Pharmaceutical Research, Vol. 7, No. 7, 1990

Commentary

Academic Pharmaceutics: The Challenge of Excellence

AAPS Task Force[1]

1. INTRODUCTION

The discipline of pharmaceutics has undergone profound changes during the last 30 years. It was largely responsible for the transformation of pharmacy from a body of predominantly empirical and descriptive knowledge and art to a rigorous scientific discipline and to being an essential component of the biomedical sciences. Pharmaceutics served as the cradle of pharmacokinetics in the United States; it was the context in which bioavailability was identified as an important determinant of drug product efficacy; it developed a rational basis for drug stability determinations and drug product stabilization. Pharmaceutics provides the interface between and emphasizes the integration of the physicochemical and biological aspects of drug product development, evaluation, and rational utilization via its component disciplines of physical chemistry of pharmaceutical systems (physical pharmacy), biopharmaceutics, and pharmacokinetics.

In the early years of pharmaceutics, there was a very strong orientation to solving formulation and production problems of primary interest to the pharmaceutical industry, particularly those regarding the design and manufacture of pharmaceutical dosage forms. In recent years, the intellectual horizon of pharmaceutics has expanded greatly. It now includes the most sophisticated methods of chemical analysis and physical characterization of drugs, recently developed techniques of population pharmacokinetics, experimental and theoretical aspects of pharmacodynamics, and new systems and routes of systemic drug delivery. New challenges are presented by the increasing significance of peptides, proteins, and other macromolecular substances in the diagnosis and treatment of disease. Thus, in addition to their traditional interests in drug and dosage form fabrication and quality control, pharmaceutical scientists[2] are now actively involved in drug optimization via individualized dosing regimens and the use of new drug delivery systems. These activities, in turn, require a greater knowledge base in several areas of physiology, pharmacology, polymer and material science, surface and interfacial chemistry, and other disciplines.

The important role of pharmaceutics in the biomedical sciences has resulted in a substantially increased demand for scientists in this discipline by industry. The output of pharmaceutical scientists by universities has not been sufficient to meet this demand. Consequently, there is also a shortage of qualified pharmaceutical scientists for academic positions. The situation in academia is exacerbated by the increasing difficulty of obtaining research support from national agencies, which discourages young scientists from embarking upon an academic career and causes others to leave academia for positions in the pharmaceutical industry. Moreover, the national trend of decreased interest in graduate study has also had a pronounced effect on graduate programs in academic pharmaceutics.

In addition to the easily documented problems of the supply of and demand for new pharmaceutical scientists and the issue of retention of experienced academic pharmaceutical scientists, there is a growing, but poorly documented, perception that the quality of pharmaceutics graduate programs, and hence the quality of scientists from these programs, needs strengthening. Given the relatively small number of programs and scientists in this field, it is important that these aspects of quality be addressed.

The opportunities and problems exemplified in this brief introductory summary of developments affecting academic pharmaceutics led to the creation, in 1989, of a Task Force under the joint sponsorship of the Section on Pharmaceutics and Drug Delivery and the Section on Pharmacokinetics, Pharmacodynamics and Drug Metabolism of AAPS

(a) to review critically the quality and progress of research in pharmaceutics at academic centers in the United States and

(b) to propose steps that must be taken to foster excellence.

The Task Force has identified problems and proposes, as possible solutions, certain policies and strategies that relate to the public awareness of the pharmaceutical scientist, stimulating interest in graduate study, fostering academic excellence in research and teaching, facilitating faculty development, and assuring academic leadership by department chairpersons and deans. The recommendations offered by the Task Force focus on specific actions which can be implemented or initiated without delay and with a high probability of success. We earnestly appeal to our colleagues in pharmaceutics to give careful consideration to our recommendations and to act on them promptly and incisively.

2. ENHANCING PUBLIC AWARENESS OF THE PHARMACEUTICAL SCIENTIST

The strength and vitality of a scientific discipline reside

[1] The Task Force: Gerhard Levy (Chairman), Gordon L. Amidon, Leslie Z. Benet, Ronald T. Borchardt, Kim R. Brouwer, Ho-Leung Fung, Kathleen M. Giacomini, Patricia D. Kroboth, Arnold J. Repta, Joseph R. Robinson, John T. Slattery, Vincent H. L. Lee (ex officio), Douwe Breimer (Consultant), and Hitoshi Sezaki (Consultant).

[2] In this Report, the term pharmaceutical scientist refers to those individuals engaged in pharmaceutics, broadly defined.

0724-8741/90/0700-0782$06.00/0

in its practitioners; its future depends on the quality of its students. Young people are drawn to a scientific discipline because of its image and promise. Ideally, this attraction should occur while the student is still in high school. Among high-school students and those college students who major in the sciences, the pharmaceutical sciences including pharmaceutics have no image. Pharmaceutics as a scientific career option is unknown to these students and, equally important, unknown to their parents, teachers, and counselors. That situation must be changed. To raise the visibility and enhance the public image of the pharmaceutical scientist and to stimulate interest in pharmaceutics we recommend the following.

(a) Development of recruitment and public relations literature (brochures, advertisements, video tapes, etc.) by AAPS alone and in collaboration with pharmaceutical industry and/or other interested parties. These materials should be designed to familiarize students, guidance counselors, and the public at large with the pharmaceutical sciences and to stimulate interest in the pharmaceutical sciences, including pharmaceutics. These materials must undergo wide and persistent distribution.

(b) Regular press releases by AAPS highlighting recent research developments in the pharmaceutical sciences. These should emphasize the role of the pharmaceutical scientist and mention that term prominently.

(c) Summer outreach research programs sponsored by academic pharmaceutics departments. Such programs should be designed for science-oriented high-school and college students.

(d) Pharmaceutical science forums for high-school and college students. Ideally, these should take place on university campuses or in industrial pharmaceutical laboratories. The forums should include exhibitions, demonstrations, lectures and informal meetings with individual scientists and graduate students.

(e) Development of interactions between faculty in departments of pharmaceutics and high-school science teachers. These interactions should acquaint high-school science teachers with pharmaceutics as a science and career opportunity for their students.

3. STIMULATING THE INTEREST OF UNDERGRADUATE STUDENTS IN SCHOOLS OF PHARMACY IN GRADUATE STUDY

Pharmaceutics has provided much of the intellectual basis and the stimulus for the development of academic programs in clinical pharmacy in schools of pharmacy. Unfortunately, this did not result in a heightened interest by pharmacy students in academic pharmaceutics per se. Most students enter a school of pharmacy because they want to become pharmacy practitioners. The current educational orientation and posture of most schools of pharmacy do little to acquaint the students with other career opportunities made possible by their professional education. A more complete view of pharmacy leads to the recognition that it encompasses not only community and hospital pharmacy practice but also academic and industrial pharmaceutical research as well as pharmaceutical education. It is as appropriate and necessary for pharmacists to engage in the discovery and development of new therapeutic agents as it is to engage in the delivery of pharmaceutical care. Schools of pharmacy have an obligation to address the needs of the entire spectrum of pharmacy.

Inasmuch as the pharmacy curriculum is now more clinically oriented at the expense of its basic science components, there is need for an additional, more basic science-oriented undergraduate program in pharmacy schools. Such programs should be designed for students who are interested in eventual graduate studies in the pharmaceutical sciences and should be viable baccalaureate programs in their own right. It is equally important to provide programs that allow students to earn the Pharm.D. and Ph.D. concurrently.

If the very substantial demand for pharmaceutical scientists cannot be satisfied by schools of pharmacy, then industry and academic institutions will increasingly turn to other disciplines for the required manpower and will attempt to compensate for their lack of pharmaceutical education and experience by in-house and commercial training programs. This practice is unsound and could create a vicious cycle whereby the limited availability of newly graduated pharmaceutical scientists eventually reduces the demand for them, which in turn further reduces the viability and productivity of graduate programs in the pharmaceutical sciences. To avoid such developments and to fulfill their role as an academic institution, schools of pharmacy are obligated to offer high-quality educational programs in the pharmaceutical sciences that prepare qualified students for a research career. The faculty must make strong efforts to make students aware of and to interest them in the pharmaceutical sciences as a career. We therefore recommend the following.

(a) Greater flexibility in present professional pharmacy programs to permit interested and qualified students to take electives in the basic sciences and to participate in research activities. We consider this recommendation particularly important and urgent.

(b) Encouragement of qualified students to engage in research under the supervision of experienced faculty. Efforts should be made to allow recognition of research as a component of professional experience requirements.

(c) Aggressive development, in some schools, of 4-year baccalaureate programs in the pharmaceutical sciences. The curriculum should emphasize basic and contemporary physical, chemical, and biological sciences as well as laboratory skills and should qualify graduates for admission to graduate programs in the pharmaceutical sciences. Students might also enroll in such undergraduate programs to qualify for B.S.-level technical positions in industry, universities, and research institutes.

(d) Development of integrated Pharm.D.–Ph.D. programs in those schools that offer the Pharm.D. degree.

(e) Making clear to students that the pharmaceutical sciences are at the cutting edge of health sciences research. Teaching strategies should emphasize the relationship between research and practice in pharmacy. The new developments in molecular biology and immunology relevant to pharmacy should be incorporated into the curriculum and outdated material should be removed promptly. Instruction should emphasize logical thinking, problem-solving ability, and creativity. Verbal communication ability and effective writing skills must be developed.

4. GRADUATE STUDENTS IN PHARMACEUTICS: FOSTERING ACADEMIC EXCELLENCE AND INTEREST IN TEACHING

All graduate programs should stimulate and foster a commitment to excellence and love of learning. This is best done by faculty members serving as role models. To attract graduate students to an academic career, they must be convinced that a professor's life is interesting, meaningful, rewarding, and enjoyable and that it provides ample opportunity for intellectual growth and scientific creativity. Thus, the attitude of graduate students in pharmaceutics toward an academic career is determined to a considerable degree by how they perceive the career satisfaction of their own professors. Faculty preoccupation with matters other than academic scholarship and exhibition of attitudes that do not reflect enthusiasm, integrity, and a commitment to excellence will have a negative impact on the intellectual climate of an academic department.

The trend of academicians in pharmaceutics to leave their universities and assume positions in pharmaceutical industry can only discourage graduate students from embarking upon an academic career. Another discouraging factor appears to be the increased competition for federal research grant support. Our graduate students must be prepared to compete effectively for such support. Moreover, they must have good reason to believe that they can compete effectively with their peers in other scientific disciplines. Thus, our specific recommendations are designed to make our graduate students better teachers (thereby stimulating their interest in an academic career) and better qualified to compete effectively for research grant support by making them better scientists.

We recommend the following.

(a) Implementation of the recommendation of the AACP Commission on Graduate Education that faculties involved in graduate education evaluate their program(s) on a regular basis and that

(i) the self-evaluation should result in a set of objectives and a timetable for achievement,

(ii) the self-evaluation process should include an external review component, and

(iii) schools should make public the date of the most recent self-evaluation.

(b) Every graduate student, whether or not he/she is supported by a teaching assistantship, be engaged in supervised teaching. This should be viewed as much more than a job. The students should be properly prepared for and oriented to their teaching assignment, pedagogic and ethical principles should be presented and discussed by experienced mentors, and good communication skills should be developed. Faculty members must endeavor to transmit to their graduate assistants their own love of and commitment to teaching. At its best, the involvement of graduate students in the teaching process will improve their interpersonal skills, enhance their ability to instruct others, and deepen their understanding of fundamentals in the pharmaceutical sciences. All of these qualities are equally useful to the future professor and industrial pharmaceutical scientist. Moreover, we believe that this policy will stimulate interest in academic careers.

(c) Ph.D. graduates in pharmaceutics be strongly encouraged to undertake postdoctoral study. Postdoctoral training is presently considered essential in almost all the sciences. Pharmaceutics has been a notable exception, largely because of the great demand for new Ph.D.'s to fill academic and industrial positions. Because of the broad inter-disciplinary nature of pharmaceutics, graduate training often does not allow in-depth specialization in a particular area of research. This in-depth training requirement is best met by postdoctoral study. The increased knowledge, experience, and maturity and the more substantial professional record (including publications) resulting from postdoctoral research experience will make our graduates more competitive careerwise as well as in their ability to obtain research support. A recent study of researchers in academic medicine (*Ann. Intern. Med.* 109:414–418, 1988) has shown that at least 2 years of postdoctoral research training was a primary determinant in defining successful scientists in terms of generating NIH peer-reviewed grant support.

5. FACILITATING FACULTY DEVELOPMENT

Academic excellence requires continued intellectual growth and programmatic development on the part of the faculty. This demands the setting and pursuit of long-term research goals and is impeded by transient and superficial research involvements interrupted by frequent periods of relative research inactivity. Junior faculty face the additional challenge and difficulties of getting started, especially obtaining sufficient research support to sustain an active laboratory with staff and supplies. One of the most effective means of preventing junior faculty from becoming discouraged and leaving academia is to assist them in obtaining research support. Moreover, the ability to compete with peers is an important and valuable indicator of faculty competence and accomplishment.

One particular problem for faculty development is the small size of most pharmaceutics departments (where such exist) and, for that matter, of most school of pharmacy faculties. Especially the young faculty members may have no colleague in their subdiscipline available for advice, dialogue, and assistance. Effective action must be taken to overcome this lack of critical mass.

We recommend the following.

(a) Greater emphasis in faculty performance evaluation and guidance on a sustained commitment to long-range research goals.

(b) New junior faculty be given full research support for 2 to 3 years and teaching and service requirements be reduced during these years to allow the development of strong research programs.

(c) A requirement for pharmaceutics faculty to compete aggressively and consistently for peer-reviewed research grants. We suggest that research grant applications and the evaluations ("pink sheets") resulting from the peer review of research grant applications can constitute a valuable and independent assessment of a faculty member's professional competence. Administrators and faculty in the smaller and/or less research-active schools should seek the services of experienced pharmaceutical scientists at other institutions for the voluntary preliminary review of research grant applications before their formal submission or revision.

(d) Multidisciplinary research, including particularly collaboration with campus colleagues outside the pharmaceutical sciences, be strongly encouraged and facilitated. Such activities can be very effective in overcoming the adverse effects of a lack of critical mass on research and graduate education in some departments of pharmaceutics. The pharmaceutical scientists must, however, assume the role of principal investigator on at least some of the projects evolving from such multidisciplinary research.

(e) Short leaves for young faculty members to visit research-intensive departments and/or laboratories in their subspecialty for study, research, instruction in new research techniques, intellectual stimulation, and inspiration. Where this can be useful, senior investigators from other institutions should be invited for short visits to serve as advisors and intellectual resources to faculty and graduate students.

(f) Small specialty conferences for faculty and graduate students in pharmaceutics, to be organized nationally or regionally. A good start may be to organize "fireside chats" at AAPS meetings which will be open to a limited number of active investigators and senior graduate students in a given subspecialty.

6. CHAIRPERSONS AND DEANS: THE IMPORTANCE OF ROLE MODELS AND COMPETENT LEADERSHIP

Higher education in general and pharmaceutics in particular are experiencing great changes requiring a commitment to graduate training by deans and strong leadership by departmental chairpersons to develop and guide a strong, research-oriented faculty. Unfortunately, many schools of pharmacy are not departmentalized and not all department chairpersons are given the freedom of action, adequate resources, and authority to exert leadership.

Most of the recommendations of this Task Force call for action that must be initiated by chairpersons or deans. The performance of department chairpersons as teachers, scientists, academic role models, mentors, leaders, and administrators is perhaps the most critical determinant of our quest for continued and increased excellence in academic pharmaceutics. They will have to face and take a decisive stand on such critical issues as faculty recruitment and development, the proper integration of the increasing number of pharmaceutics faculty who were educated in an academic environment other than pharmacy and the pharmaceutical sciences, curricular revision to accommodate both practice- and academically oriented undergraduate students, and faculty entrepreneurship.

We recommend the following.

(a) Structuring of schools and colleges with a critical mass of pharmaceutics faculty to allow vigorous leadership in the basic sciences to emerge. This is best facilitated by departmentalization and the appointment of strong chairpersons who fulfill the characteristics and assume the responsibilities described in the preceding paragraph.

(b) Emphasis on the appointment of chairpersons of departments of pharmaceutics who have the requisite qualifications and commitment to excellence in education and research, and on giving these individuals the authority, resources, and freedom of action to exert strong and effective leadership.

(c) A renewed and increased commitment to the budgetary support and strengthening of Ph.D. programs in pharmaceutics following many years of (what was then appropriate) priority support of the clinical pharmacy programs.

(d) Recognition of consistent and long-term commitment to programmatic research involving graduate students, and encouragement of undergraduate research participation, as important determinants of qualification for promotion and other rewards (including merit salary increases) of faculty members.

(e) Inclusion of an assessment of their commitment to, and effectiveness in, mentoring and developing junior faculty in the performance evaluation of department chairpersons and deans.

(f) Special efforts to orient faculty not possessing a pharmacy background to the characteristics and missions of a school of pharmacy and to integrate them as faculty colleagues who participate fully in faculty governance and who willingly share the general responsibilities of a pharmaceutics faculty.

(g) Attention to possible adverse effects of inappropriate aspects of faculty entrepreneurship including secrecy provisions, publication restrictions, impaired freedom of action in dissertation research, unequitable stipends and postdoctoral salaries, and neglect of teaching responsibilities.

(h) Institution of greater flexibility in the undergraduate program, to permit interested and qualified pharmacy students to take electives in the basic sciences and to participate in research. The implementation in some schools of a 4-year baccalaureate program in the pharmaceutical sciences and/or of an integrated Pharm.D.–Ph.D. program is encouraged.

7. IN CONCLUSION

Academic pharmaceutics has made truly extraordinary contributions to the pharmaceutical sciences and to the practice of pharmacy. Pharmaceutical scientists have pioneered the rational formulation of pharmaceutical dosage forms based on rigorous physicochemical principles, the biopharmaceutical evaluation of such dosage forms, the development of pharmacokinetics and its extension to clinical pharmacokinetics, and the design of sophisticated new drug delivery systems. The discipline now faces even greater challenges in extending pharmaceutical techniques to peptides and proteins, interfacing pharmacokinetics with pharmacodynamics, exploring effective and convenient routes of administration for macromolecular medicinal agents, and applying its knowledge base to aspects of drug discovery. There is a critical need for properly trained individuals to carry out these tasks. To attract outstanding young men and women to pharmaceutics as a career, to face the challenges before us, and to assume our proper role in the biomedical scientific effort requires a strong commitment to excellence. This document is intended to serve as a practical and realistic guide for achieving that aim.