In addition to continuing the charges of the 1994-95 Research and Graduate Affairs Committee (RGAC), President Koda-Kimble presented the 1995-96 RGAC with the following additional charges:

- What is or what will be the effect of workforce downsizing in the pharmaceutical industry on postprofessional and graduate education programs in pharmacy?
- Are our traditional areas of graduate study likely to create graduates with the necessary skills to fulfill the emerging needs of the industry and academy?
- Is the structure of our graduate education and postgraduate training programs appropriate to accommodate rapidly-changing and newly-evolving disciplines?
- What is the appropriate range of skills needed by graduate students in order to maintain their productivity in a changing, multidisciplinary environment?

The 1995-96 RGAC considered its charges in light of the continuing national debate on the future of the PhD degree and has made recommendations for AACP and its member schools and colleges. The committee also discussed at some length the structure of postprofessional research education and training (post-PharmD. fellowship) and proposes a policy statement for consideration by the membership.

It also became apparent to the committee that the issues presently facing graduate and postprofessional research education and training in our schools and colleges of pharmacy are so important to the future of pharmacy education that they are beyond the scope of a once-a-year meeting of the RGAC. Graduate education and research have been previously considered by a special AACP committee and a commission(1,2). However, the excellent recommendations found in those previous reports appear to have had little effect on the graduate education enterprise in our institutions. The committee believes that the restructuring of the pharmaceutical industry, the end of significant growth in federal support for biomedical science research, the oversupply of PhD scientists, and the impact of managed care and government reimbursement policies for academic health centers places the future of graduate programs in pharmacy schools in jeopardy, conversely opportunities now exist for those who have the foresight to recognize them and the courage to take appropriate action.

RECOMMENDATION 1: AACP should convene a “Commission on the Future of Graduate Education in Schools of Pharmacy.” The commission should include representation from the national and international pharmacy academic community, the pharmaceutical industry, pharmaceutical science associations, managed care organizations, and other important stakeholders.

THE CRISIS IN GRADUATE EDUCATION

Background

President Koda-Kimble’s new charges were consistent with many of the questions addressed in a report by the Committee on Science, Engineering, nd Public Policy (COSEPUP), a joint committee of the National Academy of Science, National Academy of Engineering, and the Institute of Medicine(3). The COSEPUP report, published in 1995, has drawn considerable comment from the scientific and lay community, particularly over the recommendations in the report that addressed the issue of the perceived oversupply of PhD graduates(4-6).

The PhD oversupply issue initially arose in the physical sciences and mathematics, but has spread to chemistry, engineering, and the life sciences. “The U.S. science PhD seems to have hit a wall—hard. After decades of expansion, the number of scientists seeking research grants and research jobs appears, in the eyes of many, to have outrun the money available to support them.”(4) Interestingly, as recently as 1990, the president of the American Association for the Advancement of Science was calling for increases in PhD production to forestall a critical shortage predicted in a late 1980s study by the National Science Foundation. This increase in PhD production was called for despite the evidence of an approximately 30 percent increase in PhD production and a 60 percent increase in postdoctoral positions over the previous decade(7).

How large is the PhD oversupply? The most pessimistic predictions indicate a 22 percent oversupply across all fields, with extremes of >40 percent overproduction in mechanical and electrical engineering to no oversupply in chemistry(8). The latter figure is disputed by the American Chemical Society which states an overproduction of 250-400 PhD chemists/year or about a 12 percent oversupply(5). The lack of data on scientist employment contributes to some uncertainty about the accuracy of any specific predictions on supply and demand, but what is inescapable is that recent PhD graduates are experiencing employment difficulties, either unemployment or more commonly underemployment. Some recent PhD graduates have been very vocal in expressing their consternation over being mislead by the academic scientific community about a future in research(9). This “employment crisis” has been seized by the press, as noted in the 1994/95 RGAC report and by President Koda-Kimble in her president-elect address(10,11).

Reactions to this crisis in the scientific community have varied from doing nothing(4), to exhorting graduate programs to practice “birth control” by reducing the number of graduate programs and/ or students(12), to calls for broadening the education of PhD students to include a wider range of skills(primarily to prepare PhD graduates for nonresearch careers)(3). One definite trend seen across all scientific disciplines is that PhD scientists are being increasingly employed in nonacademic environments rather than in full-time academic positions. The “idealized” PhD career, a full-time tenure-track faculty position in a research university conducting extramurally-funded research and mentoring graduate students is becoming a reality for fewer PhD trained scientists. The COSEPUP report strongly recommended that students receive accurate and timely information to help them make informed decisions about professional careers. Even the NIH is planning to require counseling on academic and nonacademic careers for all...
What is the situation facing graduates of PhD programs in schools and colleges of pharmacy? Unfortunately, there is no nationwide data available which provides a longitudinal view of the career paths of PhD graduates from schools and colleges of pharmacy. Some graduate programs in pharmacy schools maintain good data on the career paths of their graduates, particularly if they have applied for a NIH training grant, because one of the application requirements is evidence of the success of the program's graduates. However, those career path data are not generally available. If attendance at the 1995 AAPS Annual Meeting Special Seminar on “The Changing Job Market” is any indicator, there is considerable concern among pharmaceutical scientists about their future career options. The recent and controversial Pew Commission report that called for closing 20-25 percent of all medical and pharmacy schools also raises concerns about the future needs for pharmaceutical sciences faculty(14).

Inasmuch as the numbers of PhDs granted (~300) by schools of pharmacy is only a small fraction of the nation’s total, it would be inappropriate to extrapolate from the situation in chemistry, engineering, or the life sciences to the pharmaceutical sciences. However, it would be just as inappropriate to assume PhD graduates from pharmacy schools are immune from the market forces and government funding policies affecting career opportunities for PhD graduates in other disciplines. Additionally, PhD graduates in chemistry, engineering, and the life sciences are potential competitors for positions traditionally occupied by PhD graduates of schools of pharmacy. To remain successful, pharmacy school graduate programs and their students must be able to adapt to change better than graduates of other science PhD programs.

RECOMMENDATION 2: To assist in the strategic planning effort of all its member institutions, AACP should, with the cooperation of member schools, survey PhD graduates (1975-1995) in order to determine their career paths since graduation. AACP should continually update this data base and periodically resurvey the cohort to determine the influences of the market on the careers of PhD graduates.

RECOMMENDATION 3: Pharmacy faculty must remain aware of the changing research and funding environments, both in academia and the pharmaceutical industry, and develop formal procedures, e.g., seminars, for keeping their graduate students apprised of the potential impact these changes may have on their future careers.

RECOMMENDATION 4: Schools and colleges of pharmacy must seriously consider the role, if any, graduate and postprofessional education programs have in their overall strategic plan. Decisions to maintain, modify, add, or terminate graduate programs should be made by the entire college community, not just by individual deans, faculty, or departments. An institutional mission statement that declares a commitment to research, scholarship, or graduate education without providing supporting goals and objectives agreed upon by the faculty is incomplete.

CHANGES IN THE PHARMACEUTICAL INDUSTRY

Background

The 1994-95 RGAC noted in its environmental scan that the increasing numbers of mergers within the pharmaceutical industry were producing a decrease in the numbers of scientists employed in the research and development infrastructure(10). The 1995-96 RGAC continued the analysis of the changes in the pharmaceutical industry with a particular emphasis on how these changes could impact on graduate education and postprofessional training programs in our schools and colleges of pharmacy. The RGAC emphasized that pharmacy faculty understand that the changes occurring in the pharmaceutical industry, both qualitatively and quantitatively, are permanent, and not some temporary aberration with an eventual return to business as usual.

The industry structure most faculty envision, large fully-integrated pharmaceutical companies (FIPCOs) performing all aspects of drug discovery and development, will continue merger activity and become increasingly multinational and global(15). In addition to decreasing employment in FIPCOs due to mergers, many activities will be outsourced, further reducing the demand for FIPCO researchers. These reductions will be discipline-specific, with medical chemistry and pharmaco-chemistry affected more than pharmaceuticals, analytical chemistry, and pharmaceutical sciences. This shift could result in less demand for PhD level graduates and more demand for BS and MS level graduates with appropriate technical expertise(16).

Initially, many biotechnology companies had plans to develop into FIPCOs. Unsuccessful efforts in obtaining marketable products refocused the mission of many of these companies to only discovery, with development, clinical testing, approval efforts, and marketing left to others(17). The financial investment in the drug discovery industry by FIPCOs through stock purchases or alliances in the last year is also evidence of this change in focus in the biotechnology industry. A Wall Street Journal article on the Swiss pharmaceutical giants (Roche, Ciba-Geigy, and Sandoz) observed that the three companies have spent at least $7 billion over the past six years amassing biotechnology products through major holdings and alliances, almost exclusively with U.S. discovery companies and research institutes(18). Among the reasons for buying the products of discovery from small companies rather than employing internal efforts are the significant cost savings. Roche now spends 50 percent of its research budget externally, compared to an average of 10 percent for U.S. companies. It will not be known for five or more years if the Swiss strategy of outsourcing discovery efforts is better than maintaining significant internal discovery efforts. However, outsourcing by FIPCOs to smaller entrepreneurial companies will continue to increase.

It is important to understand that the structure and missions of the small entrepreneurial companies that constitute the “other” pharmaceutical industry (OPI), as they will increasingly become potential employers of our PhD graduates. Diversity of mission characterizes this sector. It consists of both large and small biotechnology companies with several large biotechnology companies approaching FIPCO stature while others remain primarily discovery-oriented. Small discovery companies often focus on a particular disease or organ and use technical expertise in combinatorial chemistry, genetic manipulation, and rapid throughput molecular screening to identify potential lead compounds for sale or licensure to FIPCOs(19). Other companies, often referred to as contract research organizations (CROs), specialize in areas or niches ranging from pharmacology/toxicology testing to manufacturing and marketing(20). Some CROs are involved in specialized formulation and drug delivery technology for both small and large molecules such as proteins, peptides, and gene fragments, while others develop potentially effective molecular entities abandoned by FIPCOs because their market was considered too small for continued development. The generic industry continues to grow as drug costs remain a convenient target for health care savings. Health services research firms are emerging to examine the access to, use, costs, quality, delivery, organization, financing, and outcomes (efficacy and efficiency) of health care services, including drug therapy. Another potential area of growth is the medical communications industry, which will target messages to both health professionals and patients.

Because the restructuring of the pharmaceutical industry has been so rapid and extensive, many pharmacy faculty members do not have personal contacts in the OPI, and therefore are unfamiliar with their research activities and needs regarding the education and training of new employees. Conversely, many OPI companies are unfamiliar with the research and graduate programs in schools of pharmacy. The recent restructuring and downsizing of FIPCOs...
have also resulted in loss of industry contacts for many pharmacy graduate faculty. Unrestricted industry research grants, which have historically been important to pharmaceutical science research are being replaced, if they are being replaced at all, by specific contractual arrangements that are not as graduate education friendly.

RECOMMENDATION 5: Pharmacy faculty involved in graduate education must attempt to establish collaborative relationships with colleagues in the pharmaceutical industry, particularly the OPI, the managed care industry, and health service research firms, which could be potential major employers of PhD graduates from schools of pharmacy.

RECOMMENDATION 6: Schools and colleges of pharmacy need to reconsider the master’s (MS) degree as something other than a “reward” for completing a portion of the PhD degree requirements (e.g., preliminary exams) or a “punishment” for not successfully completing same. A properly structured master’s degree can provide students with valuable technical skills that are in considerable demand in the pharmaceutical industry, in much less time and with fewer school resources than required for the PhD degree.

Impact of Changes in the Pharmaceutical Industry on the Structure of Graduate Education Programs in Pharmacy

Previously, PhD preparation that focused on producing an independent investigator specialist was appropriate for a career in pharmacy academia or a FIPCO. Postdoctoral experience was often taken to increase mastery of a specialty discipline or the acquisition of additional complementary research techniques. A career in most FIPCOs favored the independent investigator model. Some FIPCOs used an academic administration model for their research and development scientists, with promotion up through the scientific ranks similar to academia. Publishing by FIPCO scientists was often encouraged, even on drugs currently in development. Those industry scientists with personnel management and communication skills had administrative opportunities not unlike academic colleagues. Examples of individuals successfully crossing-over between academia and the FIPCOs are not uncommon.

The reorganization of the FIPCOs has changed the academia-like culture of the independent investigator to a team-oriented, interdisciplinary-research culture. The term “seamless” development has been used to describe this effort to eliminate barriers among the discovery, preclinical development, and clinical development processes, with the goal of speeding up the expensive drug discovery/development process. Unless a marketing advantage is anticipated for a compound under development, it is dropped or sold. Thus, reassigments to new areas of research and development are more frequent. Also, FIPCO scientists are often called upon to collaborate with other scientists at international research and manufacturing sites.

The work environment for the OPI scientist is also unique. These smaller companies often expect scientists to perform multiple tasks. The OPI was started with venture capital to exploit an innovative technique, most often from a scientific discipline not found in pharmacy schools. A PhD graduate from a school or college of pharmacy may either be unqualified to perform the research required, or more commonly, not recognized as able to contribute to the company. The RGAC agrees with the COSEPUP report that “A world of work that has become more interdisciplinary, collaborative, and global requires young people who are adaptable, flexible, as well and technically proficient” also applies to the graduates of PhD programs in pharmacy. Additionally, there is increasing demand for industrial scientists to possess excellent verbal and written communication skills, team-building attitudes, critical thinking, problem-solving skills, leadership ability, and scientific integrity. Development of these skills occurs through informal mentoring, but the efficiency and efficacy of this method vary considerably among institutions, graduate students, and their faculty advisors. The challenge is to develop these skills in graduate students, who are primarily focused on completing their dissertation research and often narrowly focused in a discipline subspecialty, without significantly adding to the time required to complete the degree.

For the most part, graduate education has produced technical proficiency and mastery of a specific discipline. In some instances, the focus on specialization (learning more and more about less and less) has produced primarily “super” technicians. One approach to developing interdisciplinary awareness is to expand the breadth of exposure through the incorporation of minor or collateral fields of study outside the specialty in the graduate curriculum. To develop the traits of adaptability and flexibility, students must experience research environments where scientists exhibit these traits. Therefore, the RGAC agrees with the COSEPUP report that students obtain supervised industrial experience as a required part of the graduate program. It should be noted that the new biotechnology NIH training (NRSA) grants require industrial experience as part of a student’s experience.

Required frequent oral and written presentations to peer and mixed audiences develops communication skills. Interactions with scientists and students in other science cultures that exist on campus or at other institutions enhances adaptability and flexibility. For example, U.S. schools and graduate programs could establish educational collaborations with pharmacy academic institutions in other developed countries to allow for graduate student exchanges.

If a collaborative and interdisciplinary drug discovery and development process is the research environment of the future for the pharmaceutical industry, the educational environment which produces its scientists should become collaborative and interdisciplinary as well[21,22]. Schools and colleges of pharmacy are inherently interdisciplinary with faculty possessing skills across the entire spectrum of the drug discovery/development process (Figure 1). Despite this advantage over other university colleges, many pharmacy faculty members remain wedded to a traditional disciplinary department structure, particularly for their graduate programs. Taking advantage of faculty expertise all along the drug discovery/development process spectrum could create an interdisciplinary educational experience that could greatly enhance the future careers of pharmacy school graduate students. The development of an interdisciplinary graduate degree educational experience can only be accomplished by engaging in an interdepartmental strategic visioning and planning process.

RECOMMENDATION 7: Graduate programs must be modified to incorporate more breadth into the educational experience. Additionally, students should be exposed to other research cultures through supervised internships in nonacademic settings such as the pharmaceutical industry, health maintenance organizations, or through research experiences in laboratories of international colleagues.

RECOMMENDATION 8: Pharmacy faculty should identify and develop unique and high quality interdisciplinary research programs built on the collective strengths of all existing and potential new faculty, within and external to the school/college of pharmacy.

RECOMMENDATION 9: AACP should assist member schools in developing interdisciplinary research and education programs through appropriate programming at its annual and interim meetings.

RECOMMENDATION 10: Faculty and administrators should closely monitor the “time to degree” of their graduate students and take appropriate action if students are taking too long to finish their degree requirements.
THE DEVELOPMENT OF CLINICAL RESEARCH SCIENTISTS

POLICY STATEMENT: AACP recommends that all schools with active or planned post-PharmD clinical fellowship programs convert them to, or set them up with graduate program status accompanied by the appropriate requirements and financial support, and grant commensurate graduate degrees (MS/PhD) to the those individuals who successfully complete the program.

Background for Policy Statement

The appropriate method to prepare clinical practitioners to become clinical research scientists has been addressed by RGACs from 1989-90 through 1993-94. In addition, the American College of Clinical Pharmacy (ACCP) produced a white paper on the issue(23), a special committee of the AACP Council of Faculties developed a white paper on the financing of clinical fellowships(24), and the AACP Commission to Implement Change in Pharmaceutical Education made recommendations on need, support, goals and outcomes, scholarship, and quality of clinical fellowships(25).

Presently, the primary method of preparing clinical scientists is through the clinical research fellowship. Most fellowships are a minimum of two years in length and require that candidates possess a PharmD and have completed a clinical residency. Most fellowships primarily involve participants in a clinical research project and sonic fellowships have a didactic component to provide additional scientific background. The majority of clinical research fellowships are supported by pharmaceutical industry grants and contracts to individual faculty members who use part of the funding to support the fellow to assist in carrying out the research project. There are also industry-sponsored clinical research fellowships available through competitive programs offered by ACCP and ASHP and one fellowship offered by the American Foundation for Pharmaceutical Education (AFPE). Some schools provide internal funds for support of clinical fellows, but institutional support only accounts for a small percentage of fellowship funding(24).

During the RGAC’s discussions about graduate education, it became apparent that the same issues facing the new pharmaceutical scientist PhD, such as career pathway, research funding, and research environment, also face the new clinical pharmaceutical scientist. The major difference between the two areas at present is that there does not appear to be an oversupply of clinical pharmaceutical scientists. However, just as pharmaceutical scientists will find competition from PhD life scientists and engineers, the clinical pharmaceutical scientist will face increasing competition from physicians and nurse clinicians as those professions approach oversupply conditions.

Post-PharmD research fellowship programs have developed competent clinical scientists, but the quality varies considerably among preceptors and institutions. The inconsistency of the didactic background for fellows does not always provide for theoretical grounding of the scientific methods employed in the research project. Furthermore, the extensive dependence of fellowship financing by pharmaceutical industry contract research places program stability in jeopardy from year to year. While all these problems can and do exist in graduate programs, there is no structure or potential for quality control in a fellowship program that is inherent in a properly structured graduate program. The best arguments for a graduate degree program model for training clinical pharmaceutical scientists can be found in the ACCP white paper(23).

They (graduate degree programs) 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. This format provides them with a universally accepted credential (the PhD degree) to carry with them throughout their professional career.

Graduate program status for the clinical fellowship should increase the scope of research and training for the participants, who will be required to work with a research committee in addition to their faculty mentor. Another advantage to moving toward a graduate degree program model for clinical pharmaceutical scientist training is that it officially recognizes the research and education activities of pharmacy practice faculty within the school, and more importantly, within the university.

An incentive to convert clinical fellowships to graduate program status is the potential availability of NIH funding for development of outstanding clinical research scientists, the Mentored Clinical Scientist Development Award (K08)(26). This program accepts applications from individuals with a clinical degree, including the PharmD, who are involved in a three-, four-, or five-year period of supervised research experience that may integrate didactic studies with laboratory or clinically based research. Some NIH Institutes that participate in the program require that this supervised research lead to the PhD degree.

The RGAC makes no recommendations as to the degree title, didactic courses, or research directions for a graduate degree in the clinical pharmaceutical sciences. There are many potential pathways for a graduate degree in this area and the direction and strengths of the programs will strongly depend on the expertise of the faculty, financial resources, and the existing research infrastructure at each individual institution that decides to offer such a program.

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