

# **Central Issues Relevant to Clinical Pharmaceutical Scientist Training Programs**

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and Patricia D. Kroboth, Ph.D.

# ACCP White Paper

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Over the past two decades a number of papers, letters, and editorials have articulated the need to develop pharmaceutical clinical scientists.<sup>1-7</sup> The Millis Commission report played a critical role in bringing attention to this issue by advocating that pharmacy initiate programs directed at meeting this need, with the "clinical scientist" envisioned as being equally skilled and trained in science and practice.<sup>1</sup> The authors of that report chose not to elaborate on either a formal definition of clinical scientists or the methods to develop such individuals. Nevertheless, the Millis Commission was clearly advocating the development of training programs which integrated science and the direct application of science to pharmacy problem solving.

The value of this integration was recently echoed by reflecting on the words of Pasteur, who said, "there does not exist a category of science that one can designate as 'applied science.' There are science and the applications of science, bound together as the fruit to the tree which it bears."<sup>8</sup> Pharmacy is only beginning to appreciate the value of Pasteur's words.

After the Millis Commission report appeared, a number of schools of pharmacy independently initiated programs to develop pharmacy-based clinical researchers. The majority of these early programs were linked to post-Pharm.D. residency or fellowship programs of one to two years' duration. Recently, fundamental differences between residency and fellowship programs have been recognized, and post-Pharm.D. fellowships have become the more acceptable method for preparing clinical researchers for pharmacy. This is analogous to the approach medicine has utilized for training clinical researchers. To date, a few

graduate programs in pharmacy have been developed in the clinical pharmaceutical sciences as a further attempt to formalize the training of clinical scientists.

Clinically oriented research programs in pharmacy initially evolved through the efforts of individuals conducting research in pharmacokinetics. These people were often members of departments of pharmaceuticals or medicinal chemistry who conducted research in animals and humans. The initial sites for the development of these programs were closely correlated with departmental strengths in pharmacokinetics. As the discipline of clinical pharmacy grew during the 1960s and 1970s, clinical pharmacists began making significant contributions to the growth in knowledge of drug disposition, particularly with regard to specific drug entities, drug interactions, and special populations. These researchers often had their roots in basic science disciplines, such as pharmaceuticals or pharmacology, and frequently were members of interdisciplinary and multidisciplinary research teams. Although a few of them emerged from this period as recognized, independent clinical scientists, there was little in the way of formal research training to develop and cultivate more of such individuals.

Over the past 10 years a maturation in clinical pharmacy programs has stimulated considerable interest in postgraduate research training. Residency programs evolved and incorporated opportunities for interested individuals to acquire introductory skills in clinical research methodology. These soon gave way to one- and two-year fellowships as the primary vehicle for training clinical pharmacy researchers. This evolution was motivated by the desire to prepare people who were capable of independent research. This resulted in longer fellowships and diversification of research interests. The focus was no longer solely on the discipline of pharmacokinetics, but included more general therapeutic and pharmacologic

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issues. Consequently, a healthy mixture of research in clinical pharmacy developed ranging from efforts in molecular biology, pharmacodynamics, clinical efficacy, clinical toxicology, biotechnology, and pharmacometrics to the more traditional drug disposition-disease state studies. These programs developed principally on the basis of individual effort with only minimal organized support from pharmaceutical organizations, academic groups, or patientcare institutions.

Although post-Pharm.D. fellowships now serve as the primary mechanism for training clinical pharmaceutical scientists, a few graduate programs are emerging as an alternative. Some schools have master's degree programs that provide structure to postgraduate training of clinical scientists. A few institutions offer Ph.D. degree programs that emphasize the integration of clinical and basic research interests. This is in contrast to traditional Ph.D. programs (e.g., pharmaceuticals, medicinal chemistry) which may attract clinically trained individuals into their research programs. These programs often lack a clinical emphasis, and the graduates tend to ally themselves more closely with basic research than with clinical endeavors. Consequently, these students ultimately become a product of their most recent past.

Despite significant progress in stimulating the development of programs for clinical pharmaceutical scientists, much remains to be done. The quality of fellowships varies between preceptors and institutions. Clinical fellows often lack the fundamental knowledge to embark immediately on an independent research project and the time to probe sufficiently deeply into the hypothesis being tested. Unlike postdoctoral fellows from other disciplines who enter fellowships to broaden their abilities to apply the tools and research knowledge from their graduate work, the Pharm.D. postdoctoral fellow seeks experiences to develop, usually for the first time, hands-on, experimental (laboratory and/or clinical) research skills.

Graduate programs in the clinical pharmaceutical sciences are not without their detractors. Some would say they are unrealistic and too long to attract a sufficient number of quality students. Others argue that they are merely new packaging of traditional graduate programs and lack a significant clinical focus. Despite these concerns, the ideals of both clinical fellowship and graduate training programs in the clinical pharmaceutical sciences should be strongly supported. Subsequent discussion principally focuses on these two training initiatives as the most likely mechanisms for developing clinical scientists for the profession of pharmacy.

Before a profession takes on the many challenges of developing new training initiatives, it must first understand, translate, and articulate a societal and/or professional need. At that point, the profession must develop appropriate strategies and

programs to respond to such needs. In other words, clinical pharmaceutical scientists should be trained because they possess the potential to make a unique and valuable contribution to society as well as to the pharmaceutical-medical scientific community. Society is the ultimate driving force behind these new program initiatives as it continues to demand safe, effective, cost-efficient, state-of-the-art medical care despite concerns over health care costs.

The clinical pharmaceutical scientist represents a new and emerging individual whose evolutionary development closely coincides with a need within our profession. Opportunities have emerged for such highly trained scientists in academia, industry, and government to minimize the gap in clinical research between the development of drug therapies and issues of safety, efficacy, and efficiency. In addition, the clinical pharmaceutical scientist represents a tremendous opportunity for pharmacy to enhance its contribution of new knowledge to the biomedical community.

Five primary and two secondary issues are worthy of further discussion by the pharmacy community relative to the continued development of programs to train clinical pharmaceutical scientists.

### Central Issues

1. What is the definition or description of a clinical pharmaceutical scientist and how is he different from other highly trained health care-oriented research professionals? \*
2. What is the market for these highly trained individuals?
3. How is our profession currently training clinical scientists?
4. What critical components should make up the training of these scientists?
5. How should these programs be structured and implemented to meet the future needs of our profession?

### Secondary Issues

1. How will these programs compete for quality postdoctoral fellows and students?
2. How will these training initiatives be supported?

### Review of Central Issues

*What is the definition or description of a clinical pharmaceutical scientist and how is he different from other highly trained health care-oriented research professionals?*

The term clinical pharmaceutical scientist needs clarification but not necessarily definition. Defining this term now will tend to restrict its continued

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\*Throughout this paper the masculine pronoun is used to connote individuals of either gender.

evolution. According to Levy, "this term will be defined by the activities of those we consider to be (and those who see themselves as) clinical pharmaceutical scientists."<sup>9</sup>

Functionally, a clinical pharmaceutical scientist can be considered a pharmacy-trained specialist who independently derives new knowledge through observation, study, and experimentation that is focused on drug therapy outcomes in patients, and the factors and mechanisms determining those outcomes. In most cases this individual maintains contact with the patient care environment sufficient to ensure his continued awareness of clinical problems and clinical relevance. He may become involved in research of a very basic nature, but a key distinction remains his knowledge of clinical pharmacy.

It is important to consider those characteristics which make this pharmacy-trained clinical scientist distinct from graduates of existing pharmacy and medicine programs, and to identify the background (basic and clinical knowledge, laboratory and clinical experiences) expected of this individual. He should be different from the Ph.D. in pharmaceuticals, medicinal chemistry, or pharmacology because of his background in pathophysiology and pharmacotherapy, and direct experience with patient care. In addition to this broad clinical base, he must possess the capability to develop a research focus that can sustain a vertical investigation of a relevant aspect of biomedical science. His research arena may be entirely laboratory based, clinic based, or a mixture of the two.

The characteristics that would distinguish a pharmacy-trained clinical scientist from an M.D. or M.D.-Ph.D. clinical pharmacologist are his training in the pharmaceutical sciences (e.g., product formulations, bioavailability issues, diversity of drug products and devices, pharmacokinetics, etc.) as well as his interest in pursuing problems principally related to drug therapy. His training in medicine is considerably less, particularly with regard to diagnostics and nonpharmacologic therapeutic modalities, but his overall knowledge of pharmacotherapy should equal or surpass that of the medically trained clinical pharmacologist.

Consideration should be given to the appropriate descriptor for the clinical scientist or clinical pharmaceutical scientist. These terms may not adequately describe the type of scientist being educated. On the surface, it appears that these names are too broad, and fail to connote the credentials or expectations of this scientist. In addition, it is important for this descriptor to be distinguishable from scientists in the traditional pharmaceutical sciences. Pharmacy must also be concerned with the potential conflict with other disciplines, such as clinical pharmacology, within the medical community.

#### Recommended Actions

1. Clarify the scope of the training initiatives in the clinical pharmaceutical sciences.
2. Identify priority areas (e.g., pharmacoeconomics, clinical pharmacology, pharmacoepidemiology, etc.) in need of development.
3. Evaluate and clarify the term clinical pharmaceutical scientist with due consideration of organizational politics.

#### *What is the market for these highly trained individuals?*

It is currently unknown what the true market is for the clinical pharmaceutical scientist. There appear to be tremendous opportunities in both industry and academia for such individuals with a training emphasis in clinical pharmacology (extensive training in pharmacokinetics and pharmacodynamics with direct application to a specific therapeutic modality). It is unclear whether this perceived need is the consequence of difficulties in M.D.-Ph.D. training programs.

#### Recommended Actions

1. Survey industry and academia regarding career opportunities for the clinical pharmaceutical scientist in both basic and clinical units, particularly in the area of clinical pharmacology. Special attention should be directed toward assessing the opportunity these scientists have to develop an independent, competitive research program within a college of pharmacy clinical unit.
2. Identify and set priorities for other areas of emphasis (e.g., pharmacoeconomics, pharmacoepidemiology), and survey industry and academia regarding career opportunities.
3. In light of the problems associated with M.D.-Ph.D. programs in clinical pharmacology, investigate the difficulties in these programs and determine what it is that pharmacy should do differently to avoid the same pitfalls and failures.

#### *How is our profession currently training clinical pharmaceutical scientists?*

Postdoctoral fellowships and graduate programs are presently available for training clinical pharmaceutical scientists. Certainly, the majority of these scientists are self-trained or products of such fellowships. Pharmacy professional organizations should continue to support the further establishment of post-doctoral fellowship programs and graduate program initiatives committed to developing competitive clinical pharmaceutical scientists. Although such programs have similar intentions (i.e., to train highly skilled clinical pharmaceutical scientists), the training and experiences as well as advantages and disadvantages are far from similar.

Clinical fellowships provide the trainee with an opportunity to develop specific research skills

within the context of an established clinical research program. They enable the student to focus immediately on his research interests without committing a large portion of time to the classroom. A fellowship experience can take on a structure and character compatible with the training and educational goals of the preceptor while providing the student with the opportunity to have a significant influence on the design of the program. This allows the fellow considerable flexibility regarding the nature of the experience (i.e., choice of laboratory or clinical project) as well as access to graduate-level didactic courses. This format provides an efficient mechanism for clinically trained individuals to acquire specific research tools.

Most good fellowship programs require a two- or three-year commitment. Since they traditionally provide the fellow with the opportunity to remain in the clinical arena, the trainee tends to seek out career opportunities that include clinical activities. Considerable variability exists in the depth and breadth of didactic and research experiences provided by different fellowship programs.

Graduate degree programs offer an alternative mechanism for training clinical pharmaceutical scientists. They provide a greater degree of structure in both didactic courses and research than does the typical fellowship. They also undergo intense college and university scrutiny, requiring program justification and a critical mass of scientists in the area of degree concentration. Students are required to work through a formal committee system and meet with the committee's approval prior to program completion. They must demonstrate through didactic course work and experiences their depth and breadth of knowledge in both the pharmaceutical sciences in general and in their area of research focus. Students must demonstrate the ability to function as independent investigators. This format provides them with a universally accepted credential (the Ph.D. degree) to carry with them throughout their professional career.

An important element of graduate programs is the benefit of interacting with peers. These programs require a suitable critical mass of students and faculty who have some commonality in background and purpose, but who possess some scientific diversity. The learning and challenging that take place in the laboratory and in discussions within a research group or at departmental seminars become central to the educational process and sharpen the self-critical skills so important in research. Both can exist in good postdoctoral clinical fellowship programs, giving fellows the opportunity to interact with graduate students in the basic sciences and with other fellows.

Graduate programs in the pharmaceutical sciences have generally been limited to traditional

training in pharmaceuticals, medicinal chemistry, pharmacology, or pharmacy administration, and are only beginning to recognize the need to educate highly trained clinical scientists. The difficulty in developing such programs within many of our schools of pharmacy is principally due to environmental conditions. These programs must be closely integrated between basic and clinical academic units, and highly focused to capitalize on institutional resources and strengths. It takes academic institutions considerable time to respond to the growing market demand for this product because it takes several years to develop new graduate program initiatives within the framework of a university or college structure. In addition, most students require four to six years to complete traditional graduate studies in the pharmaceutical sciences. It is easy to appreciate why fellowship programs have been so successful in responding to society's need for highly trained clinical scientists. Therefore, the development of new programs in clinical pharmaceutical science will likely be restricted to selected university-based centers.

#### Recommended Actions

1. Survey schools of pharmacy and other academically affiliated institutions regarding the availability of both fellowship and graduate programs relative to the training of clinical pharmaceutical scientists. A description of program structure and requirements should be obtained.
2. Inform and initiate a dialogue with those organizations currently supporting training programs in the biomedical area (e.g., American Foundation for Pharmaceutical Education, Pharmaceutical Manufacturers Association, National Institutes of Health, the pharmaceutical industry), with the goal of increasing support for these new program initiatives.
3. Articulate the differences between a clinical pharmaceutical scientist (as developed in this report) and a clinical faculty person with research training (e.g., an individual with broader interests in clinical teaching, service, and research). A comparison of training requirements and job expectations should be considered.

*What critical components should make up the training of these scientists?*

The components outlined below apply to both fellowship and graduate program initiatives for producing highly trained, independent clinical pharmaceutical scientists.

#### *Institutional*

Clinical pharmaceutical scientists will be trained in selected institutions. Institutions possessing a critical mass of faculty or collaborators in a focused area of emphasis, working in a highly integrated environment

that provides clinical and basic science resources, will have an advantage in developing such program initiatives. The emphasis (e.g., clinical pharmacology, pharmacoepidemiology, pharmacoconomics) of the program will principally reflect these institutional strengths. These programs require a fertile intellectual environment, with scholars capable of establishing a mentor relationship with the fellow or student. The mentor should be an established investigator with the potential to fund and direct clinically oriented research projects.

#### *Program Prerequisites*

Fellows or students entering into a clinical pharmaceutical science program should possess a solid knowledge base in the areas of pathophysiology, therapeutics, clinical pharmacokinetics, and statistics. In addition, they should enter into such a program with a sufficient amount of clinical experience to give them a perspective toward identifying clinical problems. To provide the best possible opportunities for the fellow or student, the program should build on this base of experience. In general, the Pharm.D. degree should be the minimum standard for entry into the program. Although additional residency training may be advantageous (as recommended by most association-sponsored clinical fellowship programs in pharmacy), it may not be required for all postdoctoral fellowship or graduate programs.

There has been considerable discussion about developing combined Pharm.D.-Ph.D. graduate programs in order to enter students more rapidly into traditional graduate programs. This approach has been endorsed as a means to minimize the negative impact that universal adoption of the entry-level Pharm.D. is expected to have on graduate student recruitment.

Although this approach may be a viable mechanism to improve the recruitment of pharmacy students into traditional graduate programs (e.g., pharmaceuticals, medicinal chemistry), it would likely compromise the prerequisites for the clinical pharmaceutical science program. Students would be encouraged to opt out of clinically oriented didactic and clerkship experiences so as to devote more time to graduate work. However, students entering the clinical pharmaceutical science program need these didactic and clerkship experiences to meet program expectations.

It may be possible to utilize the B.Sc. degree in pharmacy as a precursor to the development of the clinical pharmaceutical scientist.<sup>10</sup> This requires students simultaneously to have as part of their graduate program, clinical and basic didactic course work as well as clinical clerkship experiences.

#### *Program Requisites*

Didactic course requirements are likely to vary among programs and according to each program's

area of emphasis. Most experience is based on training clinical pharmaceutical scientists with emphasis in clinical pharmacology (e.g., pharmacokinetics and pharmacodynamics). It must be emphasized that clinical pharmaceutical science programs should not be limited to this one area of emphasis. Regardless of the area of emphasis, however, several common program elements should be present in most of these initiatives.

#### *Didactic Requirements*

The fellow or student should acquire a broad knowledge in his program emphasis area as well as his primary area of research. Specific course requirements will be based on both areas.

In addition, the fellow or student should be expected to demonstrate competence in his area of emphasis. Generally, he will meet this requirement by participating in professional or graduate-level courses, discussion groups, seminars, and research activities. Although these opportunities are readily available to both fellows and graduate students, a well-structured graduate program offers the greatest assurance that these expectations will be adequately met.

Finally, clinical experiences in the form of involvement with the patient care environment should be incorporated into the student's or fellow's education.

#### *Research Requirements*

It is important that the fellow or student be in an environment with a viable research program. He should have at his disposal the necessary tools to permit him to test his research hypothesis appropriately. The well-trained clinical pharmaceutical scientist must leave this research environment with the contemporary tools of his area of emphasis. An appropriate project that blends fundamental analytical principles with clinical problems is essential to the development of an independent, competitive clinical investigator. A sufficient amount of time is necessary for the fellow or student to acquire the depth and breadth of understanding necessary to probe his research hypothesis sufficiently. This aspect of training often differentiates one fellowship program from another. Graduate programs are probably less sensitive than fellowships to time restraints and are more likely to meet this expectation.

#### *Recommended Actions*

1. Interested pharmacy organizations should reevaluate existing guidelines for fellowship programs and identify the components critical to training clinical pharmaceutical scientists.
2. A forum should be provided for institutions and mentors who have established contemporary fellowship and graduate programs in the clinical pharmaceutical sciences to present and/or publish descriptions of their programs for public

review and discussion.

3. Interested pharmacy organizations should reevaluate "Definitions of Pharmacy Residencies and Fellowships" and "Guidelines for Clinical Fellowship Training Programs." This reevaluation should specifically focus on training program requirements and should consider a fellowship of two years' duration the minimum acceptable experience.
4. Identify important areas of research emphasis relevant to clinical pharmaceutical scientists; define the minimum knowledge and experiential base required for each of these areas; and define the minimum amount of time necessary to demonstrate competence in these areas.

*How should these programs be structured and implemented to meet the future needs of our profession?*

Both fellowship and graduate programs will continue to be the major suppliers of scientists in the foreseeable future. The guidelines outlined above should serve as a starting point for the development of program requirements. It should be apparent from these guidelines that all environments will not be well positioned to mount competitive programs. The impact on the profession at large of immediately implementing such guidelines should be assessed.

The continued movement toward adopting the Pharm.D. as the only entry-level degree in pharmacy may significantly affect the nature and quality of clinical pharmaceutical scientist training programs, in that the degree is generally considered a minimum prerequisite for admission to these programs. If widespread implementation of the entry-level Pharm.D. results in a degradation of standards, the qualifications of future Pharm.D.s for research training would be negatively affected. On a positive note, the adoption of the entry-level Pharm.D. could create new job opportunities for clinical pharmaceutical scientists in our colleges and schools of pharmacy.

#### Recommended Actions

1. Assess the impact that the movement to the universal entry-level Pharm.D. degree may have on (a) the quality and number of future applicants to clinical pharmaceutical scientist programs; and (b) the future job market for clinical pharmaceutical scientists and clinical faculty with research training.
2. Assess the need to establish faculty development programs leading to clinical scientists or clinical faculty with research training.

#### Review of Secondary Issues

*How will clinical pharmaceutical science programs compete for quality fellows and graduate students?*

Recently, the American Association of Pharmaceutical

Scientists reviewed several problems facing graduate education in the pharmaceutical sciences.<sup>11</sup> Although directed principally at traditional graduate programs, many of the issues raised appear relevant to programs in clinical pharmaceutical science. Pharmacy educators and researchers must take a more active role in identifying and encouraging quality pharmacy undergraduate students to pursue careers in the pharmaceutical sciences. This process should start as early as possible in a student's life. Pharmacy must work harder at informing its students of the career opportunities in science. Most important, traditional basic and newer clinical science programs should cooperatively exist with one another and should not be viewed as hostile competitors. Initiatives in the clinical pharmaceutical sciences should be viewed as a positive step in providing our students with additional career opportunities.

*How will these training initiatives be supported?*

Funding of training programs is principally the responsibility of the institution and the preceptor. However, support for clinical pharmaceutical scientist programs should be sought through training grants from the American Foundation for Pharmaceutical Education (AFPE) and the National Institutes of Health (NIH). Although funding for training grants from NIH has not increased substantially over the past few years, there appear to be opportunities in selected areas (i.e., clinical pharmacology) at both the pre- and postdoctoral levels. A challenge for pharmacy is effectively to convince agencies like NIH to recognize the Pharm.D. degree as an appropriate precursor for graduate education in the area of clinical pharmacology.

In addition, pharmacy professional organizations currently supporting research projects and fellowships should carefully reassess their priorities. The following of questions should be addressed:

1. What emphasis areas should be funded?
2. Fellowships are being supported for only one year. How can additional funding be acquired to extend these to two or three years?
3. Can more significant support be provided to fewer investigators for any given year? Can the various sponsors of these research grants and fellowships be convinced to provide additional support without namesake recognition? Funding research training programs will always be a challenge for pharmacy. It should be recognized that it is likely to cost more to train scientists in the clinical pharmaceutical sciences than in the traditional pharmaceutical sciences because of the need to integrate basic and applied research activities into the programs.
4. How will the quality of clinical pharmaceutical scientist programs be controlled and monitored? This question is a most important and

controversial one which should be seriously considered once general agreement is reached regarding the ideal structure for training clinical scientists.

This document was prepared by a subcommittee of the Research Affairs Committee of the American College of Clinical Pharmacy in response to a request by then President John Rodman, Pharm.D. The subcommittee was charged with (1) preparing a background paper summarizing the central issues that must be addressed to ensure the continued development of highly competent, independent clinical scientists necessary to build the academic fabric of pharmacy; and (2) recommending specific action for ACCP and its membership to consider.

Subcommittee members included James C. Cloyd, Pharm.D., University of Minnesota; Patricia D. Kroboth, Ph.D., University of Pittsburgh; Thomas M. Ludden, Ph.D., University of Texas; and Robert A. Blouin, Pharm.D., Chairman, University of Kentucky. The subcommittee thanks the following people for their helpful comments and suggestions: Jordan Cohen, Ph.D.; William E. Evans, Pharm.D.; Curtis Johnson, Pharm.D.;

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