

The Kellogg Pharmaceutical Clinical Scientist Program: History and Development

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It was not until the last half of this century that the importance of the clinical effects of drugs and their relationship to pharmacy practice were given adequate consideration. Angaran and Elenbass have produced an annotated time line of important events in the development of clinical pharmacy, events that have served as stimuli to forward our knowledge of drugs and the pharmacist's utilization of drugs (1). The events included in this time line provide the background for the Kellogg Pharmaceutical Clinical Scientist Program.

In 1950 *The General Report of the Pharmaceutical Survey* was published. Better known in pharmacy as the Elliott Report, it was issued in 11 parts totaling over 1,100 pages (1). This document made sweeping recommendations for pharmacy practice and education and pointed out the need for mandatory accreditation of schools of pharmacy through the American Council on Pharmaceutical Education (ACPE); the need for stronger, full-time, adequately trained faculty at schools of pharmacy; the need for some standardization among individual state pharmacy acts; the need for improvements in the state board licensure examination process; and the need for better continuing education for pharmacists (1).

Of particular importance to our program was the recommendation for the development of a six-year program leading to a Pharm.D., such a program containing two years of general educa-

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tion and basic sciences and four years of professional study. Unfortunately, the American Association of Colleges of Pharmacy (AACCP) rejected the six-year Pharm.D. program as the sole entry-level professional degree, a mistake it would repeat in 1954 by the adoption of a compromised five-year B.S. in Pharmacy program and again in 1975 and 1985 by voting not to proceed to a single Pharm.D. program. This shortsightedness has slowed the development of a curriculum in all pharmacy schools that adequately prepares a pharmacist to deliver the pharmaceutical care needed in today's health care system. Nevertheless, two schools of pharmacy, the University of Southern California (1950) and the University of California-San Francisco (1954), adopted the six-year degree (two preprofessional plus four professional years) and thus became the first schools in the modern history of pharmacy education to offer the Pharm.D. The programs were not clinically-oriented at that time, however.

The 1951 Durham-Humphrey amendments created the current system of prescription and nonprescription drugs that severely restricted the pharmacist's autonomy and professional judgment by limiting the products that could be dispensed without a prescription (2). A year later (1952), though, the first poison control center was established by a pharmacist at Presbyterian-St. Luke's Hospital, in Chicago, followed in five years by a National Clearinghouse for Poison Control Centers created by the Department of Health, Education and Welfare (1, 3). A pharmacist was a member of the first clearinghouse staff. All colleges of pharmacy reported having a required pharmacology course (1953) (4). Reference was made by Dr. Rising at the University of Washington to the term clinical pharmacy, although with a different definition than is commonly used today (1953), and an adverse drug reaction program was implemented as a Food and Drug Administration pilot study with five hospitals to seek and report new, unpublished, and previously unrecognized adverse reactions not detected during preapproval testing of new drugs (1955) (5).

In 1957, Paul Parker noted that some hospital pharmacists (unidentified) had requested permission to accompany physicians as they visited patients in the hospital. He further stated that sometimes the pharmacist observed the hospitalized patient through the

entire course of the illness, seeing both the use and the effects of the drugs (6). About the same time, Francke noted an early recommendation that the hospital pharmacist be required to complete a six-year Pharm.D. program with a strong emphasis on the biological sciences (7). Bellafiore (1958) outlined the potential problems that pharmacists would have in filling the role of therapeutic consultant (e.g., lack of time, inadequate training, liability, no reimbursement) (8). He also commented that "the course in Pharmacy school must be revamped . . . to add human anatomy, human physiology, pharmacology and therapeutics." Brodie and Myers suggested (1961) that the hospital pharmacist should provide consulting services in the area of pharmaceuticals, pharmacology, and therapeutics (indications, equivalents, and comparisons) (9). "No greater contribution [could be made] to American Pharmacy than to develop a pattern for a truly consultive pharmacy practice."

In 1962, pharmacist Albert Ripley at the Indian Health Hospital in Crow Agency, Montana began filling out patient prescriptions directly from the patient's medical record. This system was eventually adopted throughout the Indian Health Service and led to incorporation of private patient consultation offices in almost all Indian health facilities where pharmacists could assess the patient's condition and provide counseling (1). Much later, in 1972, a pharmacist-practitioner training program was initiated at the Phoenix Indian Medical Center that included prescribing authority being given to selected pharmacists (1). This practice was further developed by Allan Brands and should have served as a model for other, similar practice sites, perhaps in the rural areas where physicians were in short supply. This did not occur and may be considered a lost opportunity.

Drug information centers were an important part of the changing role of the pharmacist. The University of Kentucky Medical Center established its drug information center in 1962 (1). Pioneered by David Burkholder, this formalized drug information service achieved interprofessional recognition of the pharmacist as an expert in the interpretation and application of the drug literature to resolve patient-specific problems, emphasizing that the pharmacist can handle knowledge and not just the product. Two years later, the American Society of Hospital Pharmacists (ASHP) sponsored a

Drug Information Conference at the University of Kentucky Medical Center. The conference was designed to stimulate interest, evaluate needs, and determine a program of action for providing drug information service centers in hospital pharmacy departments. The University of Kentucky and the ASHP followed this conference with an exploratory and planning conference on clinical drug communication services (1966) which, in part, outlined the responsibilities and requisite skills of the drug information specialist and identified the qualitative dimension of such services (10). At the same time, Donald E. Francke established the *Drug Information Bulletin*, which was published by the Drug Information Association. A year later he founded *Drug Intelligence*, later called *Drug Intelligence and Clinical Pharmacy* (1969), which helped to focus attention on clinical pharmacy as a special aspect of pharmacy practice (1). Dr. Francke was influential in shaping the philosophy of clinical pharmacy. The year 1969 also marked an increase in publications by pharmacists in selected pharmacy and medical journals (11). In 1970 Hartshorn first published the *Handbook on Drug Interactions*, followed in 1971 by Hansten's *Drug Interactions*, Wagner's *Biopharmaceutics and Relevant Interactions*, and *The Journal of Pharmacokinetics and Biopharmaceutics*, edited by Riegelman, Benet, and Rowland (1973) (1). Clinical pharmacokinetics laboratories were soon established at the State University of New York at Buffalo's Millard Fillmore Hospital (1972) and at Kansas City General Hospital by a joint pharmacy-medicine grant (1973) (1).

Documented patient medication profiles were introduced by White in 1960, bringing about a complete transformation of a typical corner drugstore into a professional pharmacy office (1). Evidence exists that this bold leadership was not followed by the profession. Some 30 years later we still have not sufficiently demonstrated the pharmacist's role in ambulatory care—especially the role of the community pharmacist—and provided the education needed to prepare pharmacists to deliver pharmaceutical care at an effective level in the various health care systems.

Medication errors in hospital studies by Barker and McConnell called attention to the need for a less error-prone system of drug distribution (12). This resulted in the development of the unit dose system (1963). This system allowed for intervention by the pharma-

cist in drug use control as developed and defined by Brodie in 1967 as "that system of knowledge, understanding, judgments, procedures, skills, controls and ethics that assures optimal safety in the distribution and use of medications" (13, 14). This became the central concept of clinical pharmacy. Dr. Russell R. Miller, as a member of the Boston Collaborative Drug Surveillance Program team, demonstrated early clinical pharmacist research involvement in a major pharmacoepidemiology program created to monitor adverse drug reactions (1). The movement toward clinical pharmacy accelerated with the "Ninth Floor Project" at the University of California-San Francisco. A satellite pharmacy providing 24-hour unit dose drug distribution was developed adjacent to the ninth floor nursing station of Moffitt Hospital. This brought the pharmacist into the patient care area so that he or she could function in collaboration with other health care professionals. The success of this project in delivering clinical pharmacy services led to major curricular changes at UCSF, and the project served as a model for pharmacy services across the country. The following year brought discussion of the health care team concept at the Pharmacy-Medicine-Nursing Conference at the University of Michigan (15).

In 1962, ASHP-approved hospital pharmacy residency accreditation standards resulted in the expansion of clinical training programs throughout the country, benefiting college of pharmacy faculties, and in the staffing of initial clinical services in hospitals. Thomas Jefferson University Hospital in Philadelphia was the first ASHP accredited residency in hospital pharmacy. One of the first descriptions of a clinical clerkship was published. Pharmacy students at Howard College (now Samford College of Pharmacy) "observed the effects of drugs on patients, discussed the advantages and disadvantages of various medications . . . and rendered an opinion . . . as to the relative merits of similar medications" (16). At the same time, Edward Pellegrino, M.D., of the University of Kentucky called on hospital pharmacists to recognize the loss of their dispensing role and the explosion of medical knowledge. He urged pharmacists to become involved in the pharmacy and therapeutics committee, evaluate drug efficacy, catalog drug reaction, provide poison control and drug information, and perform clinical research (17). Clinical education was reported by Dr. Charles Walton, one

of pharmacy's most eloquent and insightful leaders. In a comprehensive paper, Walton outlined the professional roles and requisite education and training of the clinical pharmacist (18). The National Center for Health Services Research and Development convened an interdisciplinary task force to draft a set of working criteria for the pharmacist's clinical role during Brodie's tenure there. This document provided an extensive description of the pharmacist in any health care setting (19). The ASHP/AACP invitational workshop (1970) on clinical pharmaceutical practice and education was part of a consensus building process between practitioners and educators that helped in the development of clinical pharmacy (20).

One additional force — government — influenced the development of the clinical pharmacist. This was accomplished through a number of legislative programs. Medicare Title XVIII and Medicaid Title XIX legislation in 1965 brought significant federal funds for expanding health services and increasing the number of health care providers. The following year, according to the U.S. Department of Health, Education and Welfare's "Conditions of Participation for Extended Care Facilities," extended care facilities were required to have a staff pharmacist, a consultant pharmacist, or a pharmaceutical advisory committee to qualify for Medicare reimbursement (21). The Health Manpower Act of 1968 (PL90-490) provided for institutional grants supporting pharmacy education (22). The Task Force on Prescription Drugs (Department of Health, Education and Welfare, 1969) recommended "training pharmacists to serve as drug information specialists on the health team" and that pharmacists be supported by the education of a class of pharmacist aides to take care of routine functions under pharmacists' supervision. This essentially remains an unresolved problem that the profession must act upon soon if it is to develop pharmaceutical care services. The very important, comprehensive Health Manpower Training Act of 1971 (PL-157) gave colleges "capitation grants for expansion of their undergraduate classes." Without the capitation grants, many schools of pharmacy would never have had the resources to accelerate their clinical programs. The enabling legislation and funding probably made possible the academic discipline of clinical pharmacy (22). Five years later, through the effectiveness of AACP, the Health Professions Educational Assistance Act passed (PL94-84).

The act mandated that clinical training be provided in colleges of pharmacy in order for those colleges to receive government assistance (22). While this list is not complete, these were some of the most important contributions that were moving pharmacists from a mundane distribution practice toward a role as specialists in drug use control.

A group within AACP recognized the need to do an in-depth study of the pharmacy profession. Responding to the recommendation and challenge laid down by President Dr. Arthur E. Schwarting in an address in 1971, the AACP took prompt steps to consider and implement a careful external examination by the Study Commission on Pharmacy, fondly known as the Millis Commission after Chairman John S. Millis (23). In his preface to the study, Dr. Millis noted that:

Pharmacy has not been oblivious to the criticism and questioning of the health service system which has been so evident in the United States during the past ten or fifteen years. There has been criticism of drug related services from both without and within the profession of pharmacy. A number of leaders of Pharmacy education have urged the necessity of an external examination of the state of the practice and education of pharmacists, recognizing the vast changes which have occurred in biomedical knowledge and the expectations and demands of the public.

The Study Commission devoted more than two years to the examination of the practice of pharmacy as an integral part of the health services system and to examination of the process of pharmacy education.

The recommendations of this Study Commission on Pharmacy stimulated Dr. Albert I. Wertheimer to propose that the Department of Social and Administrative Pharmacy at the University of Minnesota College of Pharmacy undertake the development and implementation of a model program for the training of the clinical scientist envisioned by the Millis Commission. Thus it is important that we consider those persons involved in the commission, the structure

of the commission, its leadership, the study, and the commission's findings and recommendations (23).

An *ad hoc* committee consisting of Drs. Schwarting, John A. Biles, Jere E. Goyan, George Hager, William J. Kinnard, Jr., and Charles W. Bliven (*ex officio*), did the initial consultation with leaders in all areas of the pharmacy profession about the need for the study, who should serve on the commission, and who should be its chairman. Because of his past experience with similar studies, Dr. John S. Millis was selected as chairman. Due to the efforts of several persons then involved in responsible roles in AACP, Dr. Millis finally accepted the leadership role. The Study Commission on Pharmacy was composed of prominent leaders in pharmacy education, pharmacy practice, the pharmaceutical industry, medical education and practice, nursing, and higher education. There were about 80 consultants who met formally with the commission and many more who gave their input on a direct, informal basis. It was one of the most important studies of pharmacy ever conducted. The AACP Advisory Committee for the Study Commission on Pharmacy consisted of Drs. Bliven, Goyan, Kinnard, and Schwarting from the original *ad hoc* committee and myself, *ex officio*.

The report of the commission became available in December 1975. Fourteen recommendations were made, three of which have direct application to the Kellogg Pharmaceutical Clinical Scientist Program. They are Recommendations 2, 3, and 10.

Recommendation 2. "The Study Commission advances the concept that pharmacy should be conceived basically as a *knowledge system* which renders a *health service* by concerning itself with understanding drugs and their effects upon people and animals. Pharmacy generates knowledge about drugs, acquires relevant knowledge from the biological, chemical, physical and behavioral sciences; it tests, organizes and applies that knowledge. Pharmacy translates a substantial portion of that knowledge into drug products and distributes them widely to those who require them. Pharmacy knowledge is disseminated to physicians, pharmacists and other health professionals and to the general public to the end that drug knowledge and products may contribute to the health of individuals and the welfare of society." This may well have been the most important recommendation made by the commission. It supports

the activities considered important in the development of the clinical pharmacist concept. It brings together those various strengths that support the drug use control roles of the pharmacist.

Recommendation 3 states: "The Study Commission believes that a pharmacist must be defined as an individual who is engaged in *one of the steps of a system called pharmacy*. We cannot define a pharmacist simply as one who practices pharmacy. Rather, he must be defined as one who practices a part of pharmacy which is determined by the activities carried on in one of the subsystems of pharmacy. A pharmacist is characterized by the common denominator of drug knowledge *and the differentiated knowledge and skill* required by this particular role." The importance of this recommendation is that all pharmacists are different. While they may have a common body of knowledge about drugs, pharmacists fulfill their particular roles by adding to this core of knowledge and skill from other sources. It becomes most apparent when the pharmacist specializes.

It was Recommendation 10 that presented the challenge that Dr. Wertheimer chose to address: "It is the opinion of the Study Commission that the greatest weakness of the Schools of Pharmacy is a lack of an adequate number of *clinical scientists* who can relate their specialized scientific knowledge to the development of the practice skills required to provide effective, efficient, and needed patient services. The Study Commission recommends that support be sought for a program to train a modest number of clinical scientists for pharmacy education." It was Dr. Wertheimer's belief, and he convinced others, that the Department of Social and Administrative Pharmacy in the University of Minnesota College of Pharmacy was capable of experimenting with the development of a program to meet the needs expressed by the commission — "one can envision a program to give a hundred or more well-trained pharmacy practitioners the opportunity to acquire deeper scientific knowledge, the skill of rigorous research, and broadened understanding of the management and the control of disease."

It was immediately apparent that guidance and perspective from other sources would be valuable to the success of the project. The natural first step was to ask Dr. Millis to chair this group. He agreed to do so, and we were quite pleased because he knew the complete

workings of the original study commission and was knowledgeable in this realm, in pharmacy as well as in other professions. A physicist by education and subsequently a medical educator, university chancellor, and Director of the National Fund for Medical Education, Dr. Millis was widely regarded as one of the most brilliant and insightful thinkers of the day. Dr. Paul B. Batalden, a pediatrician and then Director of the Health Services Research Center at the St. Louis Park Medical Center, was asked to serve as a project co-director. He had extensive experience in program evaluation endeavors.

With the assistance of Millis and Batalden, the remainder of the advisory group was assembled. Each member was selected for his personal traits, accomplishments, and affiliations. Dr. Leighton Cluff, then Vice President of the Robert Wood Johnson Foundation of Princeton, New Jersey was invited to serve as a member. A physician and foundation officer, Cluff's medical qualifications enabled him to anticipate the reaction of the medical community to our products, and his foundation experience gave him a wealth of knowledge about the characteristics of successful projects and change agents. As with Dr. Millis, we were never in doubt about our choice, as Dr. Cluff was generous in contributing his opinions and ideas.

As Dean of the University of Minnesota College of Pharmacy at that time, I was invited to participate. Perhaps this was a politically wise step, but the invitation was not intended as a charitable act. I had distinguished myself as a pharmacologist in industry and as a visionary in pharmacy education. As President of the American Association of Colleges of Pharmacy, I participated in establishing the study commission and in persuading Dr. Millis to direct it. I also participated in the fund raising. Later, I served as a consultant to the commission and testified before it.

Mr. Jerome Halperin was, at the time, the Acting Director of the Bureau of Drugs of the U.S. Food and Drug Administration. Halperin was a pharmacy graduate who subsequently earned a M.P.H. degree. As a frequent and eloquent speaker at professional meetings and as a thoughtful contributor to the literature, his perspective from the regulatory scene was thought to be valuable. It turned out that his contributions came from his perspective, of

course, but also from his fertile thinking and analytically-based opinions and projections. Mr. Halperin recently assumed the position of Executive Director of the U.S. Pharmacopeia, and we know that he will take it to new heights of achievement.

When we asked who from the higher echelons of the pharmaceutical industry might be interested in assisting with this endeavor and who would be our optimal choice, the same name surfaced repeatedly. To our great satisfaction, we were able to obtain a commitment from Mr. Lawrence C. Hoff, then Vice President and, later, President of the Upjohn Company. Mr. Hoff was an economist who had spent over 30 years in the pharmaceutical industry, all of it with Upjohn. He proved to be a phenomenal judge of character and had a feel for making wise decisions. He continually amazed us by his deep knowledge in areas in which we had expected him to have no familiarity.

The closest role model to a clinical scientist already in practice was Dr. Gerald Schumacher, Dean of the College of Pharmacy at Northeastern University. Dr. Schumacher had earned a Ph.D. and was a clinical pharmacist who later continued his studies, earning a Ph.D. in pharmaceutics. Professor Schumacher was a valuable member of the group, always calling us to task and asking whether the options we were debating were sufficiently rigorous.

The advisory group worked with the project codirectors, Dr. Albert Wertheimer and Dr. Paul Batalden, via the mail, telephone, and annual in-person meetings. The panel created policy, guided the codirectors, and evaluated performance. In addition to these roles, all members gave generously of their time to the fellows and staff who needed advice about virtually anything. The panel reviewed the progress of each fellow and provided technical suggestions as well as employment guidance. In large part, what we hope will ultimately be seen as a successful venture is due to the considerable involvement of an outstanding national advisory committee.

The goal of the program was to produce clinical scientists in pharmacy. It was designed to give "well trained pharmacy practitioners the opportunity to acquire deeper scientific knowledge, the skills of rigorous research, and broadened understanding of management and control of disease" (23). The graduates should fill important places on pharmacy faculties and leadership positions in a

variety of potential careers in recognized and unrecognized areas related to pharmacy.

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