

## AACP REPORTS

### Report of the AACP Educating Clinical Scientists Task Force

Robert A. Blouin, PharmD,<sup>a\*</sup> Richard F. Bergstrom, PhD,<sup>b</sup> Vicki L. Ellingrod, PharmD,<sup>c</sup> Courtney V. Fletcher PharmD,<sup>d</sup> Richard D. Leff, PharmD,<sup>e</sup> Andrew Morris, PharmD,<sup>f</sup> Richard T. Okita PhD,<sup>g</sup> Jeanette C. Roberts, PhD,<sup>h</sup> Timothy S. Tracy, PhD,<sup>i</sup> Rosalie Sagraves PharmD,<sup>j</sup> and Kenneth W. Miller, PhD<sup>k</sup>

<sup>a\*</sup>School of Pharmacy, University of North Carolina at Chapel Hill, Chair

<sup>b</sup>Lilly Research Laboratories, Eli Lilly and Company

<sup>c</sup>College of Pharmacy, University of Michigan

<sup>d</sup>School of Pharmacy, University of Colorado at Denver & Health Sciences

<sup>e</sup>School of Pharmacy, Texas Tech University Health Sciences Center

<sup>f</sup>School of Pharmacy, Hampton University

<sup>g</sup>National Institute of General Medical Sciences, National Institutes of Health

<sup>h</sup>School of Pharmacy, University of Wisconsin-Madison

<sup>i</sup>College of Pharmacy, University of Minnesota

<sup>j</sup>College of Pharmacy, University of Illinois at Chicago

<sup>k</sup>American Association of Colleges of Pharmacy

AACP President Marilyn Speedie chose to appoint an Educating Clinical Scientists Task Force (Task Force) instead of the AACP Research and Graduate Affairs Committee to explore how academic pharmacy can increase its capacity for training clinical scientists to expand pharmacy's involvement, given the national emphasis on clinical and translational research, in bench to bedside and bedside to patient care research. President Speedie noted that academic pharmacy presently has at least five models for educating clinical scientists in our colleges/schools, but the output from the programs is relatively low. These graduates are in demand for academic positions, and are highly sought by other private-sector employers. By clarifying the competencies required and pathways needed to attain those competencies, President Speedie postulated that academic pharmacy will be more prepared to attract students to these programs, and better able to communicate with federal agencies that might fund our training programs. She asked the Task Force to:

1. Define the various career opportunities for clinical scientists.
2. Define the competencies and outcomes required for each type of position.
3. Explore the demand for such individuals.
4. Examine the state of clinical scientist preparation (models, capacity, demand).
5. Make recommendations for unifying the way clinical scientists are trained for various positions. Is one model sufficient for all; if not, can two models suffice? What are the advantages of having one or two models with clearly defined outcomes?

6. Discuss the collaborations (between schools, across professional boundaries) needed in order for us to expand our graduation of clinical scientists.

7. Explore how we can best obtain further funding to allow us to expand our numbers of graduates.

The Task Force met October 18-19, 2006 in Washington, DC, discussed the charges, and came to consensus on a Policy Statement for the Association on the education and training of a "new" Pharmacist Clinical Scientist. The Task Force report presents academic pharmacy's previous deliberations on these charges to provide a context for the Task Force's Policy Statement.

## BACKGROUND

### Translational and Clinical Research

These two terms are often used interchangeably and even in combination as in translational clinical research. According to the Request for Application for the National Institutes of Health Institutional Clinical and Translational Science Award (CTSA):

"Clinical research comprises studies and trials in human subjects meeting the NIH definition in the PHS 398 instructions. Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. The term science describes the discovery of new knowledge about health and disease prevention, pre-emption,

and treatment, as well as methodological research to develop or improve research tools.”<sup>1</sup>

Others have developed slightly different definitions for these two terms.<sup>2,3</sup> Most have a concept of clinical research involving human subjects, either taking a more narrow view that it is research in a patient-care setting, to the broader view described by the NIH Director’s Panel on Clinical Research which included: 1) patient-oriented research conducted with human subjects or material of human origin, 2) epidemiologic and behavioral studies, and 3) outcomes and health services research.<sup>4</sup> The term “translational” on the other hand, evolved from the view and findings that much biomedical NIH funded research facilitated a critical understanding of the processes of disease but the results were not being effectively or efficiently “translated” into drugs, diagnostics, and devices to treat disease.<sup>5</sup> Furthermore, those drugs, diagnostics, and devices that were developed from basic research findings, even after they were approved and shown to be effective through the New Drug Application (NDA) process, were not being prescribed or ordered by a significant number of physicians, who continued using less effective means to assist their patients. Why were these more effective approaches for treating and diagnosing disease being “lost in translation?”<sup>6</sup>

Translational research was discussed in the 2004-05 AACP Research and Graduate Affairs Committee report and that definition is still current with the exception of the new use of the terminology, T1 and T2.<sup>7</sup> The term T1 is used to refer to the bidirectional pathway between bench research and the bedside (initial clinical trials) while T2 is the bidirectional pathway between the bedside and the patient being seen by a physician or other health professional for diagnosis and/or treatment. T1 research activities encompass many of the pharmaceutical sciences such as pharmaceuticals, pharmacology/toxicology, and medicinal/natural products chemistry whose roles include “translating” newly developed receptor ligands into drug molecules and bioavailable drug products that can be administered to healthy subjects and highly selected diseased patients in Phase I, II, and III clinical trials. In summary, T1 research encompasses all those required studies that lead to defining a drug’s safety and effectiveness in treating disease in selected patients. This definition makes it clear that the pharmaceutical sciences are translational sciences. T2 research activities refine the conditions and parameters for the efficient use of drugs and approved drug products in the general population and/or define the drug’s use in specific patient populations not included within the scope of the original clinical investigations. Comparative effectiveness trials, quality of life evaluations, drug-drug interactions, refinement of dosage regimens for selected

patients, and the study of factors which influence patient outcomes are some examples of T2 studies. In summary, T2 research encompasses all those studies that lead to an enhanced efficiency in treating disease and to broader applicability among a wider array of patients.

From the description of translational research, clinical or patient-oriented research occurs in both the T1 and T2 pathways. Clinical scientists play an important role in drug discovery and development from earliest points in drug discovery, such as target identification and pre-clinical evaluation, until the late stages of a drug product’s life cycle, where the drug may have become the foundational standard of care. Clinical scientists involved in the T1 pathway are employed directly or indirectly by the pharmaceutical industry to conduct Phase I-III pre-NDA clinical trials. Academic Health Centers (AHCs) and clinicians at those AHCs are often contracted by the pharmaceutical industry to conduct pre-NDA clinical studies. T2 clinical studies include, but are not limited to, Phase IV studies that address drug-drug interactions, individualized dosing regimens, comparative outcomes studies, and studies of patient and health provider behaviors and their impact on patient outcomes. Clinical studies examining approved drug effectiveness in previously unstudied populations (eg, pediatrics) or in patients with disease states not included in the NDA approval process (ie, unapproved uses) could fall into either the T1 or T2 category. Core competencies such as pharmacokinetics, regulatory sciences, statistics, study design, epidemiology, and research ethics are essential for clinical scientists in either of the pathways. Pharmacogenetic/genomic studies designed to either identify the optimal therapeutic entity and/or dosing regimen based on genetic typing also falls into both the T1 and T2 phases.

### **The Pharmacist Clinical Scientist-AACP Activities**

The concept of a pharmacist clinical scientist, “people who are equally skilled and trained in a science and in pharmacy practice” was introduced in 1975 to academic pharmacy in the report, “Pharmacists for the Future” by the AACP-commissioned Study Commission on Pharmacy also known as the Millis Commission, after the committee’s chair, Dr. John S. Millis.<sup>8</sup> The Millis Commission’s clinical scientist recommendation emerged as a pathway to design the most appropriate curricular content for pharmacy education in view of the Millis Commission’s other significant new recommendation, that pharmacy should be conceived as a *knowledge system* which renders a *health service* by concerning itself with understanding drugs and their effects upon people and animals. Following from this concept of pharmacy as a knowledge system, the Millis Commission posited

what and how much scientific knowledge was needed to educate a pharmacist for a role in this knowledge system. The Millis Commission argued that the profession and the academy did not have a faculty member who could bridge the gap between science and practice such as existed in medicine, the physician clinical scientist. Therefore, the education and training of a small cadre of pharmacist clinical scientists was needed for the academy to relate their specialized scientific knowledge to the development of the practice skills required (by pharmacists) to provide effective, efficient, and needed patient services. The knowledge and activities of this new pharmacist clinical scientist would then be used to guide and improve the quality and content of the pharmacy curriculum.

The Millis Commission report is often misquoted as stating that a pharmacist clinical scientist is equally at home in the laboratory and at the bedside. When the Millis Commission report was published, few pharmacists were serving at the patient bedside. What the Millis Commission did state is that "A clinical scientist in medicine is one who is equally at home and equally expert as a physician at the patient's bedside and as a basic scientist in the laboratory." This supposition of dual expertise enabled the physician clinical scientist to assist his/her colleagues in making the choice of those parts of his/her *scientific* discipline which must be given the highest priority within the *medical school curriculum*. Thus, the Millis Commission's concept of the physician clinical scientist was primarily viewed as an expert whose most important role would be to provide feedback to his/her colleagues as to *what curricular science content was most relevant to practice*. From this view that physician clinical scientists had a significant impact on medical school curricula emerged the idea that a pharmacist clinical scientist would do the same for the pharmacy curriculum. The validity of the role of physician medical scientists in influencing the science content of the medical school curriculum is questionable, as there is no evidence to suggest that it actually occurred. Although the importance of physician clinical scientists performing clinical research was not dismissed, the Millis Commission stated that most clinical knowledge about drug action and use as well as drug products was developed in the research laboratories of the pharmaceutical industry, not academia.

The Millis Commission's suggestion that pharmacy was a knowledge system was not universally embraced but the recommendation for a small cadre of pharmacist clinical scientists had an immediate impact on academic pharmacy. The 1977 AACP Teacher's Seminar addressed the concept of the pharmacist clinical scientist in a session titled, "Responsibilities of Graduate Faculty in Pharmaceutical Sciences for the Training of Clinical Scientists."<sup>9</sup>

The major education/training model recommendation resulting from this session was a two-year post-PharmD fellowship program. Concomitantly, the University of Minnesota College of Pharmacy, under the leadership of Albert Wertheimer, PhD and Paul Bataldan, MD successfully applied for and were awarded approximately \$1,000,000 for the initiation of a clinical scientist training program from the Kellogg Foundation. Eventually, 13 Kellogg Fellows graduated from Minnesota with a PhD degree from the graduate program.<sup>10</sup> The loss of continued funding from Kellogg ended what was a good start toward the formation of a cohort of clinical scientists, most of whom were focused on what is presently termed health services or outcomes research, a category of clinical research.

AACP's Research and Graduate Affairs Committees (RGACs) repeatedly considered the issue of the appropriate educational model for pharmacist clinical scientists.<sup>11</sup> The fellowship training model remained primary in most recommendations until 1995-96, when the RGAC recommended that colleges/schools with appropriate resources move from the post-PharmD fellowship education/training model to a graduate degree (MS/PhD) model of education/training. Although this recommendation to move to a graduate degree model was not accepted by the AACP House of Delegates (HOD) in July 1996, a similar proposal was reintroduced by the 1997-98 RGAC and was accepted as policy in July 1998.<sup>12,13</sup> The 1998 policy statement adopted by the HOD states:

AACP supports the development of graduate degree programs for the purpose of educating and training pharmacist-clinical scientists at all schools and colleges of pharmacy with adequate pharmaceutical science and clinical faculty and facility resources. The pharmacist clinical-scientist graduate programs should contain appropriate coursework and research requirements to award the appropriate graduate degrees (M.S./Ph.D.) to those individuals who successfully complete the program.

While these discussions over appropriate pathways to educate/train pharmacist clinical scientists were ongoing, a number of colleges/schools of pharmacy initiated dual-degree PharmD/PhD programs to take advantage of the increasing number of students entering pharmacy with three or more years of pre-professional education who expressed interest in a research career, but who were concerned with the length of time required to obtain both degrees in a sequential manner. Some of these dual doctorate degree programs focused on preparing pharmacist clinical scientists, while other PharmD/PhD pathways prepared students in the more traditional pharmaceutical sciences, such as medicinal/natural products chemistry, pharmacology/toxicology and pharmaceuticals, with less

focus on utilizing the clinical preparation provided by the PharmD degree. While these dual degree programs provide opportunities for pharmacy students at research-intensive universities, those students with interest in or developing interest in research, either clinical or pharmaceutical sciences, who attend pharmacy colleges/schools without PhD programs, cannot avail themselves of a dual PharmD/PhD degree.

### **The Pharmacist Clinical Scientist-ACCP Activities**

The American College of Clinical Pharmacy (ACCP) addressed the issue of the education/training of pharmacist clinical scientists in the ACCP White Paper, "Central Issues Relevant to Clinical Pharmaceutical Scientist Training Programs," in 1991.<sup>14</sup> The paper made a comprehensive investigation of the pharmacist clinical scientist, from his/her differentiation with other health professional research scientists (eg, MD, MD/PhD), the market for these individuals, the education/training approaches, and related issues. This ACCP White Paper was issued when the profession was in the midst of the debate about the single (PharmD) vs. dual-degree (BS and PharmD) approach for educating pharmacy practitioners. In 1991, most pharmacist clinical scientists were post-BS PharmDs with residency and/or fellowship training. The White Paper recognized the issue of funding for the education and training as a major challenge for the growth and quality of training programs for pharmacist clinical scientists.

The ACCP Research Affairs Committee (RAC) issued a White Paper, "The State of Science and Research in Clinical Pharmacy," in 2006, which covered much of the same ground as did the 1991 White Paper.<sup>15</sup> The RAC White Paper explored the current state of education/training models of clinical pharmacy scientists, including the PharmD/PhD, PharmD/MS, PharmD/Residency, and PharmD/Fellowship pathways. The RAC also published the results of a survey of ACCP member involvement in clinical research and found that a majority of survey respondents were not doing clinical research, but for those that were, most obtained funding for their research from corporate or industry sources. AACP has presented data demonstrating that a very small number of PharmD educated faculty have been successful in competing for National Institutes of Health (NIH) awards. The 2006 ACCP report did not recommend any particular pathway to obtain the education and training required to conduct clinical research, but suggested that there were multiple pathways to prepare clinical scientists.

### **The Physician Clinical Scientist Crises**

Coincidental with the recommendation of the Study Commission that pharmacy needed a clinical scientist like

those in medicine to bridge the gap between practice and curricular content and practice and research, the first warning that physician clinical scientists were an endangered species was published.<sup>16</sup> This was followed by numerous articles expressing concern regarding the demise of physician clinical investigators, this despite the NIH-sponsored dual MD/PhD granting Medical Scientist Training Program (MSTP) for medical students to undertake research training in addition to their medical education and training, available since 1964.<sup>17-21</sup> The growing crises in clinical research, primarily viewed as a crisis in physician clinical scientists, was addressed in 1996 by the NIH Director's Panel on Clinical Research, composed of physicians from academia and industry, "to review the status of clinical research in the United States and to make recommendations to the Advisory Committee to the Director, NIH about how to ensure its effective continuance."<sup>24</sup> Several important recommendations emanating from the report of the Director's Panel included a definition of clinical research, the initiation of NIH training awards (K08, K23) for physicians and other health care professionals to acquire additional research skills, support for clinical scientist mentors (K24), and specific institutional awards (K30) for developing and providing education and training programs in clinical research for persons with health professions degrees.

Following the response of NIH in the mid-1990s to the crises in clinical research, evidence suggested that the situation was not improving quickly enough. While physicians (MDs) competed favorably with PhD scientists for NIH support, grants involving human subjects did less well. Additionally, a significant percentage of successful physician K awardees were not subsequently applying for R01 awards, suggesting that a number of potential problems, other than interest in a clinical research career was impeding progress.<sup>22-24</sup> Lack of a clinical research infrastructure, new regulations on the use of human subjects in research, and surprisingly, a "lack of respect" for clinical research involving human subjects were identified as impediments.<sup>25-27</sup> The "lack of respect" theme reemerged at a 2005 NIH-sponsored conference which discussed options for increasing and improving clinical research and appears to be the major reason for requiring an independent academic home (Center, Institute, Department) for clinical research in the NIH Request for Proposal for the Clinical and Translational Science Awards (CTSAs).<sup>28</sup>

### **Medical Education's Response to the Physician Clinical Scientist Crises**

The Association of American Medical Colleges (AAMC) explored what the nations' medical colleges/schools could do to increase the interest in and prepare

medical students for careers in clinical research. AAMC convened their first Task Force on Clinical Research (CRTF I) in 1998.<sup>29</sup> A number of outcomes forthcoming from CRTF I, included support for the Clinical Research Enhancement Act which authorized loan repayment programs for clinical researchers. Concomitantly, AAMC partnered with the American Medical Association and Wake Forest University School of Medicine to sponsor a national summit on translational and clinical research.<sup>30</sup> This Clinical Summit in turn led to the creation of the Clinical Research Roundtable in the Institute of Medicine.<sup>31</sup>

A second AAMC Task Force on Clinical Research (CRTF II), "Promoting Translational and Clinical Science: The Critical Role in Medical Schools and Teaching Hospitals" was issued in 2006 with twelve recommendations for 1) attracting more investigators to translational and clinical research, 2) creating an infrastructure for these investigators to be successful, and 3) financing translational and clinical research.<sup>32</sup> This excellent report should be read in its entirety by the academic pharmacy community as many of the recommendations are directly applicable to pharmacy. While all twelve (12) recommendations are important, the following recommendations are particularly germane to academic pharmacy and the preparation of future pharmacist clinical scientists.

**CRTFII Recommendation 1:** Every future physician should receive a thorough education in the basic principles of translational and clinical research, both in medical school and during residency training.

**CRTF II Recommendation 2:** The Liaison Committee on Medical Education (LCME) should add education in translational and clinical research to the requirements for medical school accreditation, and the Accreditation Council for Graduate Medical Education (ACGME) should embed understanding of translational and clinical research within its required core competencies.

**CRTF II Recommendation 3:** Training for translational and clinical investigators should comprise completion of an advanced degree with a thesis project (or equivalent educational experience), tutelage by an appropriate mentor, and a substantive postdoctoral experience.

**CRTF II Recommendation 11:** Academic medical institutions should establish collaborations with community healthcare providers and practice-based research networks to broaden the diversity and size of the population base for translational and clinical research and to increase opportunities for health services, epidemiological, and outcomes research.

**CRTF II Recommendation 12:** Medical schools and their affiliated teaching hospitals should explicitly recognize and vigorously promote translational and

clinical research as a core mission, and accord it a high priority for institutional funding.

CRTF II, which conducted its work at approximately the same time as the RFA for the Clinical and Translational Science Awards (CTSA) was issued, but before the first CTSA awards were made, addressed many of the same issues posed to the AACP Educating Clinical Scientist Task Force, particularly the appropriate type of education/training for a clinical scientist.<sup>33</sup> CRTF II proposed an advanced or graduate degree approach along with postdoctoral training for the physician clinical scientist. Interestingly, CRTF II recommended that waiting until medical students completed medical training before exposing them to clinical research was too late, and that *all* medical students needed to be educated in the basic principles of translational and clinical research, including comprehension of the scientific method, ethics and contemporary moral dilemmas, and the interdisciplinary nature of clinical research. The CRTF II reinforced this recommendation by proposing to the appropriate accreditation bodies that this training should be required as part of the accreditation standards for both medical education and graduate medical education (residency). The Liaison Committee on Medical Education (LCME) considered and approved a new accreditation standard at its February 2007 meeting which reads, "The curriculum must introduce students to the basic principles of clinical and translational research, including how such research is conducted, evaluated, explained to patients, and applied to patient care."<sup>34</sup>

In terms of the appropriate education/training of an independent clinical scientist, CRTF II recommended at a minimum, a masters degree level degree program with a core curriculum and thesis project of approximately two years in length. At the masters degree level, the CRTF II concluded that an additional 2-3 years of mentored postdoctoral experience was needed to prepare trainees for independence. The CRTF II noted that the attrition rate of junior translational and clinical science faculty was "disturbingly" high, and insufficient education/training was one of the major reasons given for this high drop out rate. The recommendation for graduate level education/training of clinical scientists is consistent with that of NIH Director, Elias A. Zerhouni, MD, who stated that "Today, there is good reason to believe that the scope of knowledge and expertise needed to be an effective translational or clinical scientist can no longer be acquired on the job as was done in the past."<sup>35</sup>

To attract physicians to careers in translational and clinical research, the CRTF II recognized this career pathway will only become attractive, "if this choice is seen as offering an academically and financially viable long-term

career path that is valued and supported by the leadership in academic medicine.”<sup>32</sup> The same could be said for translational and clinical research in academic pharmacy.

### **The Education and Training of the Pharmacist Clinical Scientist**

**Contemporary Education and Training of the Pharmacist Clinical Scientist** For over thirty years, the post-PharmD research fellowship, essentially a mentored on-the-job research training program has been the primary pathway for the pharmacist clinical scientist. Although this pathway has produced some excellent pharmacist clinical scientists, the fellowship pathway has been hampered by a lack of consistent funding and uneven program completion criteria. Many fellows have been funded via pharmaceutical industry grants, resulting in fellows learning how to conduct clinical research by insuring that a clinical protocol, designed either by a pharmaceutical company or the fellow’s mentor and the company, is properly carried out. Some fellows receive additional didactic education to supplement their practical training, but the experience in supervising a clinical trial varies greatly, so that it is difficult to estimate the overall value of the fellowship program model. Despite a lack of measurable outcomes, the fellowship pathway retains strong support among many PharmD clinical scientists, and selected programs with a didactic component along with the on-the-job research experience do provide some fellows with the ability to independently conduct clinical research.

Despite the long history of the clinical fellowship track, the Task Force agreed that if these PharmD educated individuals are to successfully conduct hypothesis-driven patient-oriented research, they must go through a degree-granting program at a minimum. With the initiation of the Clinical and Translational Science Award (CTSA) program, those colleges/schools of pharmacy which are located in institutions with CTSA awards will be afforded clinical scientist education/training programs at both the MS and PhD level. PharmD practice faculty already at institutions with NIH-funded clinical investigators can and should apply for K08 and K23 training grants which provide opportunities to pharmacy faculty to obtain graduate degrees in clinical research.<sup>36</sup> Institutions with existing K12 and K30 awards also provide education and training leading to certificates and the Masters degree in clinical research. PharmD graduates and faculty can and should avail themselves of these programs. Several pharmacy colleges/schools already offer education/training at the MS and PhD level for pharmacy students in the pharmaceutical and clinical sciences, and opportunities for graduate degree education/training in

the clinical research area of outcomes and health services research are available in some graduate programs in the Social and Administrative Sciences. To build a stronger clinical and translational science research infrastructure in colleges/schools of pharmacy, it will be necessary for more PharmD graduates and faculty to avail themselves of opportunities for advanced education and training leading to a PhD in the clinical sciences. Improving the expertise and capability of existing and future pharmacy faculty to conduct clinical and translational research (ie, a rising tide lifts all the boats) is consistent with the AAMC’s CRTF II report and the focus of the new CTSA programs in developing a more effective clinical research infrastructure.

### **The Need for a New Pharmacist Clinical Scientist**

In addition to supporting graduate programs at the MS and PhD levels to enhance the clinical and translational abilities of pharmacy faculty and students, the Task Force discussed how pharmacy could make a more significant impact on the entire translational science enterprise than at present. Something bold was needed; a “new” program that would raise the impact and recognition of our faculties and colleges/schools as significant and essential members of the clinical and translational science enterprise. Pharmacy colleges/schools are the only university academic units that potentially house all the component science expertise (ie, medicinal/natural products chemistry, pharmacology/toxicology, pharmaceuticals, clinical, and outcomes scientist) essential to translating a new drug molecule to a useful drug product for patients. With the exception of drug marketing and sales, colleges/schools of pharmacy faculty provide the component expertise of a pharmaceutical company. At research-intensive universities, particularly those within an AHC or with an AHC affiliation, pharmaceutical sciences faculty provide scientific expertise not found in medical schools or any of the other health professions schools. While the important research expertise of pharmacy clinical scientists has been recognized in AHCs applying for CTSA grants and planning grants, the clinical and outcomes and health services research output of pharmacy faculty, with exception, have had a much lower profile in pharmacy colleges/schools. Like their counterparts in medical schools, physicians who primarily provide patient care and instruction of students, pharmacy clinical faculty are often not considered essential to the institution’s clinical research mission.<sup>37</sup>

Therefore, to obtain more recognition at the national level for the value of pharmacy educated clinicians and clinical scientists, and most importantly, to improve the public’s health particularly in the rational and optimal use of medications, the academy needs to take a bold step to

create a “new” pharmacist clinical scientist. While this person would have a PharmD/PhD, the Task Force does not suggest a recreation of the MD/PhD MSTP program. Instead, the education and training of these new pharmacist clinical scientists needs to take advantage of the unique environment provided by colleges/schools of pharmacy associated with AHCs.

**Policy Statement:** Research intensive university pharmacy programs associated with academic health centers (AHCs) should accept as a necessary component of their research/graduate training mission, a significant interdisciplinary education/training program for clinical scientists in experimental pharmacotherapeutics at the PhD level. (*Note: This Policy Statement was accepted by the 2006-07 House of Delegates with minor wording changes.*)

The Task Force does not recommend that every PhD program that admits PharmD students should be designed to achieve the outcomes of the recommended program. However, individuals with the education/training described for this new clinical scientist have been missing from the academic milieu of colleges/schools of pharmacy and as a result, pharmacy has not played as significant a role as might be possible in the clinical research portfolio of the AHC.

One of the distinguishing characteristics of the proposed program is its interdisciplinary nature. The Task Force recognized that existing graduate programs utilize individuals from other disciplines on graduate student examination committees and that thesis research work is often conducted with the assistance and mentoring of faculty outside the primary discipline. This “new” interdisciplinary program differs from these informal arrangements in requiring formal co-mentors for the students in this program, one from the sciences, either the pharmaceutical or biomedical sciences, and one clinician clinical scientist (eg, MD, PharmD). For example, there could be a pharmaceutical scientist mentor and a clinical scientist, either a PharmD from the pharmacy faculty or an MD from the medical school. Conversely, a PhD from the biomedical sciences (medical school) and a PharmD clinical scientist from pharmacy may serve as co-mentors. Preferably, the graduate program should be housed in the college/school of pharmacy, so one of the mentors must have an appointment in the pharmacy college/school. However, given that the CTSA program has significant education and training program components, this program could be administered in a separate clinical and translational research institute, center, or department. The analogy of shared parenting (co-mentors) rather than cloning (disciplinary mentor) was used to describe the requirement for the co-mentors.

### **The Program Name**

The initial policy statement used the term clinical pharmaceutical scientist, but upon further discussion, Task Force members decided this term did not sufficiently convey the needed focus on patient-oriented clinical research. Clinical pharmacology was ruled out because of its potential confusion with existing post-doctorate clinical pharmacology training programs. The terms experimental pharmacotherapy, experimental therapeutics, and experimental pharmacotherapeutics were considered in describing the type of skills possessed by an individual graduating from the program. Therapeutics implies interventions other than drug therapy, and the objective of the program was to educate/train individuals whose major focus is drug use in humans with the ability to discover gaps in drug design and use, and to develop studies in humans. The finalists, experimental pharmacotherapy and experimental pharmacotherapeutics both exemplify the research focus of the graduate with the term experimental. Pharmacotherapeutics was chosen over pharmacotherapy because the former term was thought to suggest pharmacy practice more than research.

### **The Program Requirements**

A health professions clinical doctorate would be required for admission (e.g., PharmD, MD, DDS, DVM, DN, DO, etc.). The Task Force recognized that a program restricted to PharmD students or graduates would not have a reasonable chance of obtaining training grant support from NIH, and would negate the interdisciplinary nature of the program. A residency would not be required for admission, although it may be advantageous for some students. Licensure in the candidate’s health profession may be required for the graduate student to work with patients in a clinical study or within an AHC setting. Core requirements would include areas such as pharmacokinetics, pharmacodynamics, pharmacogenetics/genomics, biopharmaceutics (ADMET), bioethics, statistics, clinical trial design, and research methods. Rotations in selected laboratory environments would be required to develop analytical and other laboratory skills. Electives supporting the student’s research dissertation work would be essential. The thesis must include a hypothesis and specific aims to address a clinically relevant issue in pharmacotherapeutics and must include a clinical investigation involving patients or healthy volunteers. In addition to the co-mentors (clinician and scientist), the thesis committee should be multidisciplinary and include faculty from outside the college/school of pharmacy.

A concern that has been raised about utilizing a graduate program to develop clinical scientists is that graduate work will pull the student away from patients and turn

them into a laboratory scientists rather than the desired clinical or patient-oriented scientist. This has been seen with graduates of the MSTP.<sup>38</sup> In order to negate this concern, the program must provide for continual clinical rotations. These rotations could be part of a student's mandatory teaching assistantship for the first year. Following the first year, the student would focus on a thesis project and through mini clinical rotations in the potential area of interest to intensive clinical experience in the chosen area of investigation, and develop and maintain relationships with clinical practitioners necessary to conduct clinical research in their chosen area of pharmacotherapeutics.

### **Pathways to the Degree**

The program described could be completed using several different pathways. Obtaining the initial health professions doctorate degree and then entering the PhD program is traditional, but may not be the most attractive to clinical doctorate students. Students could enter the program utilizing the clinical doctorate/PhD dual degree option, but it is important to emphasize that the student should not be shortchanged on any clinical experience in order to take graduate courses or laboratory rotations. The graduate of this program is a *Clinical Scientist*, and clinical experience is as important as any other component of the graduate program. A third pathway, which might be advantageous for students at colleges/schools of pharmacy not associated with an AHC would be the completion or partial completion of the core curriculum utilizing a dual degree PharmD/MS pathway. As these programs develop in AHC-affiliated colleges/schools of pharmacy, it would be possible to provide core curricular graduate coursework to interested students at other institutions through distance learning. This could be facilitated through formal affiliation agreements among colleges/schools of pharmacy. Again, it is important to reiterate that the clinical (patient-contact) components of the PharmD program not be compromised by dual degree course or laboratory requirements.

The interdisciplinary program described may already be offered with minor variations at AHC-affiliated health professions colleges/schools in research-intensive universities. However, it is the Task Force's belief that most of these programs do not require their students to be involved in clinical trials with patients/human subjects for all or significant parts of their thesis research project(s). Research on human tissues or specimens is clinical research in its broadest definition, but the PhD in experimental pharmacotherapeutics that the Task Force is recommending requires the research focus to be the study of drug action in human subjects. Those clinical studies can and should be supplemented with laboratory work,

but the focus of the research should be on the drug-patient interaction.

### **Developing the Infrastructure for Success in Clinical Research**

It is not realistic to assume that a relatively small number of PhD graduates in experimental pharmacotherapeutics each year will rapidly or significantly change the clinical research environments of colleges/schools of pharmacy "overnight." These individuals and others with advanced education/training will not succeed if both the culture and infrastructure of the academy do not change and appropriately utilize their unique expertise and those of other clinical scientists, including outcomes and health services researchers. What are some of the infrastructure changes that are needed?

The Task Force was impressed with Recommendations 1 and 2 of the AAMC's CRTF II, which stated that all medical students and medical residents receive a thorough education in the basic principles of clinical and translational research, and also carried through this recommendation to the respective accreditation organizations. Pharmacy needs to take this step with both the Accreditation Council for Pharmacy Education (ACPE) which accredits professional degree programs, and the American Society of Health-System Pharmacists (ASHP) which accredits post-PharmD residency programs as well, not only to attract more pharmacy students into graduate programs in translational and clinical research, although that is a very desirable outcome.

**Recommendation:** *The AACP BOD should propose to ACPE that a new competency be added to Standard 12 of the 2007 Standards and Guidelines similar in wording to that recently added by LCME to the medical school curriculum accreditation standards regarding the necessity to introduce students to the basic principles of clinic and translational research, including how such research is conducted, evaluated, explained to patients, and applied to patient care.*

Pharmacy practitioners, as well as graduate students and pharmacy faculty need the tools to solve important problems, ergo, they must have the abilities of a research scientist.<sup>39</sup> Practitioners and scientists will face different problems, but there should be commonalities in the manner in which they approach and solve them. It is common to speak of evidence-based medical and pharmacy practice, but to practice in this manner presumes the practitioner understands how the evidence was obtained and the limitations of the evidence obtained in clinical studies. While professional degree pharmacy students are exposed to the medical literature, it is doubtful that they understand research principles and possess the competence to critically analyze the conduct and results of

clinical trials. Furthermore, principles of clinical and translational research will be wasted if health professions practitioners do not practice constant quality improvement and/or participate in practice-based research. AAMC recognized the necessity of increasing the opportunity for community practitioners to participate in practice-based research, and encouraged Academic medical institutions to establish collaborations with community healthcare providers and PBRNs through CRTF II Recommendation 11. Academic pharmacy also needs to increase its collaborations with community pharmacy, and establishment of pharmacy-based PBRNs is one way that this may be accomplished.<sup>40</sup>

### **Changing the Academic Culture and Infrastructure**

Considerable time has elapsed since the pharmacy profession and the pharmacy academy have recognized and accepted that the future of the profession is patient-oriented, (ie, clinical). The academy was initially pulled into educating pharmacy students for a more patient-oriented role by Federal legislation which provided financial assistance to colleges/schools to hire clinical educators and offer students clinical experience.<sup>41</sup> In a turnabout, the academy pushed the profession toward the concept of pharmaceutical care and professional doctoral education.<sup>42,43</sup> In the past, the academy supported the concept of pharmacist as a product-oriented practitioner, through development of an excellent research infrastructure and graduate programs, whose PhD graduates provided faculty members and scientists for the pharmaceutical industry.

Presently, the pharmacy academy educates its students to provide clinical services without the research infrastructure needed to provide the unique body of knowledge required for evidence-based pharmacy practice. Turning again to the CRTF II report, the authors recognized in Recommendation 12 that “Medical schools and their affiliated teaching hospitals should explicitly recognize and vigorously promote translational and clinical research as a core mission, and accord it a high priority for institutional funding.” If pharmacy is to recognize and strongly endorse translational and clinical research in addition to clinical practice as a core mission, it too must accord a high priority for institutional funding to support the research and graduate programs necessary to develop clinical scientists.

### **POSTSCRIPT**

#### **The NIH Conference on PharmD Pathways to Biomedical Research**

Shortly after AACP President Marilyn Speedie charged and appointed the Educating Clinical Scientists Task Force, a Special Conference on Pharmacy Research

was announced by the NIH. The Conference took place on the NIH campus, December 13-14, 2006 and was attended by many deans of college/schools of pharmacy, a number of active pharmacist clinical scientists, and a majority of the AACP Task Force. Task Force Chair, Dr. Robert Blouin presented the preliminary findings of the Task Force, including the Policy Statement.

The conference explored the education/training pathways taken by pharmacist clinical scientists to achieve successful research careers, and explored programs and pathways available to current PharmD students and practitioners to attain a research career. Presentations on available NIH programs that could potentially fund the education and training of pharmacist clinical scientists were made along with the obstacles which appear to be preventing PharmD students and practitioners from a research career. The attendees also broke up into a number of groups to discuss specific obstacles to a clinical research career and actions that might be taken to overcome these obstacles. A complete summary of the Conference and the PowerPoint presentations of the speakers are available on the AACP Web site.<sup>44</sup> Several of the recommendations forthcoming from the speakers and breakout sessions are as follows:

1. There is more than one pathway of education/training that an individual can take to become a successful clinical scientist, but with the present focus on clinical training programs sponsored by NIH, such as the K awards and the CTSAs, a masters degree appears to be the minimally accepted pathway to becoming an independent clinical scientist.
2. Attracting PharmD students to a clinical research career must begin early in the professional degree program, preferably the first professional year. The major obstacle to attracting students to clinical research however, is the lack of a significant number of clinical researcher role models or mentors at many institutions. Curricular modifications such as tracking, summer research opportunities and dual degree programs can assist in attracting students, but most students are enticed into a research career by a faculty member whose career they wish to emulate and who encourages the student to join them in their research program. With few clinical scientist mentors, in addition to the difficulty in attracting students into clinical research, there is insufficient funding to support them in a graduate degree program.
3. The Task Force’s report was well received by the conference as one of several options to

increasing the size of the pharmacist clinical scientist manpower pool. Many of the other education/training options discussed at the conference are consistent with those discussed by the Task Force.

### The Future of the Task Force

The primary focus of CRTF II and the present Task Force has been on that aspect of translational and clinical research that deals primarily with the bench to bedside process, the T1 step, in contrast to the bedside to patient use process, or T2. Practice based research networks (PBRNs) were identified by CRTF II as providing opportunities for T2 research for both academic medical center faculty and community healthcare providers. AACP convened a conference on “Embracing the PBRN Model to Improve the Medication Use Process” in Charlotte, NC, February 22-24, 2007. Selected speaker presentations were captured for future video streaming through the AACP Web site. Additionally, the proceedings of the conference, which was supported in part by a small conference grant from the Agency for Healthcare Research and Quality (AHRQ) will be published.<sup>40</sup>

### REFERENCES

1. Institutional Clinical and Translational Science Award (U54). National Institutes of Health Guide for Grants and Contracts. Available at <http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-07-002.html>.
2. Marincola FM. Translational medicine: A two-way road. *J Transl Med.* 2003;1:1. Available at [www.translational-medicine.com/content/1/1/1](http://www.translational-medicine.com/content/1/1/1).
3. Mankoff SP, Brander C, Ferrone S, Marincola FM. Lost in translation: Obstacles to translational medicine. *J Transl Med.* 2004; 2:14. Available at [www.translational-medicine.com/content/2/1/14](http://www.translational-medicine.com/content/2/1/14).
4. The NIH Director’s Panel on Clinical Research Report, December 1997. Available at [www.nih.gov/news/crp/97report/index.htm](http://www.nih.gov/news/crp/97report/index.htm).
5. Contopoulos-Ioannidis DG, Ntzani EE, Ioannidis JPA. Translation of highly promising basic science research into clinical applications. *Am J Med.* 2003;114:477-84.
6. Lenfant C. Clinical research to clinical practice—Lost in translation? *N Engl J Med.* 2003;349:868-74.
7. Beck WT, Ablordeppey SY, Elmquist WF, et al. Impact of the NIH roadmap on the future of graduate education in colleges/schools of pharmacy. *Am J Pharm Educ.* 2005;69:S18. Available at <http://www.ajpe.org/supview.asp?art=aj6905S18&pdf=yes>.
8. *Pharmacists for the future: The report of the study commission on pharmacy.* American Association of Colleges of Pharmacy. Health Administration Press, The University of Michigan, Ann Arbor, Mich. 1975.
9. Responsibilities of graduate faculty in pharmaceutical sciences for the training of clinical scientists. Proceedings of the 1977 AACP Teacher’s Seminar. *Am J Pharm Ed.* 1977;41:394-402.
10. Wertheimer AI. Millis applied: The Minnesota program. In: Worthen DB, ed. *The Millis Study Commission on Pharmacy: A road map to a professions future.* Binghamton, NY: The Haworth Press, Inc.; 2006:115-24.
11. Miller KW. RGAC actions on the clinical scientist. American Association of Colleges of Pharmacy. Available at [http://www.aacp.org/Docs/AACPFfunctions/Governance/7697\\_ClinicalScientist.pdf](http://www.aacp.org/Docs/AACPFfunctions/Governance/7697_ClinicalScientist.pdf).
12. Borchardt RT. Chair report for the research and graduate affairs committee. *Am J Pharm Educ.* 1996;60:18S–22S. Available at [http://www.ajpe.org/legacy/ajpe\\_metaview.asp?ID=1460](http://www.ajpe.org/legacy/ajpe_metaview.asp?ID=1460).
13. Stavchansky SA. Chair report of the research and graduate affairs committee. *Am J Pharm Educ.* 1998;62:21S–26S. Available at [http://www.ajpe.org/legacy/ajpe\\_metaview.asp?ID=868](http://www.ajpe.org/legacy/ajpe_metaview.asp?ID=868).
14. Blouin RA, Cloyd JC, Ludden TM, Kroboth PD. Central issues relevant to clinical pharmaceutical scientist training programs. *Pharmacotherapy.* 1991;11:257-63.
15. Fagan SC, Touchette D, Smith JA, et al. The state of science and research in clinical pharmacy. *Pharmacotherapy* 2006;26:1027-40.
16. Wyngaarden JB. The clinical investigator as an endangered species. *N Engl J Med.* 1979;301:1254-9.
17. Gill GN. The end of the physician-scientist? *Am Scholar* 1984;53:353-68.
18. Goldstein JL, Brown MS. The clinical investigator: Bewitched, bothered and bewildered—but still beloved. *J Clin Invest.* 1997;12:2803-12.
19. Nathan DG. Clinical research: Perceptions, reality, and proposed solutions. *JAMA.* 1998;280:1427-31.
20. Rosenberg LE. Physician-scientists—endangered and essential. *Science* 1999;283:331-2.
21. Medical Scientist Training Program-Overview. Available at [www.nigms.nih.gov/Training/Mechanisms/NRSA/InstPredoc/PredocOverview-MSTP.htm](http://www.nigms.nih.gov/Training/Mechanisms/NRSA/InstPredoc/PredocOverview-MSTP.htm).
22. Nathan DG, Wilson JD. Clinical research and the NIH—A report card. *N Engl J Med.* 2003;349:1860-5.
23. Kotchen TA, Lindquist T, Malik K, Ehrenfeld E. NIH peer review of grant applications for clinical research. *JAMA.* 2004;291:836-43.
24. Kotchen TA, Lindquist T, Sostek AM, Hoffmann R, Malik K, Stanfield B. Outcomes of National Institutes of Health peer review of clinical grant applications. *J Invest Med.* 2006;54:13-9.
25. Campbell EG, Weissman JS, Moy E, Blumenthal D. Status of clinical research in academic health centers. *JAMA.* 2001;286:800-6.
26. Snyderman R. The clinical researcher—An “emerging” species. *JAMA.* 2004;291:882-3.
27. Murillo H, Reece EA, Synderman R, Sung NS. Meeting the challenges facing clinical research: Solutions proposed by leaders of medical specialty and clinical research societies. *Acad Med.* 2006;81:107-12.
28. Enhancing the discipline of clinical and translational science: Executive summary. National Center for Research Resources. National Institutes of Health. Available at <http://www.ncrr.nih.gov/clinicaldiscipline/CTSA052305meeting.asp>.
29. For the health of the public: Ensuring the future of clinical research. Association of American Medical Colleges. Washington DC, 2000. Available at <https://www.aamc.org/publications>.
30. Clinical Research: A national call to action. Association of American Medical Colleges and the American Medical Association. Washington DC, 1999. Available at <https://www.aamc.org/publications>.
31. Institute of Medicine Board: Board on health sciences policy. Clinical research roundtable. Available at <http://www.iom.edu/project.asp?id=4881>.

*American Journal of Pharmaceutical Education 2007; 71 (4) Article S05.*

32. Promoting translational and clinical science: The critical role of medical schools and teaching hospitals. Report of the AAMC's Task Force II on clinical research. Available at <https://www.aamc.org/publications>.
33. Institutional Clinical and Translational Science Award. National Institutes of Health Guide for Grants and Contracts. Available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-06-002.html>.
34. Liaison Committee for Medical Education (LCME). Accreditation Standards: Current standards, latest additions to standards, and standards awaiting approval. Available at <http://www.lcme.org/standard.htm>.
35. Zerhouni EA. Translational and clinical science—Time for a new vision. *N Engl J Med*. 2005;353:1621-3.
36. K Kiosk-Information about NIH career development awards. National Institutes of Health Office of Extramural Research. Available at <http://grants1.nih.gov/training/careerdevelopmentawards.htm>.
37. Holcombe RF. Who's watching out for the clinical academician? *Acad Med*. 2005;80:905-7.
38. Sutton J, Killian CD. The MD-PhD researcher: What species of investigator? *Acad Med*. 1996;71:454-9.
39. Leslie SW, Corcoran GB III, MacKichan JJ, Undie AS, Vanderveen RP, Miller KW. Pharmacy Scholarship Reconsidered: The report of the 2003-2004 Research and Graduate Affairs Committee. *Am J Pharm Educ*. 2004;68:S6. Available at: <http://www.ajpe.org/view.asp?art=aj6803S6&pdf=yes>.
40. AACP Practice Based Research Networks Web site. Available at <http://www.aacp.org/site/page.asp?VID=1&CID=1400&DID=8104&TrackID=>.
41. Buerki RA. In search of excellence: The first century of the American Association of Colleges of Pharmacy. *Am J Pharm Educ*. 1999;63(Suppl):159-62.
42. Papers from the Commission to Implement Change in Pharmaceutical Education. Background Paper I. What is the mission of pharmaceutical education? *Am J Pharm Educ*. 1993;57:374-6.
43. Papers from the Commission to Implement Change in Pharmaceutical Education. A Position Paper. Entry-level education in pharmacy: A commitment to change. *Am J Pharm Educ*. 1993;57:366-74.
44. Pharm.D. Pathways to Biomedical Research. National Institutes of Health Campus. December 13-14, 2006. Available at [http://www.aacp.org/Docs/AACPFunctions/Governance/7967\\_PharmD\\_conf\\_summarypdf.pdf](http://www.aacp.org/Docs/AACPFunctions/Governance/7967_PharmD_conf_summarypdf.pdf).