NIGMS, approximately 500 clinical pharmacologists would be required to meet all the national needs. However, less than 250 will be trained by 1976 at the present rate of training.

As pointed out previously, there is not only a need for additional training funds but the image of the clinical pharmacologist must be improved with security and career opportunities greater than are available at present. The NIH program, in general, must be made to support community needs in addition to the traditional research needs in the biomedical sciences. Adequate drug therapy is an important part of health care and some effective means must be found to distribute the medical personnel and paramedical skills to reach a greater number of patients if the program of training is to continue to receive congressional support.
Some clinical pharmacologists believe that the discipline is
eyoung and not enough time has elapsed to allow the academic scientists
to find their proper place in teaching, research and service. They
contend that the research role of the clinical pharmacologist is the
most important from all points of view and that service functions are
secondary. They feel that direct patient care for them would be
especially private practice of medicine and thus, would be more
rewarding financially.

The most comprehensive study of manpower needs in
pharmacology, toxicology, and clinical pharmacology was under-
taken in 1971 by the ASPET ad hoc Committee on Manpower and Goals
(Pelikan, 1972). This was a prospective study based on a questionnaire
sent to chairmen of pharmacology departments in schools of medicine,
pharmacy, dentistry, and veterinary medicine, appropriate representatives
in the pharmaceutical industry and the Federal Government. Other non-
pharmaceutical groups were included, representing museums, oceono-
graphic institutions, and research institutes. Projection of manpower
needs in these three specialties were requested through 1980.

Of the responding 65 departments of pharmacology in schools
of medicine, 14 had budgeted for clinical pharmacologists, but the
positions were unfilled. It was reported that for the 65 schools the
minimum clinical pharmacology staff required was 282 with an optimum
of 443. The most conservative projection of available manpower
resources, based on the mean annual number of trainees who com-
pleted training through 1969-70, would provide only 163 clinical
pharmacologists trained by 1979-80. The report concluded that if
the recent mean annual production rates and employment patterns for
clinical pharmacologists are sustained, they will not be sufficient to
meet the projected needs.

It may be assumed that the projections made in the report
of the ASPET Committee took into account total manpower needs
including anticipated contributions by clinical pharmacologists to
direct patient care as based on present manpower utilization patterns.
The accelerated use of the skills and talents of clinical pharmacologists
as envisaged in this concept would require many more of these specialists
than has been anticipated in the past.
B. COST FACTORS AND TRAINING REQUIREMENTS

The cost of training a clinical pharmacologist is difficult to estimate. The total cost might be calculated from the beginning of medical school education. A more realistic cost might be estimated on the basis of the two or more years required for training beyond the internship and residency. In any event, the contributions of the clinical pharmacologist might be weighed against the dollar cost of training plus the loss of a general medical practitioner. If the major concern in health care delivery is for the primary patient care physician then it could be debated that the specialist is more costly, and like other medical specialists, less available to most patients for direct patient care. It has been well documented that many physicians, including those providing primary patient care, need the assistance and guidance of a drug therapy expert. If many patients are hospitalized as a result of adverse drug reactions and then require special care it may be timely to seek ways to have the clinical pharmacologist guide the physician to prevent these untoward drug effects. These are cost factors that override training costs per se.

There appears to be good agreement that a clinical pharmacology unit in a medical school should be supported equally by and be responsible equally to two departments - the department of pharmacology and a clinical department, usually the department of medicine. The concept of a separate department or division has not been tested in this country presumably because the interests span basic preclinical needs and requirements for hospital beds. An experimental program of this character should be funded to explore the opportunities for clinical pharmacology service and research that could be provided by a clinical service unit attached to a department of pharmacology.

Traditional privileges within departments must be shared if a clinical pharmacology unit is to function efficiently. The costs of these activities, salaries, office space, paramedical personnel costs, laboratory space and clinical facilities must be allocated by the medical school departments involved (Goldberg, 1965). There have been repeated suggestions that expanded financial support be provided to medical schools to enable them to develop clinical pharmacology units as an integral part of the medical curriculum. However, no significant results have come from these recommendations presumably because other public health and professional medical interests have been overriding. This is surprising because fiscal economy could
be achieved, although this has not been proved, by having more clinical pharmacology units in more hospitals. It may be assumed that the period of hospitalization could be reduced and better drug therapy assured.

The model training program in clinical pharmacology described by Goldberg (1965) has variations in other schools but the essential elements illustrate the type of training required. The program has two parts: the first, basic pharmacology, the second, the clinical area.

The trainee is assumed to be a young physician who has completed two or more years of postgraduate clinical experience. He has no research experience and he has had no basic pharmacology since his medical school years. Variations of this background would permit adjustment in the trainees' program.

The first year in the department of pharmacology would include a research project supervised by a department member to give training in techniques and research methodology, a review of basic concepts by participation in course work and graduate seminars, courses in biometrics, and clinical pharmacology seminars. Essentially no clinical demands would be made on the trainee during this year.

The second year would be devoted to the development of a clinical research project, ideally one started at a basic level the first year. By concentrating on a specific clinical study the trainee can learn the details of complicated methodology related to his own study on patients. This also illustrates the requirements of a controlled clinical trial. By attending the clinical pharmacology clinic he learns of the progress and problems in other projects. The trainee is given the responsibility for answering requests for assistance on some drug therapy problems, e.g., drug reactions and poisonings. As a result of these roles the physician emerges as an experienced person who can relate effectively to the house staff in resolving issues of rational drug therapy throughout the hospital. Finally, by teaching, staff conferences, and during rounds he develops experience and confidence in the field of clinical pharmacology.

Obviously, this specialized training experience is adjusted to meet individual requirements and some trainees will become the drug therapy experts that are so badly needed. Others may prefer to
continue their medical careers in a medical specialty with board certification. It is equally obvious that it is impossible to train many clinical pharmacologists unless the present limited number of academic clinical pharmacology units is increased.
VI.  SOCIOECONOMIC COSTS OF DRUG THERAPY AS A PART OF DIRECT PATIENT CARE: NEEDS FOR RESEARCH

A.  THERAPEUTIC DRUGS

Recommendations to improve the quality of drug therapy in patient care will very likely include increased professional time. Realistic appraisals that recommend future contributions of the clinical pharmacologist must include an estimate of the potential costs of increasing the number of these highly-trained medical specialists and increasing the amount of physician patient care time. Superior drug therapy can be provided but the economic cost may be too great for most patients. Unfortunately, it is difficult to estimate the cost benefit ratio. If the cost could be determined by an appropriate study, then it must be decided who pays and how much. The high quality medical care that is deemed to be the right of the citizens of the United States may be costly but not necessarily prohibitively costly. Wisely conceived and skillfully consummated research can lead to programs that achieve the desired goals at a cost the economic system can support. These problems are broader than the issues of drug therapy. The potential contributions of clinical pharmacologists may impose economic constraints that may not permit achievement of ideals. Essentially these questions of socioeconomic costs apply to all the medical specialties (See Section VII).

It is assumed that clinical pharmacologists may reduce drug costs by demonstrating to the hospital staff that some lower cost drugs are equally effective therapeutically. He may help reduce costs by improving the effectiveness of a smaller hospital drug inventory. The clinical pharmacologist is the logical physician who does the clinical research that provides a valid basis for these savings. In addition, the clinical pharmacologist will be the investigator who proves the effectiveness and safety of a new drug - one that may make revolutionary changes in therapy, shorten hospitalization, and speed recovery from illness.

The report of the International Conference on Adverse Reactions Reporting Systems (National Academy of Sciences, 1971b) emphasized the need for an organized system to detect adverse drug
reactions in patients. It was suggested that a National Center for Drug Surveillance be established within the Office of the Commissioner of the Food and Drug Administration. The purpose of the center would be to measure the safety of the use of drugs by documenting at an early date adverse reactions not discovered in the preliminary animal and clinical investigations. As key individuals in patient care systems, clinical pharmacologists would have the major responsibility for intensive surveillance and reporting of these adverse drug effects. This system provides obvious opportunities to reduce the cost of medical care for large numbers of patients by increasing the efficiency of rational drug therapy and to develop early warnings of undesirable effects.

Epidemiologic evaluations of this character provide objective data on the quality of drug therapy. Good drug therapy is based on a dosage regimen which in turn is based on a clear understanding of pharmacokinetics. This is the best way to avoid adverse drug reactions (Vesell, 1972). Vesell emphasizes that studies of the genetic factors controlling major differences between individuals in rates of drug metabolism, will provide insight into the nature of these variations and furnish a more rational basis for drug administration. At the same time, this information would reduce the alarmingly high incidence of toxicity. Research of this kind will provide more adequate drug therapy, reduce adverse reactions that increase the days of hospitalization and the subsequent increased costs of health care (Laurence, 1966).

B. THE HOSPITAL ADMINISTRATOR

The effectiveness of the clinical pharmacologist in patient care will be influenced by the image he creates among his colleagues and the hospital administrators. The support of the hospital administrator is important because drug costs, personnel costs, service costs for private patients, and third party patient care payments are administrative aspects of direct patient care.

Among other aspects of the hospital administrator's role there is the major responsibility to keep costs manageable by developing new methods and utilizing personnel and equipment most efficiently. With increasing use of new techniques in drug therapy, e.g., drug blood levels, a paramount question arises as to who is to pay for this
increased accuracy of dosage evaluation that may be life saving. Sophisticated analyses of complicated biological data via computers may be required and these techniques also are costly. However, if the clinical pharmacologist can show that the treatment schedule reduces the period of morbidity and shortens the hospital stay, then the cost of the elaborate technology may in the final analysis, result in a reduction in the cost of an episode of illness.

There is an urgent need for studies to document these points. On the one hand, precise drug dosage for many drugs can only be based on pharmacokinetic studies; however, not all drug therapy requires this degree of dosage control. On the other hand, accurate yet simple analytical methods that can be applied in drug therapy, undoubtedly would reduce drug overdosage and yield more effective therapy. In the present health care system funds are available for most identifiable and necessary medical services. This is the basis upon which patient charges are established and thus serves as the foundation for reimbursable cost/charge ratios negotiated between third party payors (Blue Cross, Medicare, Medicaid) and the hospital. Hospital administrators may be persuaded that improved drug therapy for more patients is sound from an economic standpoint because it may reduce the aggregate costs of patient care.
VII. TOTAL MANPOWER NEEDS FOR DRUG THERAPY IN DIRECT PATIENT CARE

The emerging place of the clinical pharmacologist in the medical care system has required maturation time and like the other medical specialties, patient needs will ultimately determine the number, eminence, and prestige of these practitioners. The decreasing number of general practitioners engaged in private practice in the past 15 years in the United States and the increasing percentage of all physicians devoting their skills to one of the 19 recognized medical specialties, has resulted in fewer primary care physicians (Fein, 1967). The availability of many highly trained medical specialists will increase the quality of medical care for those relatively few patients who can afford and who can reach these experts. However, the multiple health care delivery problems are so great and numerous that the issues of cost, coordination, and access become overriding. Economies in the utilization of the limited skilled physician manpower are essential and the total manpower needs for rational drug therapy in direct patient care must be estimated. It may be possible for the clinical pharmacologist to provide adequate drug therapy for more patients by supervising the large number of paramedical personnel available to assist in this critical area of health care delivery.

There have been relatively few studies on the utilization of physicians' skills and time in the delivery of health care. Two reports have demonstrated that paramedical personnel can contribute significantly by sparing the physician and by enhancing the quality and quantity of medical care (Ginsberg, 1966; Lewis and Resnick, 1967).

Careful studies are required to measure the total manpower needs for rational drug therapy in all aspects of direct patient care. The complexities of this major task may be simplified by mounting a series of investigations, each directed to one aspect of the total issue. For example, reports have been published on the number of therapeutic drug users, their financial requirements, and related topics, such as patterns of drug therapy for group needs (Task Force on Prescription Drugs, 1968) and on laboratory control of drug therapy and drug surveillance in pediatrics (Børeus and Jalling, 1972; Lawson et al., 1972; McEvilla and Gainor, 1971).
These examples suffice to illustrate how the total manpower needs can be divided for analysis and study. Relatively few reports, however, have addressed manpower requirements per se. In this study the emphasis has been to demonstrate the requirements for adequate drug therapy for large numbers of patients, unmet needs, and how new approaches could be evolved. In general, prior studies have illustrated that there is poor utilization of medical and para-medical skills in terms of good quality drug therapy for health care. However, any system that can spare physicians and still maintain good quality and rational drug therapy is to be sought and developed.

The present trend to provide health care to patients without hospitalization through community health care centers is a significant new factor in the United States. Adequate drug therapy has been identified as one way to decrease the total demand for physicians' services (Fein, 1967). The rapid cure of infectious diseases by antibiotic therapy is an example. If some technique can be devised to utilize the talents of clinical pharmacologists in more widespread community health care programs, this would be a major contribution in terms of better drug therapy for more patients. Obviously, this can be achieved at present only through interaction of the clinical pharmacologist with his medical colleagues and by a corps of assistants. As noted in this report (Section IV, D) a few such programs have been developed successfully.

If should be noted that the studies to date have been based on data from patients treated in university hospital centers. No studies have been found that address the health needs in drug therapy for the large number of patients cared for in outpatient clinics, rural health centers and similar noninstitutional medical facilities.
VIII. FUTURE OPPORTUNITIES

A. RELATED TO HSMHA PROJECTIONS

As a result of this study several observations can be made that document the present medical care functions of clinical pharmacologists. These are:

- A major role in the drug therapy programs of those few hospitals that have clinical pharmacology units;
- Teaching and general educational responsibilities for students and other medical practitioners;
- Guidance for medical practitioners in the prevention and treatment of adverse drug reactions; and,
- The evaluation of new drugs and established drugs to assess their efficacy and hazards.

If the clinical pharmacologist is to be a recognized medical specialist, his salary and research funds must be provided through the same sources as for the other medical disciplines. Although token private grants or even chairs of clinical pharmacology established by the pharmaceutical industry are laudable and provide encouragement and critical finances in the formative years of the discipline, these will not yield the long-term financial support vital to a medical specialty. Recognition of the contributions of clinical pharmacologists to medical practice and essential health care by the medical community can best be demonstrated by providing within the medical school's budget the necessary funds for the discipline of clinical pharmacology. This form of recognition is pragmatic and related to the economic value of the clinical pharmacologists' contributions to health care. Unfortunately, the representative professional societies have not been successful in achieving national visibility so that this professional group can be so recognized.

Lasagna (1966) predicted that every medical school would very likely have the equivalent of a clinical pharmacology department
within five to ten years. He estimated that it might cost five million dollars a year to maintain these programs. Some experts believe these time and cost figures are grossly underestimated. The Task Force on Prescription Drugs (1969) in their final report recommended that the Department of Health, Education, and Welfare provide expanded support to enable medical schools to include a course in clinical pharmacology as an integral part of the medical curriculum. Contrary to this recommendation, training support has not been increased but has decreased and no specific plans have been proposed to assist the schools in developing these new courses.

The recommendation has been made to study the manpower and organizational guidelines necessary for adequate drug supply systems for group practice and HMO's (Knoben, 1972). It is proposed to establish demonstration projects to upgrade pharmacy services within group medical practice arrangements to include a highly developed drug utilization review program with a mechanism for comprehensive peer review. These approaches to reduction of patient cost through good central management imply adequate professional involvement to insure good drug therapy. It is unfortunate there is no provision for joint participation by the clinical pharmacologist with the clinical pharmacist in the proposed programs.

The research program of HSMHA includes studies to develop a data base on which to build improved therapy for disease, including drug therapy. This study found no reports that demonstrate a significant impact of the clinical pharmacologist on primary patient care or on drug therapy for nonhospitalized patients, e.g., patients in nursing homes or in "extended care units." Therefore, studies should be made to determine if it is possible to involve the clinical pharmacologist in drug therapy for these patients.

Objective evaluations should be attempted to prove that superior drug therapy as developed under the direction of a clinical pharmacologist will indeed shorten the period of hospitalization for most patients. It may be possible for the clinical pharmacologist to develop the criteria that permit an assessment of a cost-benefit study for drug therapy for all types of patients. Adverse drug reactions are but one aspect of drug therapy that increases the cost of health care. However, the proposed National Center for Drug Surveillance (Section VI) should be explored by HSMHA to determine the value of the concept.
Manpower needs must be evaluated by appropriate research to equate social change, requirements, and costs, and to develop a plan of why, where, and how the obvious goals may be reached, at least in part. The clinical pharmacologist is well qualified to meet his requirements as are clinical pharmacists and nurse specialists. Methods should be sought to prove the value of the numerous plans that have been proposed to meet the expectations of our society for more effective health care delivery. The concepts reviewed present more of a statement of the problems than suggested solutions. HSMHA could sponsor manpower studies to develop factual information related to present and projected health care needs.

B. RELATED TO SOCIETAL NEEDS AND EXPECTATIONS

At the present time there is national concern about the quality of health care. Great variability exists in the amount, type and caliber of health services provided in different regions of the country and in different hospitals and clinics. It is unfortunate that techniques to assess the quality of health care are inadequate or do not exist. Training qualifications for health care personnel are formalized by law but there are few evaluations of the outcome of health services (Lewis and Hassanein, 1970). On the other hand, the attributes of good drug therapy are known and criteria are available to assess the quality of this aspect of health care delivery. Indeed, the entire schedule of training of the clinical pharmacologist is attuned to this requirement. If the appropriate studies were made, the conclusions might justify the inclusion of clinical pharmacologists in many facets of the new health care plans suggested for the Nation (U.S. Senate, 1972). Analyses of this character may give clear indications of significant financial savings coupled with improved drug therapy in direct patient care.

It is remarkable that although so many reports have stressed the needs, so little has actually been accomplished to develop more viable programs to provide the specific services and advice the clinical pharmacologist can give. It is also surprising that more attention has not been paid to the Nation's needs for more efficient drug utilization at all levels of society. More research is required to develop new approaches to evaluate significant data on which to base future predictions and to undergird the present programs.
Sociologists point out that the need for improved drug therapy for more patients is not an absolute goal that can be achieved to everyone's satisfaction. What society expects and what is received is tinctured by many influences. United States citizens have very strong value expectations for health care. These may exceed their actual needs. The criteria for performance and expectations go up as the ability of the health care delivery system improves. This spiral is unending. We live in a world of endemic social pressures, and health care is but one of many. It is unfortunate that health care programs are more often conceived and directed by political decisions than by professional biomedical standards.

The proposed Health Maintenance Organizations (HMO's) now awaiting Congressional enactment, boldly direct that prescription drugs are to be used in a:

"...rational way with the appropriate and most efficient prescription drug preparation in a particular situation." 

The Senate Welfare Committee noted:

"In providing drug services, the Committee expects that the HMO will establish patterns of patient drug utilization, and will utilize the services of clinical pharmacologists, or pharmacists qualified to evaluate the appropriateness of drug usage within the HMO." (U.S. Senate, 1972.)

The Committee is strangely silent about where the clinical pharmacologists are to be found and no mention is made of training funds to provide the skilled physicians who must evaluate the proper and rational use of these drugs.

The medications are available for superb therapeutic achievements and clinical pharmacologists have demonstrated remarkable skill in applying them in medical practice. What is required is delivery of this same quality of medical care to more patients. The cost of this health care for everyone who requires it may appear excessive when estimated in dollars, manpower or medical resources. On the other hand, the benefits too may be calculated in terms of dollars, patient work productivity, or simply "good health." A cost benefit analysis should be attempted on the basis of the present programs to assess how much more might be justified in the immediate future.

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For example, the hospital administrator's role in keeping a hospital functioning is clear but he must search for new concepts to assist in the delivery of better drug therapy for more patients. It is impossible to analyze the costs and benefits of a clinical pharmacologist on a hospital staff if there is no financial opportunity to institute such a program. However, if a model program demonstrates that the services rendered by a clinical pharmacologist and other drug therapy assistants can reduce the number of hospitalization days, these savings will warrant fiscal support through medical care insurance programs.

New organizational units should be developed experimentally within a variety of hospitals. Clinical pharmacology may emerge as a service resembling other essential "hospital-based" medical services. Similar to diagnostic laboratories or radiological diagnostic and treatment services, a pharmacological unit could offer upon request, consultative services to patients and their physicians. It could serve as the authoritative arm of the medical staff to monitor and upgrade drug therapy within the hospital. Just as hospitals have established epidemiological units to control infection, so too should hospitals consider pharmacological units to educate and serve as the professional hospital resource in drug therapy.

From experimental studies conducted in large urban hospital centers where the facilities exist, it may prove possible to extend the concept to smaller medical care centers and institutions where no clinical pharmacologist is available.

Studies have attempted to document the scientific advances in medical care in terms of their benefits (Burch, 1972). As pointed out by Titmuss (1964) these evaluations need to be analyzed more fully in terms of some criteria of cost to benefit. Concrete and controlled studies are lacking and the use and misuse of drugs is one aspect of health care that lends itself to cost versus benefit analyses (Peterson et al., 1956). There are rare opportunities developing with the advent of new systems of organized medical care to implement innovative programs. These new systems will be financed by health care insurance plans. With convincing studies to support the concepts, the clinical pharmacologist may be able to play an unexpected yet key role in developing superior drug therapy programs for more direct patient care for all types of health care facilities.
IX. BIBLIOGRAPHY

American Association of Colleges of Pharmacy.
Clinical Pharmacy Education and Training Programs: A Special Report.

American Pharmaceutical Association.
Reprinted from Health Services Research and Development Briefs No. 4, 1971.

American Society for Pharmacology and Experimental Therapeutics.
This is the Profession of Pharmacology.
ASPET Brochure, Bethesda, Maryland, 19 p (not dated).

American Society of Clinical Pathologists.
The Registry of Medical Technologists of the American Society of Clinical Pathologists. Brochure.

Barber, B.
Drugs and Society.

Becker, M.H.; Stolley, P.D.; Lasagna, L.; McEvilla, J.D.; and Sloane, L.M.
Differential Education Concerning Therapeutics and Resultant Physician Prescribing Patterns.

Boréus, L.O.; and Jalling, B.
Laboratory Control of Drug Therapy in Pediatrics.

Brodie, D.C.
Drug Utilization and Drug Utilization Review and Control.
Burch, G.E.
Clinical Medicine.

Burroughs Wellcome Fund.

Carr, E.A., Jr.

Cluff, L.E.

Cluff, L.E.; Thornton, G.F.; Seidl, L.G.

Cluff, L.E.; Thornton, G.; Seidl, L.; and Smith, J.

Creasy, W.M.

Crout, J.R.
Academic Clinical Pharmacology and the University Medical Center. Pharmacologist 7: 82-85 (1965).
Department of Health, Education, and Welfare. 
Extending the Scope of Nursing Practice; A Report of the Secretary's 
Committee to Study Extended Roles for Nurses. 

Fein, R. 
The Doctor Shortage: An Economic Diagnosis. 

Feinstein, A.R. 
Clinical Epidemiology. I. The Population Experiments of Nature and 
of Man in Human Illness. 

Feinstein, A.R. 
Clinical Biostatistics. II. Statistics Versus Science in the Design of 
Experiments. 

Feinstein, A.R. 
Clinical Biostatistics. XV. The Process of Prognostic Stratification 
(Part 1). 

Feinstein, A.R. 
Clinical Biostatistics. XVI. The Process of Prognostic Stratification 
(Part 2). 

Garrison, G.E. 
Primary Medical Care: Its Provision Can Be Made Competitively 
Attractive to Physicians. 

Ginzberg, E. 
Physician Shortage Reconsidered. 

Goldberg, L. 
In: Conference on Human Pharmacology. C.W. Murphy and J.M. Parker, 
Herfindal, E.T.; and Levin, R.H.
Clinical Pharmacy Training in an Outpatient Clinic.

Hodgkinson, B.C.; Gowdey, C.W.; Coulter, W.K.; and Parker, J.M.
Drug Reactions and Errors in Administration on a Medical Ward.

Hurwitz, N.
Predisposing Factors in Adverse Reactions to Drugs.

Kinnard, W.J.
The New Educational and Professional Experience Programs of the
University of Maryland School of Pharmacy.

Knoben, J.E.
Pharmacy Practice in Group Medical Clinics.
National Center for Health Services Research and Development Briefs
No. 5; also DHEW Publication No. (HSM) 73-3002. Government Printing

Lasagna, L.
The Doctors Dilemmas.

Lasagna, L.
Clinical Pharmacology: Present Status and Future Development.

Laurence, D.R.

Lawson, D.H.; Shapiro, S.; Slone, D.; and Jick, H.
Drug Surveillance: Problems and Challenges.
Boston Collaborative Drug Surveillance Program of the Boston
University Medical Center.

Learoyd, B.M.
Psychotropic Drugs and the Elderly Patient.
Levin, R.H.
Clinical Pharmacy Practice in a Pediatric Clinic.

Lewis, C.E.; and Hassanein, R.S.
Continuing Medical Education - An Epidemiological Evaluation.

Lewis, C.E.; and Resnick, B.A.
Nurse Clinics and Progressive Ambulatory Patient Care.

Little, D.
The Nurse Specialist.

MacDonald, M.G.; and MacKay, B.R.
Adverse Drug Reactions: Experience of Mary Fletcher Hospital During 1962.

McEvilla, J.D.; and Gainor, M.
Drug Use Data: Assessment of Terminal Devices for Acquisition and Retrieval.

Medico-Pharmaceutical Forum.
A Report by the Forum's Committee on Clinical Pharmacology on Facilities for Early Clinical Studies of New Medicines.

Melmon, K.L.; and Morreelli, H.F., Editors.
Clinical Pharmacology; Basic Principles in Therapeutics.

National Academy of Sciences.
Application of Metabolic Data to the Evaluation of Drugs.
National Academy of Sciences.

National Academy of Sciences.

National Center for Health Services Research & Development.

Palmer, R.F.
Drug Misuse and Physician Education.

Pelikan, E.W., Chairman.

Pelikan, E.W.
Projections of Manpower Needs and Resources in Pharmacology.

Pellegrino, E.D.
The Changing Role of the Professional Nurse in the Hospital.
Hospitals 35: 56, 59, 60, 62 (December, 1961).

Peterson, O.L.; Andrews, L.P.; Spain, R.S.; and Greenberg, B.G.
An Analytical Study of North Carolina General Practice.

Pharmaceutical Manufacturers' Association Foundation, Inc.
Riker, W. F.
Comments of Walter F. Riker, Jr. to the National Advisory General Medical Sciences Council Meeting of March, 1968, National Institutes of Health, Bethesda, Maryland, 5 p (not published).

Saluly, R.; and Hopkins, C.E.

Schimmel, E. M.

Seidl, L. G.; Thornton, G. F.; Smith, J. W.; and Cluff, L. E.

Silver, H. K.; Ford, C. R.; and Day, L. R.

Slone, D.; Jick, H.; Borda, I.; Chalmers, T. C.; Feinleib, M; Muench, H.; Lipworth, L.; Bellotti, C.; and Gilman, B.

Smith, W. E.

Somers, A. R., Editor.
Stolley, P. D.; Becker, M. H.; Lasagna, L.; McEvilla, J. D.; and Sloane, L. M.
The Relationship between Physician Characteristics and Prescribing Appropriateness.

Stolley, P. D.; and Lasagna, L.
Prescribing Patterns of Physicians.

Talalay, P., Editor.
Drugs in Our Society.
Johns Hopkins Press, Baltimore, Maryland, 311 p (1964).

Task Force on Prescription Drugs.
The Drug Prescribers; Background Papers.

Task Force on Prescription Drugs.
Final Report.

Tilghman, R. C.
The Division of Clinical Pharmacology at Johns Hopkins and the Alan Bernstein Memorial Laboratories.

Titmuss, R. M.
Sociological and Ethnic Aspects of Therapeutics.

Todd, M. C.
National Certification of Physicians' Assistants by Uniform Examinations.
Tuve, T.  
Training Programs of the National Institute of General Medical Sciences, 1971-1980; Summary Report.  

U.S. Senate.  
Senate Labor and Public Welfare Committee Report on Bill S. 3327.  
92nd Congress (1972).

Vesell, E.S.  
Introduction: Genetic and Environmental Factors Affecting Drug Response in Man.  

Wilson, V.E.  
Services for Health: Goals, Programs, and Organization of Health Services and Mental Health Administration.  
HSMHA Brochure, Rockville, Maryland, October, 1970.

World Health Organization.  
Principles for Pre-Clinical Testing of Drug Safety.  

World Health Organization.  
Clinical Pharmacology; Scope, Organization, Training.  
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ON

THE STUDY OF THE ROLE OF THE CLINICAL PHARMACOLOGIST IN DIRECT PATIENT CARE

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