# ACCP COMMENTARY

### Preparing Clinical Pharmacy Scientists for Careers in Clinical/Translational Research: Can We Meet the Challenge? ACCP Research Affairs Committee Commentary

Robert B. Parker, Vicki Ellingrod, Joseph T. DiPiro, Jerry L. Bauman, Robert A. Blouin, and Lynda S. Welage

Developing clinical pharmacists' research skills and their ability to compete for extramural funding is an important component of the American College of Clinical Pharmacy's (ACCP) vision for pharmacists to play a prominent role in generating the new knowledge used to guide patient pharmacotherapy. Given the recent emphasis on clinical/translational research at the National Institutes of Health (NIH) and the key role of drug therapy in the management of many diseases, there is an unprecedented opportunity for the profession to contribute to this enterprise. A crucial question facing the profession is whether we can generate enough appropriately trained scientists to take advantage of these opportunities to generate the new knowledge to advance drug therapy. Since the 2009 publication of the ACCP Research Affairs Committee editorial recommending the Ph.D. degree (as opposed to fellowship training) as the optimal method for preparing pharmacists as clinical/translational scientists, significant changes have occurred in the economic, professional, political, and research environments. As a result, the 2012 ACCP Research Affairs Committee was charged with reexamining the college's position on training clinical pharmacy scientists in the context of these substantial environmental changes. In this commentary, the potential impact of these changes on opportunities for pharmacists in clinical/translational research are discussed as are strategies for ACCP, colleges of pharmacy, and the profession to increase the number and impact of clinical pharmacy scientists. Failure of our profession to take advantage of these opportunities risks our ability to contribute substantively to the biomedical research enterprise and ultimately improve the pharmacotherapy of our patients.

KEY WORDS clinical pharmacy, research training, graduate training, clinical pharmaceutical scientists. (Pharmacotherapy 2013;33(12):e337–e346) doi: 10.1002/phar.1348

Fostering the development of clinical pharmacists' research skills and their ability to compete for extramural funding is an important component of the American College of Clinical Pharmacy's (ACCP) strategic plan.<sup>1</sup> ACCP's vision is that clinical pharmacy investigators will play a prominent role in generating the new knowledge to be used to guide patient pharmacotherapy. Given the recent emphasis on clinical/translational research at the National Institutes of Health (NIH) and the key role of drug therapy in the management of many diseases, there is an unprecedented opportunity for the profession to contribute to this enterprise. Appropriately trained clinical pharmacists are uniquely positioned to contribute to both T1 (bench-to-bedside or laboratory-to-human research) and T2 (bedside-to-patient research, health services research,

From the American College of Clinical Pharmacy, Lenexa, Kansas (all authors).

<sup>\*</sup>Address for correspondence: Robert B. Parker, University of Tennessee College of Pharmacy, Department of Clinical Pharmacy, 881 Madison Avenue Room 346, Memphis, TN 38163; e-mail: rparker@uthsc.edu.

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drug effects in large populations, and comparative effectiveness research) translational research. A crucial question for the pharmacy profession is whether we can generate enough appropriately trained scientists to take advantage of these opportunities to generate the new knowledge to advance drug therapy.

In 2007, the ACCP Research Affairs Committee was charged by the Board of Regents to develop a commentary on the optimal pathway(s) for developing clinical pharmacy scientists to contribute substantively to biomedical research. This report, approved by the Board of Regents in 2008 and published in 2009, recommended the Ph.D. degree (as opposed to fellowship training) as the optimal method for preparing pharmacists to be competitive clinical/translational scientists.<sup>2</sup> To no one's surprise, this stance generated considerable controversy within ACCP, resulting in persuasive editorials on both sides of the issue.<sup>3, 4</sup>

This issue of appropriate training for clinical scientists has been debated for more than 20 years: What is left to debate?<sup>3–6</sup> The time for arguing whether graduate versus fellowship training is optimal has passed and distracts the profession from the more important question of how pharmacy can develop a critical mass of clinical/translational researchers to meet the needs of society. Since the ACCP commentary was published, significant changes have occurred in the economic, professional, political, and research environments that pose important challenges, as well as opportunities, for developing and sustaining training programs (either graduate programs or fellowships) for clinical scientists with the Pharm.D. degree. In this report, the potential impact of these changes on opportunities for pharmacy in clinical/translational research is discussed, as are the ways in which the ACCP and colleges of pharmacy can increase the number of pharmacists participating in clinical/translational research.

#### Recent Changes Affecting the Clinical/ Translational Research Enterprise

Changes in the clinical/translational research enterprise during the past 10 years have greatly affected the potential opportunities for clinical pharmacy scientists. In September 2004, the NIH Roadmap recognized 12 roadblocks to biomedical research and categorized these along the three interrelated core "Roadmap" themes of new pathways to discovery, research teams of the future, and reengineering of the clinical research enterprise.<sup>7, 8</sup>

In response, the NIH launched the development of the clinical/translational science consortium, calling for the reengineering of the clinical research enterprise and the training of future research team members.<sup>9</sup> Now part of the new National Center for Advancing Translational Sciences (NCATS), the Clinical and Translational Science Awards (CTSAs) support ~60 institutions (see https://www.ctsacentral.org/ for more information). Although the CTSAs provide many opportunities to foster translational research within pharmacy, it is unfortunate that only 25 of the 126 colleges of pharmacy are CTSA affiliated.

The recent development of NCATS by the NIH was targeted to catalyze the development, assessment, and implementation of diagnostics, therapeutics, and devices across a wide spectrum of human diseases.<sup>10, 11</sup> Although the creation of NCATS and the CTSAs has been a great step forward for translational medicine, pharmacy research also encompasses comparative effectiveness research, which, as defined by the Agency for Healthcare Research and Quality (AHRQ), provides evidence on the effectiveness, benefits, and harms of different treatment options.<sup>12</sup> In 2010, as part of the Patient Protection and Affordable Care Act, a new nonprofit comparative effectiveness research entity known as the Patient-Centered Outcomes Research Institute (PCORI) was established (see www.pcori.org/ for more information).<sup>13</sup> PCORI provides new funding opportunities for the expanding field of comparative effectiveness, and clinical pharmacy scientists could be uniquely positioned to address many of the research priorities. However, it is uncertain whether we are preparing adequately trained individuals in sufficient numbers to conduct this type of research effectively because it requires unique approaches that are not traditionally part of most pharmacy curriculums.

Although opportunities abound, the research landscape has simultaneously grown more competitive. The net result is a substantial decline in funding success rates for competitive grant support through the NIH because of increases in R01 applications and increases in the average size of these awards (Figure 1). In fact, in the 2011 and 2012 fiscal years, the overall success rates for NIH research project grants was only 18%, an all-time low. The changing environment for clinical/translational research requires individuals to be highly trained to lead or be part of new transdisciplinary research teams to



Figure 1. Fiscal year 2012 overall success rates for National Institutes of Health research project grants.

be successful in today's highly competitive research environment.

#### Opportunities for Pharmacy in Clinical/ Translational Research

The qualifications of clinical pharmacy scientists as a whole have become well recognized; thus the profession no longer must contend with the question "Are clinical pharmacists qualified to conduct clinical research?"14 Yet some areas of clinical research have only a few prominent clinical pharmacy scientist researchers. In other fields, however, clinical pharmacy scientist researchers are recognized at the top of their discipline. Notable examples include pharmacogenomics, pharmacokinetics, and drug metabolism; clinical trials in human immunodeficiency virus treatment and cardiovascular disease; pharmacovigilance; and health service research (e.g., pharmacoeconomics and pharmacoepidemiology). These fields represent important opportunities, particularly for

research-intensive colleges and schools of pharmacy within academic health centers. Moreover, the current health care environment has opened new opportunities to expand research in areas such as comparative effectiveness research and medication safety.

This key question is central to the issue of preparing well-trained clinical pharmacy scientists: What will be the future demand for these individuals in academia, the pharmaceutical industry, and the health service industry? In academia, opportunities for clinical pharmacy scientists have been expanding, a trend that is expected to continue.<sup>15</sup> The pharmacy and medical education enterprises are expanding rapidly through the growth of existing colleges and schools. The push to increase research stems partly from the Accreditation Council for Pharmacy Education (ACPE) standards for Pharm.D. programs, which include statements related to research and scholarship.<sup>16</sup> Thus pharmacy schools are now facing competition to attract successful researchers with federal grant funding. Hence, although the specific opportunities for clinical pharmacy scientists are changing, the overall demand for these researchers is increasing.

Historically, opportunities for growth in academia have been fueled by increased funding from the NIH and have directed research careers along traditional paths of biomedical research. Projections on future funding for the NIH are for flat or declining budgets. Federal funding is now shifting to other agencies within the Department of Health and Human Services, with a concomitant shift in research focus to issues of treatment effectiveness, quality, and development of innovative wellness and health care delivery models. This shift will open more opportunities for which clinical pharmacy scientists are well positioned because of our roles as medication experts. In addition, new models of pharmacy practice and the advent of collaborative practices have begun to highlight the abilities of clinical pharmacists, creating a unique niche for the profession in research, apart from tradition.

Future opportunities for clinical pharmacy scientists in the pharmaceutical industry are uncertain and difficult to predict. Data regarding pharmacists involved in industry research are lacking, and predictions for career opportunities must be based on general industry trends. For large pharmaceutical companies, mergers resulting in the downsizing of research departments, reduced investment in new drug development, outsourcing of research activity to contract research organizations, and acquisition of drugs at advanced stages of clinical development have negatively affected opportunities for clinical pharmacy scientists. However, careers within contract research organizations and small or startup pharmaceutical companies have expanded. The issue of future opportunities for clinical pharmacy scientists in the pharmaceutical industry is thus unpredictable right now.

## Are Existing Training Programs Meeting the Demand?

There are an insufficient number of post-Pharm.D. research training programs (fellowship or graduate based) to produce the highly competitive clinical/translational scientists necessary to meet the growing demands of society. As a result, gaps persist, and pharmacy is not well positioned to contribute to the workforce needs of this rapidly evolving discipline. Pharmacyeducated clinical/translational scientists continue to have significant opportunities to make substantive contributions to the biomedical and life sciences research enterprise. However, the challenge remains the same: educating and training a critical mass of these individuals who can make substantial contributions to advancing new therapies or treatment strategies for improving human health. Despite the increased opportunities associated with the significant changes in the research landscape, our ability to keep up with the demand for properly trained and mentored junior scientists has not improved. Two major obstacles remain that limit the pharmacy profession in contributing its fair share of talent to the clinical/translational research enterprise: a critical mass of precursor talent and a critical mass of qualified mentors working in high-end research environments conducting contemporary clinical/translational research. These two issues are codependent and must be addressed in tandem. In the paragraphs that follow, we discuss contemporary gaps in pharmacy-based education programs as well as potential opportunities moving forward.

## Attracting Outstanding Students to Careers in Clinical/Translational Research

The pharmacy manpower environment has changed considerably during the past 10 years, resulting in more students who could seek post-Pharm.D. training. These changes include:

- The proliferation and expansion of pharmacy colleges and schools within the United States, resulting in an oversupply of students seeking traditional pharmacy career tracks;
- The supply of postgraduate residency positions being unable to keep pace with the demand for qualified pharmacy students;
- The desire of pharmacy students to seek ways of differentiating themselves (i.e., dual degree programs, postgraduate residencies, and postgraduate fellowships, as well as graduate training at the M.S. and Ph.D. levels); and
- The increased focus and funding opportunities at the NIH to support clinical/translational training and research.

These environmental changes offer newfound opportunities to recruit highly qualified students to clinical/translational research careers in pharmacy. However, although some colleges and schools of pharmacy require a formal research project for all pharmacy students, not all have adopted this approach. The profession in general, and research-intensive colleges and schools of pharmacy in particular, must assume a more aggressive, proactive position in orienting our students to research. All pharmacy students must have a rich, fundamental understanding of the research process. Exposure to research in the professional curriculum will be essential, regardless of students' decisions to engage actively in a research career, because the cognitive skills mastered (i.e., the scientific method) through such experiences will be critical to their ability as practitioners to evolve as perpetual learners. Yet even though research careers are encouraged by ACPE Standards 2007, the logistic realities of a compacted curriculum make incorporating research into the curriculum challenging at best.<sup>16</sup> In addition, many of the new colleges and schools do not include research as a main component of their mission; consequently, their Pharm.D. graduates have limited opportunities to become involved in or exposed to research.<sup>17</sup> To address this gap, curricular revisions should seriously consider incorporating more meaningful, impactful research experiences for all of our students.

Although student exposure to research is critical to developing our next generation of researchfocused faculty, no viable organized mechanism currently exists for interested Pharm.D. students to learn about postgraduate training opportunities, especially if they are not at a research-intensive school. National organizations (e.g., American Society of Health-System Pharmacists [ASHP], American Pharmacists Association [APhA], American Association of Colleges of Pharmacy [AACP], and American Association of Pharmaceutical Scientists [AAPS]) provide avenues for professional students to learn about postgraduate year (PGY) 1 and PGY2 residencies in community and institutional practice, graduate programs, and postdoctoral training. Certainly ASHP, with its Midyear Clinical Meeting venue and Resident Matching Program, has been successful in attracting and placing qualified students in postgraduate clinical practice training tracks (i.e., residencies); however, a similar type of networking session for research training does not exist.

#### Critical Mass of Qualified Mentors

Even if many pharmacy students were interested in clinical/translational research, a second obstacle, lack of a critical mass of qualified mentors working in high-end research environments conducting contemporary clinical/translational research, would be another important factor limiting pharmacy's contribution to the research enterprise. Although garnering student interest in research is key, having successful research faculty from whom they can learn is also part of the issue. A July 2013 search of the AACP Federal Grants database for principal investigators in departments of pharmacy practice or pharmacotherapeutics/translational research identified only 39 individuals with NIH, Veterans Administration, or AHRQ funding. Although this database has limitations (e.g., it covers only grants funded in the 2012 fiscal year, does not specify degree of principal investigator, and omits pharmacists who do not work in colleges of pharmacy), it substantiates the lack of a critical mass of qualified mentors.

Although for many clinical pharmacists, the traditional fellowship route has provided substantial training and facilitated their overall success as clinical pharmacy scientists, changes in the funding and educational landscape have left even some well-trained individuals unable to maintain a research program successfully. This disconnect between the faculty member's desire to conduct research and the often inevitable shifts in effort allocations that result from the lack of funding has created a generation of pharmacy faculty who have become disenfranchised from clinical research. In addition, inadequate research training has left many new tenure-track faculty members unable to obtain NIH funds successfully, putting them in jeopardy of not succeeding at promotion and tenure. Thus efforts to augment the research training of these faculty members, enabling them to retool their research programs through sabbaticals or other methods, should be explored. For research faculty members who have successfully obtained NIH support, use of the K24 mechanism should be encouraged because this type of research grant allows salary support for the faculty's training and mentoring efforts. By reengaging these faculty members in the pharmacy research enterprise, we can successfully increase the number of clinical scientist role models for our students, in turn facilitating students' interest in research. In addition, for those just beginning a tenure-track position, we must pay extra attention to their mentorship and continuing training needs, perhaps incorporating delays of their tenure clock through a pre-tenure position might be well advised and help facilitate their research success. Training grants such as the K30, K08, K23, or K99 may help these junior faculty members transition successfully to a tenure-track position and the overall successful attainment of an independent research program. In addition, the K awards may be used by more senior faculty who are now seeking a change in their research focus but are unable to do so without additional training in a specific area.

#### Current Postgraduate Pharm.D. Training

In the past 30 years, the pharmacy profession has developed two main training strategies to meet the challenge of producing a critical mass of highly qualified clinical/translational research scientists: fellowship and graduate training programs. The approaches adopted by pharmacy were not novel, and although they produced outstanding pharmacy scientists who have populated the academic, industry, and government sectors, they are not meeting the current demand. The commitment by the NIH to reengineer the translational research enterprise (i.e., the Roadmap and the creation of the CTSAs and NCATS), particularly in areas such as drug discovery and development, identification of therapeutic targets, pharmacogenomics, repurposing approved medications, and postmarketing research, directly aligns with work already being conducted at many research-intensive colleges of pharmacy.<sup>10</sup> Thus the pharmacy profession has a unique opportunity to contribute to the critical mass of talent that will ultimately meet this societal need; however, new challenges must be overcome if we are to take advantage of these opportunities.

#### Fellowship Programs

The number of research fellowship programs has declined since the heyday of fellowship training in the 1980s and 1990s. An online search of the *ACCP Directory* identified only 57 fellowship programs, a 33% decrease from the 85 programs noted in the 2009 Research Affairs Committee editorial.<sup>2</sup> Reasons for this include a dearth of candidates because of a previously vibrant job market, a trend that may be reversing, and a lack of reliable funding streams to support the fellow. The latter issue may have contributed significantly to the loss of these fellowship programs because these fellows were often funded by residual balance funds from industry-sponsored research or other such projects (which have substantially declined), grant awards from national organizations such as ACCP or ASHP (which have since disappeared), or modest investments by researchintensive colleges or schools of pharmacy.

Fellowship programs have also suffered from a lack of standardization, creating considerable variability in the quality and rigor of the experience. As a result, the scientific training of Pharm.D. research fellows may vary substantially, depending on the mentor and the program. The ACCP guidelines (also endorsed by the American Association of Colleges of Pharmacy [AACP]) for fellowship training, most recently updated in 2004, have not changed substantially since their inception in 1988.<sup>18</sup> These represent guidelines that are voluntary, and currently, the ACCP Directory lists only seven approved fellowships.

Depending on these fellowship programs to produce a competitive clinical pharmacy scientist is challenging, given that some programs often resemble PGY2 residency experiences with a research project attached. However, it is clear that research fellowships can produce welltrained clinical pharmacy scientists because there are several examples of highly successful individuals in both academia and industry. Although completing a PGY1 residency program before beginning a fellowship program is preferable, the recent tightening of the job market for U.S. pharmacy students has potentially made fellowships a more visible and viable route for research training once again (see "Closing the Gaps").

#### Graduate Training Programs

Pharmacy-based graduate training programs in clinical/translational science have been in place for more than 30 years. However, these post-Pharm.D. graduate training programs with their emphasis on clinical/translational science have been slow to develop. In 2006, the AACP commissioned a task force to assess and recommend strategies by which the pharmacy academy could increase the capacity and impact of competitive researchers in clinical/translational research.<sup>5, 19</sup> Several issues were identified, and specific recommendations were advanced. Unfortunately, many of the same obstacles remain today, including

• The lack of interested precursor talent entering these programs;

- The failure of colleges and schools of pharmacy to build the needed infrastructure to attract and retain scientists capable of developing and sustaining NIH-competitive research programs in the clinical/translational sciences;
- The inability of our colleges and schools of pharmacy to attract a critical mass of scientists/scholars as faculty mentors capable of providing rigorous training experiences for graduate students in the clinical/translational sciences (although we could, in the short term, look outside the profession to fill this mentorship gap, longer term goals would be to have enough pharmacy mentors who work with nonpharmacy mentors to provide a transdisciplinary mentoring program);
- The challenge of developing a sustainable business model to recruit and support the training and research expenses of these graduate students; and
- The difficulty of these programs in incorporating and maintaining a strong "clinical" practice component within the graduate training experience to ensure that students maintain a significant element of clinical competence.

Similar to fellowship training programs, challenges remain in clinical/translational graduate training programs that are associated with consistency in training experiences from one graduate program to another.<sup>20</sup> This variance includes inconsistencies associated with the identification of a core curriculum, the amount and quality of time the graduate student spends in the clinical environment, and the nature of the clinical/ translational research thesis project.

In addition, these graduate training programs are being significantly affected by the economic downturn. These economic changes have the potential of undermining, or at least challenging, how we approach the conduct and funding of all of our research and graduate training programs. Universities, particularly public universities, remain under threat because of declining state support, with the public colleges of pharmacy representing most (but, of course, not all) research-intensive institutions. These institutions shoulder the burden of providing most of the pharmacist-scientists for the nation. Unlike Pharm.D. degree programs, graduate programs are generally not a primary source of income for research-intensive colleges and schools of pharmacy. Rather, many colleges invest substantial sums in the form of teaching assistant or research assistant positions (in addition to infrastructure, etc.). Teaching assistant lines support the teaching mission of the colleges and schools but also provide support for a young graduate student when grant support is unavailable. Colleges and schools willing to invest in and pursue new opportunities in clinical/translational research must consider realigning their investments in positions such as these and creating the proper mix of support for T1-T4 research and training programs. Not all research-intensive colleges and schools of pharmacy can or should perform all types of basic and translational research, but rather, they must do some things well and perhaps not include others at all. Therefore, strategically investing in existing areas of research strength within a school/college and paying cautious attention to new and emerging areas, combined with creating internal operational efficiencies, will be necessary. These investment and operational decisions will require thoughtful engagement by the faculty and a consensus on the strategic research intent of the specific college.

#### Closing the Gaps

#### ACCP's Role

ACCP has invested considerable resources to support the development of independent clinical pharmacy scientists. This is best exemplified by the Focused Investigator Training (FIT) Program, an "intensive, 5-day, hands-on program for up to 18 experienced pharmacist investigators who have not yet been awarded significant peer-reviewed extramural funding as a principal investigator." This type of training opportunity was established as a solution to issues discussed earlier regarding faculty wishing to retool their current research program or needing additional training to be competitive in the current environment. Moreover, this program is an exceptional training opportunity for junior faculty as they enter tenure-track positions. As indicated from current ACCP data, the 2008 FIT Program class has been awarded more than \$2.6 million in new grants. In the first 3 years of the FIT, 55 individuals graduated from the program. We offer the following points for consideration as this program moves forward:

• It is time for ACCP to reevaluate its strategies to optimally prepare FIT participants for collaborative science, consistent with the CTSA and NCATS initiatives;

• The FIT Program must prepare its participants for collaborative opportunities within the CTSA network. For example, applicants to the FIT Program should consider bringing a project that builds on current CTSA pilot grant funding to take this research to the next level.

ACCP has the opportunity as an organization to capitalize on the recent emphasis on clinical/ translational research to support its members and the scientific contributions of clinical pharmacy. We offer the following recommendations for consideration and discussion by ACCP in collaboration with other professional organizations:

- ACCP should work closely with other pharmacy organizations to strengthen its position of influence within the CTSA hierarchy by collaborating with current pharmacy CTSA members to highlight the unique role pharmacy plays. Exclusion from these areas could permanently disadvantage its membership in the conduct of meaningful, effective clinical research.
- ACCP should work with other major pharmacy organizations in creating a "Pharmacy Research Council" to represent the collective research and related training interests of the pharmacy academy by initiating the following charges.
  - Develop unified standards and definitions related to the education and training of pharmacy students, residents, fellows, and graduate students regarding the preparation of clinical/translational scientists.
  - Create an electronic portal that would facilitate communication and interaction between pharmacy students and research fellowship preceptors and graduate programs;
  - Create a venue for pharmacy students to interact and ultimately match with research fellowship preceptors and graduate programs;
  - Present to the NIH a clear vision and understanding of the potential contributions pharmacy can make to the biomedical, life sciences enterprise;
  - Present to the leadership of the CTSAs and NCATS a summary of the important translational science being conducted by contemporary colleges and schools of

pharmacy, often in collaboration with existing CTSA sites;

- Develop a Web-based database of clinical pharmacy scientists with federal research support to track the number of individuals with funding so that our progress toward a critical mass of clinical/translational scientists can be monitored; and
- Provide funding for pharmacy fellowship programs by establishing a fellowship endowment through the ACCP Research Institute.

Finally, we recommend that ACCP perform a thoughtful analysis of its current guidelines related to fellowship training programs and, if necessary, reenergize the fellowship review or accreditation process. Such an analysis is warranted in light of the many environmental changes that have recently taken place within academia and the pharmaceutical industry. In addition, the emphasis currently placed on translational/clinical science by the NIH, Food and Drug Administration, and pharmaceutical industry will create new opportunities for research training programs. However, we urge ACCP to take a fresh look at these program guidelines from the perspective of prerequisite training, academic rigor, quality of mentoring, and quantity and quality of the research to be conducted by the fellow.

Reconsideration of Training Pathways to Increase the Critical Mass of Clinical/ Translational Scientists

Much has been written and debated regarding the "preferred" route of training for clinical pharmacy scientists; we will not rehash these discussions.<sup>3, 4</sup> With the perceived need to increase the number of well-trained clinical/ translational scientists, there is clearly a capacity to accommodate both pharmacists with fellowship training and those with the Ph.D. degree. In most public research-intensive colleges and schools of pharmacy, most students enter with a bachelor's degree in one of the sciences. Thus, for instance, combined Pharm.D./Ph.D. programs should be built such that the coursework necessary for the Ph.D. portion is completed during Pharm.D. training, leaving only the research thesis work required to complete the Ph.D. portion.

New models of fellowship training are also required. To ensure adequate coursework and rigor, some have combined master's-level degrees with fellowships. We support this, but of course, it lengthens the time to completion and/or may detract from performing clinical research for a 2to 3-year fixed period (as most fellowships tend to be). Some colleges have created a menu of combined degree programs (e.g., Pharm.D., master's degrees); examples of this are the Pharm.D./M.S. and the Pharm.D./MPH. Efficiencies in time to completion of the master's degrees are realized during the Pharm.D. program (electives in the Pharm.D. program apply to the master's degree), generally extending the time to completion of the combined degree by only 1 year.

One particular degree program that may hold substantial promise for training clinical pharmacy scientists is the M.S. degree in clinical/ translational science, generally funded to institutions through the NIH K30 program and often housed within the institution's CTSA. This program often targets practicing physicians, dentists, or pharmacists who are intent on increasing their skills in clinical research, but it could also be applied to medical or pharmacy students. As part of their M.S. degree program, students must complete a research project under the direction of a mentoring faculty member. If the student chooses a clinical pharmacy faculty member, an opportunity could be provided to move directly to a research fellowship (or perhaps a Ph.D. program). Hence the combined Pharm.D./M.S. degree in clinical/translational science (or other combined Pharm.D./master'slevel degrees) could provide a pipeline for and pathway to postdoctoral fellowship training. However, many research fellowship programs require at least a PGY1 residency before the actual fellowship. Because this further prolongs the time in training, perhaps it is time to rethink this requirement, with the advent of the early experiential clerkships now necessary in curriculums and with many schools increasing the time and requirements for advanced experiential rotations. Perhaps we could move instead toward training clinical pharmacy scientists through the M.S. degree in clinical/translational science.

#### Conclusions

Significant changes have recently occurred in the pharmacy profession, as well as in the surrounding economic, political, and research environments, that may substantially affect opportunities for training and developing clinical pharmacy scientists. With these unprecedented opportunities for pharmacist participation in the clinical/translational research enterprise (e.g., focus of the NIH on clinical/translational research; creation of the CTSAs and NCATS; growing interest in comparative effectiveness, health services, and patient-centered research), important questions remain about whether the profession can develop and sustain a critical mass of well-trained individuals to take advantage of them. Our profession and professional organizations have failed to articulate a clear and definitive strategy to exploit this opportunity, and our profession as a whole has deprioritized research, resulting in the inability to sufficiently foster student interest in a research career. Whether post-Pharm.D. fellowship training or a graduate program resulting in the Ph.D. degree is the "optimal" pathway for training clinical pharmacy scientists is now a relatively minor issue compared with the need to generate a larger number of appropriately trained scientists. ACCP has been a leading advocate for the importance of pharmacists' participation in clinical/translational research. The time is now for ACCP, in collaboration with other pharmacy organizations, to develop meaningful strategies for increasing the number and impact of clinical pharmacy scientists. To do otherwise would risk squandering this great opportunity for our profession to substantively contribute, not only to the biomedical research enterprise but also to advances that will ultimately improve patient care.

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