Chair Report for the Research and Graduate Affairs Committee

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INTRODUCTION
The charges to the 1994-95 Research and Graduate Affairs Committee were as follows:
1. Perform an environmental scan;
2. Consider how changes identified in the environmental scan affect implementation of the entry-level PharmD and the recommendations in Background Paper #4 of the Commission to Implement Change in Pharmaceutical Education;
3. Propose ways AACP can assist colleges and schools of pharmacy adapt and prosper with these changes; and
4. Suggest a two-year plan for AACP in the area of graduate education, research and scholarship.

Furthermore, the policy statement proposed by the 1993-94 committee which read “AACP affirms the importance of research (i.e., the scholarship of discovery) as a vital component of scholarship that is expected of every full-time faculty member to the extent that is consistent with the mission of his/her college or school of pharmacy” was referred back to the Research and Graduate Affairs Committee (RGAC) by the 1993-94 By-Laws and Policy Committee.

The environmental scan focused primarily on three main areas: a futuristic view of the changes in health care, biomedical science, and the pharmaceutical industry; the availability of funding for our research and graduate training programs; and the impact of the national shift to entry-level PharmD programs on research and graduate affairs. The report will follow these components of the environmental scan as background with the recommendations and policy statements following.

HEALTH CARE REFORM AND THE PHARMACEUTICAL INDUSTRY
Background
This past year, managed health care organizations have continued their penetration into the health care insurance industry at an accelerated pace, often replacing fee-for-service medicine with capitated payment. This has occurred despite the defeat of President Clinton’s Health Care Reform legislation. Vertical integration between pharmaceutical manufacturers and pharmacy benefit management groups has created new entities whose impact is yet to be evaluated. Additionally, horizontal integration of the pharmaceutical industry which is occurring between large manufacturers and small biotechnology firms and more recently between two or more large manufacturers is creating new hyphenated companies with enormous assets and yet unknown future potential. Almost every week, another merger candidate among the pharmaceutical industry appears in the pages of the Wall Street Journal.

The recent and future mergers within the pharmaceutical industry have their effect on people in addition to balance sheets. Downsizing of staff, which began with the debate over health care reform, have continued. Estimates of research and development positions lost over the past two years in the pharmaceutical industry exceed 3000. When all other personnel are included, these figures are in the tens of thousands. The large number of high profit products coming off patent the next few years could accelerate the downsizing of the industry as generic substitution increases with the increase in managed care programs. The pharmaceutical industry predicts another increase in R and D spending, both in absolute dollars ($14.9 billion) and percent of sales (19.9 percent) for 1995(1). How long these increases can be sustained as profit margins are reduced is open for speculation.

Downsizing of the pharmaceutical industry’s research and development infrastructure has been accompanied by an outsourcing of activities to contract research organizations. Some pharmacy colleges and faculty members have initiated efforts to take advantage of this activity which appears to be growing. However, contract research with the pharmaceutical industry is not without potential drawbacks including the necessity for confidentiality in a here-to-fore open research environment. Publication of results obtained on industry contract support may also be restricted. Extensive industry involvement may subsequently impact on a faculty member’s ability to obtain government grants and contract due to potential conflicts of interest.

Not all areas of the pharmaceutical sciences will be impacted negatively by the changes occurring in the pharmaceutical industry. Companies are less interested in “me-too” products, but see their future profitability in new and novel molecular entities. Scientists, including persons trained in cell biology, molecular pharmacology, modern pharmacognosy, molecular-based drug design, human genetics, and biotechnology, who can contribute to this “discovery” research, will continue to be in demand. It is

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anticipated that the demand for medicinal and analytical chemists, especially those with macromolecular training, and pharmacologists will remain constant, and that the demand for persons trained in dosage form development, pharmaceutics, and pharmacokinetics will decrease in the U.S. in the short-term. However, as production moves worldwide, the worldwide need for scientists trained in these areas may increase(1). It is anticipated that the demand for economists, pharmacoepidemiologists, and individuals trained to perform health services research will increase(2). The two areas of increased need that appear to require additional emphasis in schools and colleges of pharmacy are human genetics (especially pharmacogenetics) and pharmacoconomics and we shall focus further on these two areas.

Advances in genetic technology and biotechnology are occurring at a rapid rate. It is estimated that by 2001, genetically engineered pharmaceutical and biotherapies will make up one-third of all drugs sold in the U.S. and 10 percent of those sold worldwide. In addition, genetic markers and “triggers” are likely to be discovered for many diseases including various types of cancer, hypertension, diabetes, Alzheimer’s disease, hypercholesterolemia, obesity, alcoholism, etc. Furthermore, it is anticipated that individual differences in responses to drugs will be predictable through the use of individual genetic profiles(1). These advances should put increased emphasis on health promotion and disease prevention and raise many scientific and ethical issues concerning gene manipulation and confidentiality of information. Gene therapy is well into the development stage and pharmacy’s role in this important area is yet to be defined. While there certainly are individual researchers in pharmacy schools working particularly in the area of individual markers of drug absorption, metabolism, etc., there are no established programs focusing on these areas. Ignoring this rapidly developing field of medicine carries the risk of being left behind. Conversely, there are wide-open opportunities to apply the pharmaceutical sciences’ unique perspective to this new area of therapy.

Health services research has been defined by an Institute of Medicine committee as: a multidisciplinary field of inquiry, both basic and applied, that examines access to, and the use, costs, quality, delivery, organization, financing, and outcomes of health care services to produce new knowledge about the structure, processes, and effects of health services for individuals and populations(3). Emphasis on health care reform has focused attention on the potential of such research in improving the efficiency of the health care system. Rapid adoption of managed care and increased diversity in health care organization has created a need to evaluate the proliferating programs and structures(4,5).

Pharmacoconomics is a specialized area of health services research that identifies, measures, and analyzes the overall costs and consequences of drug therapy. The demand for pharmacoconomics research has grown due to the same forces that have increased demand for health services research in general. However, special emphasis has been devoted to pharmacoconomics because drug prices have grown at a faster rate than medical care and because advances in biotechnology have permitted development of unusually expensive drugs for new indications(6). Pharmaco economists are in demand not only by the pharmaceutical industry(7), but also by health care organizations such as hospitals, pharmaceutical benefit managers and insurance companies, and by government agencies and private contract research companies(6). In academia, pharmaco economics research is performed by researchers in schools of medicine and public health as well as those in schools of pharmacy.

An important issue for pharmacy schools is what role they will play in conducting pharmacoeconomic research and training individuals in the discipline. It has been estimated that 20 to 25 colleges of schools of pharmacy have doctoral-level programs incorporating pharmaco economics and approximately eight specifically award a concentration in the field. Leaders in pharmaco economics are in general agreement, if not consensus, that pharmacy school programs in pharmaco economics should offer a foundation in basic research, including instruction in a set of core skills in research design and methodology, economics, and statistics, consistent with education at the PhD level(7). Some pharmacy school programs may train individuals to fill more applied roles, but there is a need to produce a core of individuals with the depth and range of knowledge necessary to take leadership roles in multidisciplinary health services research teams and to collaborate with researchers from a variety of disciplines. An active and progressive role in this area represents an important opportunity for pharmacy schools to contribute to the nation’s health and to shape the future role of pharmacy.

Conclusions

Several issues within the futuristic view presented above appear to be of particular importance to schools and colleges of pharmacy and the pharmacy profession.

1. There will be an increased need for research in pharmaco economics, patient health-care outcomes, and pharmacoepidemiology, and for graduates trained in these fields. Health services research probably will be performed by teams of researchers. There is a need for pharmacy to provide leadership on these teams if pharmacy is to receive its due consideration. We must be cognizant of the various levels of training and the types of researchers being produced. A high level of education and training (PhD or equivalent) is essential for leadership roles. These individuals also must be aware of the practice environment. Conversely, it is also important for practitioners to have research skills to contribute to the overall research effort.

2. There also will be increased need for human genetics and pharmacogenetics researchers as genetic links to disease prediction, prevention, and therapy become more prevalent. This is an area that has received little attention in schools and colleges of pharmacy. As the genome project proceeds and gene therapy develops, the pharmacy profession will ignore it at the risk of being left out of this important and expanding field of medicine.

RECOMMENDATION 1: The RGAC recommends that schools and colleges of pharmacy be aggressive in producing/identifying well-trained faculty members in areas of high demand, especially the increasingly important areas of pharmaco economics and pharmacogenetics. Resources are and will continue to be limited, so simply hiring additional faculty members may not serve this need. Meeting the needs for developing areas may involve internal reallocation of resources, reeducation of present faculty, identification of persons outside of pharmacy, and direction of students to high demand areas (perhaps by limiting enrollment in programs of small demand). The establishment of training (fellowship, graduate programs) must take into consideration the length and level of education required to produce individuals prepared to assume leadership positions.

Changes in drug profitability for the pharmaceutical industry will result in increased importance on discovery research and, conversely, in “outsourcing” many aspects of drug development research. Schools and colleges of pharmacy may be in an excellent position to compete with small specialty research companies for some of the resulting contractual research. However, such research puts particular stresses on individual faculty members as they attempt to balance academic values with the demands of contract research. Interestingly, the anticipated “outsourcing” is a dual-edged sword in that it decreases the demand for PhD graduates by the pharmaceutical industry in the very fields in which contract research opportunities will increase. This may have particular impact upon departments/divisions of pharmaceutics and pharmacokinetics.

RECOMMENDATION 2: The RGAC recommends that AACP, through future RGA Committees and the Director of Graduate Education, Research and Scholarship, elaborate guidelines for conflict of interest and conflict of commitment that can be used as
faculty at Schools and Colleges of Pharmacy enter into contractual research activities. Guidelines also should be developed to address the balance of academic values with the demands of contract research.

FUNDING SOURCES FOR RESEARCH

Background

According to data collected by AACP from its member schools, extramural funding for research and training is derived from a number of sources. Approximately half of the funding in dollars is obtained from the National Institutes of Health with the other half coming in almost equal proportions from non-NIH federal support, state grants and contracts, corporate and industry sponsorship, grants and contracts, and “other” which includes foundations. The National Institute of General Medical Sciences through its Pharmacological Sciences, Biotechnology, and Chemistry-Biology Interface training programs supports 187 predoctoral training positions in schools and colleges of pharmacy.

Funding for the extramural grants program at the National Institutes of Health grew from $3.87 billion in 1984 to $8.52 billion in 1993. In “constant dollars,” this represents at least stable funding and perhaps a slight increase, depending upon the inflation index applied. Of these extramural funds, 44 percent goes to fund RO1s and related individual investigator-initiated research projects and 4 percent funds training programs such as the NRSA fellowships. Pharmacy schools received approximately $88 million in NIH support in 1994 (all funding categories), which represents approximately 1 percent of NIH extramural funding, while medical schools received over 50 percent. All non-medical health care schools together received $700 million in extramural NIH funding.

Competition for NIH funding has grown significantly. A 33 percent increase in applications occurred from 1984 to 1993 (18,638 applications reviewed in 1984; 24,774 in 1993). At the same time, the number of competing research projects awarded went only from 6,005 in 1984 to 6,148 in 1993 (a fall in success rate from 33 percent to 25 percent) and the number of new RO1 funded went from 5,170 in 1988 to 4,121 in 1993(8). Boyce Rensberger, in a series of three articles in The Washington Post beginning Christmas Day, 1994, entitled American Science: Losing its Cutting Edge(9), addressed these difficulties and pointed out that the number of biomedical scientists in the U.S. increased from 36,000 to 53,000 (a 47 percent increase) from 1987 and 1992; the increase due in part to revised immigration laws that gave preference to foreigners with advanced degrees. Foreign born postdocs now outnumber U.S. born postdocs, in contrast to 1979 when U.S. born postdocs held a 2:1 edge. He also discussed the enormous competition in getting jobs and grant funding and explored the future of funding for basic and applied research. The effect of recent changes in Congress with Republicans taking over both houses is as yet unknown.

With the competition for NIH dollars not likely to ease, it seems important to try to identify and expand non-NIH sources if overall funding for research in pharmacy schools is to increase. On the federal side, 1995 appropriations to various funding agencies varied with NIH receiving only a four percent increase while the National Science Foundation (NSF) and the Department of Commerce’s National Institute of Standards and Technology (NIST) received 11 percent and 17 percent boosts, respectively(10) Clearly, as we diversify our applications for federal funding, we can take advantage of year-to-year shifts in funding availability. Other opportunities for alternative sources of funding include the NIH-AREA grants, which fund scientists in colleges and universities with primarily undergraduate education missions, and the SBIR (Small Business Innovation Research) grants, which are being awarded in increasing numbers (from 412 in 1988 to 804 in 1993). The National Science Foundation does not support medical research but scientists in pharmacy schools are eligible for funding of the more basic science aspects of their research. The FDA Center for Drug Evaluation and Research coordinates clinical pharmacology fellowships that are open to PharmDs. As discussed earlier in this report, the opportunities for industry funding are mixed. While dollars are generally tight within the pharmaceutical industry, there may be opportunities for pharmacy school investigators to provide contract research in areas the industry is downsizing.

In general, the more “cutting-edge” we can keep our research, the more likely we are to be funded from any source. Therefore, paying attention to the areas identified in the first section of this report and keeping a continuous eye on developments in science and health care is essential to our continued success.

Conclusion

About half of our research funding is provided by NIH; the other half is derived mostly from industry and state grants and contracts, with some being derived from alternative federal sources and foundations. Examination of FY1995 funding of federal extramural research programs shows an increase for NSF and NIST in particular, with NIH funding staying about constant. Within NIH there are some programs such as the NIH-AREA grants, which should be of particular interest to researchers at smaller or less research intensive schools of pharmacy. There appears to be a need to renew our efforts to diversify our funding base and to identify a variety of sources of research funding. It is critical that pharmacy faculty be on the cutting edge of research and be able to adapt to and contribute to new developments in science and health care.

RECOMMENDATION 3: The RGAC recommends that AACP should be more aggressive in identifying and disseminating information about sources of funding (appropriate NSF programs, NIH-AREA grants, foundation funding) through a variety of information vehicles (e.g., newsletter, PharmLine). Section programming would also be an appropriate mode of dissemination of information.

ENTRY-LEVEL PHARM.D TRANSITION

Background

Research, as defined by Webster, is “studious inquiry or examination; especially investigation or experimentation aimed at the discovery and integration of facts, revision of accepted theories and laws in light of new facts, or practical application of such new or revised theories or laws.” This broad definition of research should be read into the discussion that follows.

Transition to the entry-level PharmD program may require many schools of pharmacy to generate a large number of practice sites for clerkships. These sites will be staffed with tenure or non-tenure track faculty whose primary responsibility will be to teach and practice. What will differentiate these individuals from non-faculty practitioners? Research must be a component of these individuals’ activities, as well as of more traditional faculty, if we are to succeed in meeting both the short-term needs of the profession and the long-range goals of the schools and colleges and the universities within which they function. Clearly, ongoing evaluation of the value of pharmaceutical care services, in the form of pharmaco-economic and quality-of-life outcomes research, and dissemination of that information in the professional and lay literature is critical to the continued viability of the profession. Furthermore, clinical research on the factors affecting the appropriate use of drugs is essential in creating the scientific basis for pharmaceutical care interventions. Practice faculty conducting research in these areas provide a critical link to new models of practice and in defining the problems requiring pharmaceutical care.

Furthermore, the discovery and application of new knowledge is an essential component of our universities, particularly those with a defined research mission. Participation in research activities clearly contributes enormously to the growth, stimulation, and credibility of individual faculty members as well as the pharmacy profession. If schools and colleges of pharmacy are to maintain their reputation and credibility within the university and, indeed, within society, pharmacy schools must be known for the research they perform as well as for their other activities.

Along with acknowledgment of the importance of research
activities to the academic enterprise and the profession of pharmacy conies a parallel recognition that different schools have different missions, some of which weigh more substantially on the teaching component. It is critical that AACP recognize this diversity among its member schools and colleges of pharmacy and tailor expectations of faculty members in individual schools to an accurate assessment of the mission of that individual school within the context of its university.

Conclusions

For all these reasons the RGAC reaffirms the following policy statements which have been previously adopted by the Association and asks that they be applied during this period of transition to the entry-level PharmD:

- All pharmacy faculty have a responsibility to generate and disseminate knowledge through scholarship. (Source: Research and Graduate Affairs Committee, 1993).
- The American Association of Colleges of Pharmacy recognizes that faculty members in clinical practice have a responsibility for scholarly activity in addition to teaching and clinical practice. (Source: Policy Development Committee, 1981).
- The Association encourages colleges to foster and support clinical faculty members in conducting research, including the development, demonstration, documentation and evaluation of innovative practice roles and the Association recognizes that such research activities are appropriate for clinical faculty members in tenure-tracks. (Source: Policy Development Committee, 1981).

The RGAC additionally wishes to reemphasize the importance of research at this particular juncture in the development of our programs and the profession and therefore proposes the following policy statement:

POLICY STATEMENT 1: As schools and colleges of pharmacy undertake the transition to entry-level PharmD programs, AACP affirms the importance of research to the pharmacy profession and the pharmacy educational enterprise. Furthermore, AACP affirms that every full-time faculty member is expected to participate in research (the generation and/or application of new knowledge) and its dissemination to an extent consistent with the mission of the school or college.

(The Bylaws and Policy Development Committee recommended acceptance of this Policy Statement; the House of Delegates voted to accept this Policy Statement.)

While the RGAC strongly supports the policy statement above it also is very concerned that faculty be hired with expectations of research, along with adequate training, mentoring, and opportunity to perform research activities. We feel that expecting research is not sufficient to make it happen. Initiating a research program, even one that occurs alongside a professional practice, requires adequate attention to time and other resources necessary for success. It may require a phased-in teaching load, establishing a mentor, and assistance in establishing meaningful collaborations, as well as appropriate start-up funding. Hiring an individual with expectations of research but without adequate administrative support to permit that individual to succeed is unfair and damaging to the morale of the individual and those around him.

RECOMMENDATION 4: The RGAC recommends that every full-time faculty member be provided an opportunity to succeed at research to the extent consistent with the interests of the individual and the mission of the department, school and university.

The issue of recognizing the importance of research to the profession and to the pharmacy educational enterprise has become of increasing concern as schools have undertaken transitions to the entry-level PharmD curricula. This concern is particularly great among research-oriented clinical faculty who recognize a danger in dividing practice faculty into research and patient-care-only practitioners, and in the diminished demand for research-oriented clinical graduates. Therefore, the RGAC recommends that these issues be discussed and considered by schools as they plan for the transition.

RECOMMENDATION 5: In planning for the transition to an entry-level PharmD program the RGAC recommends that Schools and Colleges of Pharmacy consider the impact of the program and the transition plans on the long-range research mission of the school or college. Particular emphasis should be placed on retaining (or developing) a research focus consistent with the mission of the school/college and the university within which the program operates.

Specifically, we recommend that schools consider the following questions as they develop plans for the transition to the entry-level PharmD program.

Impact on Faculty
1. Have resources been allocated in hiring new faculty (both in the practice areas and the basic sciences) to retain (or develop) a research mission consistent with the mission of the university?
2. Does the research training of new faculty adequately prepare individuals to be successful in research?
3. Is the focus of the practice/clinical department, as well as the basic science departments, supportive of research-oriented faculty?
4. Are the promotion and/or tenure guidelines consistent with the expectation that all faculty are responsible for generating and disseminating new knowledge through scholarship (see AACP policy statement above).

Impact on Research
1. How are intramural resources for research and training being allocated among and within each department/division?
2. Are changes in sources or amounts of extramural funding anticipated?
3. Are principal investigators on extramural projects found in all departments/divisions of the school/college?
4. Are there collaborative research projects? Is anything being done to encourage collaboration?

Impact on Graduate and Fellowship Programs
1. Will the number of pharmacy students applying, entering, and completing graduate and/or fellowship programs change?
2. Are efforts being undertaken to encourage pharmacy students to pursue advanced training and to facilitate their entry into such programs?
3. Will entering graduate students or fellows who are pharmacy graduates be prepared to successfully complete required courses and undertake research?
4. Are pharmacy students completing graduate or fellowship programs likely to select academic careers?

In order to provide a better basis for making decisions about the impact of the PharmD transition and other changes, it would be very helpful to have a more complete database concerning research and graduate training. We are particularly concerned about collecting data to reflect changes that may have occurred during a school’s transition to the entry-level PharmD curriculum. We understand that an instrument was established by the Lemberger Commission to collect such data, but that it has not been used on a consistent basis. Therefore, the RGAC makes the following recommendation.

RECOMMENDATION 6: The RGAC recommends that the Institutional Research Advisory Committee regularly collect detailed data concerning the status of research and graduate studies in our schools and colleges of pharmacy with particular emphasis on longitudinal data from schools who have undergone or are
undergoing the transition to the entry-level PharmD program. This data should be used by the RGAC and others to monitor the impact of the entry-level PharmD transition on research and graduate affairs.


**References**


