

## **Impact of the NIH Roadmap on the Future of Graduate Education in Colleges/Schools of Pharmacy**

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According to the Bylaws of AACP, the Research and Graduate Affairs Committee shall provide assistance to the Association in developing its research, graduate education, and scholarship agenda. This assistance may include facilitating colleges and schools in formulating and advancing legislative and regulatory initiatives and nurturing collaborative activities with organizations sharing an interest in issues related to the pharmaceutical sciences.

Consistent with a theme of exploring how AACP might foster organizational improvement and success among its institutional members, President-elect JoLaine Draugalis charged the 2004-05 AACP Research and Graduate Affairs Committee (RGAC) to:

- Examine the proposed future of biomedical, pharmaceutical, translational and clinical research as proposed in the NIH Roadmap, AHRQ, FDA, Clinical Research Roundtable, and the pharmaceutical industry.
- Recommend any changes, if necessary, in the education/training of graduate students (MS, PhD, and residency/fellowship) in the pharmaceutical and clinical sciences to ensure that our students are being optimally prepared for successful careers in academia, the pharmaceutical industry, and advanced pharmacy practice.
- Explore the feasibility of developing academic-pharmacy staffed and directed ambulatory care clinical research network(s) to conduct multi-site, multi-investigator clinical research projects.

### **Rationale**

Graduate education and research are important components of academic pharmacy. Graduates (MS and PhD) of our colleges/schools of pharmacy are sources of our future faculty and research and development scientists for the pharmaceutical industry. PharmD graduates will become the academic or industrial clinical scientists, advanced practice clinicians, and evidence-based pharmacy practitioners of the future. It is important that the academy continually assess the current and future environment of the larger biomedical research enterprise in order to maintain and improve its ability to contribute to the nation's public health needs. Additionally, the research enterprise of our colleges/schools also contributes to the financial well-being of the institution, and to pharmacy's professional and institutional prestige.<sup>1</sup>

The 2004-05 RGAC report addresses the significant changes occurring and predicted for the research environment of the future which have the potential to significantly change the education and training of the next generation of pharmaceutical and clinical scientists. The report provides the academic pharmacy community its view of these changes and how they may impact the graduate education process and the research enterprises in our member institutions. The report also examines the feasibility and makes a recommendation to examine developing academic-pharmacy directed ambulatory care clinical research networks to conduct multi-site, multi-investigator clinical research. This initiative has significant implications for the training and development of professional degree (PharmD) students as clinical scientists.

A major recommendation to all colleges/schools of pharmacy is to examine their current organizational structure for faculty research administration and graduate and professional education and training programs in view of the proposed interdisciplinary structure for solving the complex problems in biomedical and pharmaceutical research. This should be done across all the present disciplines within the college, not just within the laboratory-based sciences or the clinical sciences.

The report provides a roadmap which present several routes that the traveler may choose to take to reach a desired destination. The type of roads available, the travel vehicle, potential traffic, and the quality and quantity of drivers will all influence the route chosen and the time of the journey.

"Would you tell me, please, which way I ought to go from here?"  
"That depends a good deal on where you want to get to," said the Cat.  
"I don't much care where--" said Alice.  
"Then it doesn't matter which way you go," said the Cat  
"--so long as I get SOMEWHERE," Alice added as an explanation.  
"Oh, you're sure to do that," said the Cat, "if you only walk long enough." <sup>2</sup>

### **The Future Direction of Biomedical, Pharmaceutical, and Clinical Research**

There has been growing evidence that the research paradigm for the development of new drugs and medical products is not working efficiently or effectively.<sup>3,4</sup> The current research paradigm for development of new drugs posits that the process of discovery to patient use is linear, starting with basic research (e.g., target or ligand discovery), followed by applied research (e.g., drug/dosage form development), clinical research, and finally leading to a marketed product. Although the description of the process of moving from basic to applied research to product as linear is inaccurate,<sup>5</sup> the use of this model is highly pervasive in the pharmaceutical industry which generally organizes itself into separate discovery, development, and clinical research activities. This same division of discovery, development, and clinical research is also recognizable within pharmacy college/school academic departments.

The concern over the efficiency of translating basic biomedical science discoveries into useful marketable products dates back over two decades. In 1980, Congress passed the Patent and Trademark Law Amendments, more familiar as the Bayh-Dole (B-D) Act, after the two sponsoring Senators, Birch Bayh and Robert Dole.<sup>6</sup> The B-D Act allows for small business and non-profit organizations, including universities, to retain title (i.e., patent) to discoveries made under federally-supported funding. The B-D Act was predicated on the belief that the discoverer and the university would attempt to translate the discovery into a commercial product through licensing to businesses, with the money earned through licensing remitted to the discoverer and the university. The academic community has embraced the B-D provisions, and has spent

considerable funding on hiring technology transfer experts to assist their faculty in patenting and licensing discoveries. Although there have been a few notable commercial, financial, and public health successes emanating from university research attributable to B-D, and large numbers of start-up companies resulting from faculty discoveries, there are questions whether the B-D Act has really achieved what it designed to accomplish, and as importantly, the changes it has wrought in the academic research culture.<sup>7,8</sup>

Upon taking office in 2002 as the Director of the NIH, Dr. Elias Zerhouni, inherited an agency completing a five-year period in which its federal appropriation doubled, but was still under continued criticism from Congress and specific disease advocate groups for neglecting research on specific disease entities. The complete mapping of the human genome was coming to completion (April 2003), and there was much anticipation as to what this accomplishment would do to stimulate the discovery of new targets for drug therapy of human diseases. In the aftermath of September 11, 2001, the NIH was tasked with addressing the acute problem of dealing with the issues of bioterrorism, diverting some of its increased research support from basic biomedical research to legislatively-mandated applied research issues. The previous NIH Director Harold Varmus, a Nobel-prize winning scientist who had reinvigorated the agency with his Institute Director appointments, played a leading spokesperson role for the doubling of the NIH budget, and implemented a mechanism for reviewing and updating the organization of a majority of the study sections.

Dr. Zerhouni consulted with over 300 leaders in industry, government, and academia in his first year as NIH Director seeking ideas to speed up the translation of biomedical discoveries to products that could impact the public's health.<sup>9</sup> He also expressed the concern that big pharmaceutical companies, although spending billions on research and development, were not interested in research on or developing therapies for diseases that could not generate significant return on investment, even if a disease impacted a large number of individuals (e.g., malaria). Additionally, research on the prevention of disease was not a high research priority for much of the private sector. Zerhouni also recognized that, despite earlier attempts by NIH to address the issue, clinical research was still not adequately integrated into NIH's culture. This is revealed in several of his statements:<sup>10</sup>

“We’re the National Institutes of Health, not the National Institutes of Biology. We need to reengineer how we apply our research to humans.”

“As we go forward in academia and industry, clinical researchers are going to have to work in a circular mode in which clinical research is going to enlighten what it is in basic science that needs to be translated.”

The result of his consultations followed by considerable strategic planning on the part of the NIH Institute Directors, resulted in the NIH Roadmap (the Roadmap).

### **The NIH Roadmap**

The goal of the Roadmap is to “accelerate both the pace of discovery in the life sciences and the translation of bench to bedside.” To accomplish this goal, the Roadmap identified three major themes.<sup>11</sup> They are:

1. New Pathways to Discovery
2. Research Teams of the Future
3. Re-engineering the Clinical Research Enterprise

*The New Pathways to Discovery* theme is congruent with the primary goal of most biomedical research to increase understanding of the molecular events involved in the etiology of diseases with the payoff that this in turn will lead to new interventions to prevent, cure, decrease progression, or relieve the symptoms of disease processes. Much of the focus of the New Pathways theme is on expanding the results of the completion of the human genome; the identification of the set of proteins encoded by the genome (the proteome), along with a quantitative understanding of the interconnected networks of molecules which comprise cells and tissues (the metabolome). One new novel venture associated with this New Pathways theme is the creation of a small molecule library and establishment of screening centers, not unlike those of the large research pharmaceutical companies. This new drug discovery initiative will make chemical libraries available to academic researchers that heretofore have only been available to industry researchers.<sup>12</sup> This Roadmap industrial model of drug discovery also reflects the concern that the pharmaceutical industry is primarily interested in drug discovery for those diseases that have maximum commercial potential, particularly in the developed world, particularly the U.S.

*The Research Teams of the Future* theme is focused on building interdisciplinary and multidisciplinary teams through the funding of research centers and training programs designed to produce interdisciplinary scientists. The impetus for this theme is the belief that the research problems of the present and future are too complex to be solved by the single, independent investigator. Scientific advances are made at the interface of traditional disciplines, and that solving the puzzle of complex diseases will require understanding of the interplay of multiple factors, requiring the expertise of nontraditional teams of biological, behavioral, physical, and computer scientists, along with mathematicians, engineers, and unnamed others to solve these problems. A sub theme that permeates all the NIH literature associated with the Research Teams theme is the “difference” between multidisciplinary (good) and interdisciplinary (best) approaches to solving complex problems.

“An interdisciplinary approach is distinguished from a multidisciplinary approach in that a multidisciplinary approach brings experts from diverse disciplines to address collectively a common complex problem, each from his or her unique perspective. By contrast, an interdisciplinary approach is what results from the melding of two or more disciplines to create a new (interdisciplinary) science. Biophysics, biostatistics, bioinformatics, bioengineering, social neuroscience and psychoneuroimmunology are just some examples of existing interdisciplinary sciences. NIH recognizes the value and enormous contributions that existing interdisciplinary approaches have made and are making to our understanding of health, disease, and disability. However, the Roadmap is focused on developing new interdisciplinary approaches and the necessary interdisciplinary workforce.”<sup>13</sup>

*Re-engineering the Clinical Research Enterprise* is the third Roadmap theme. A “crisis” in the quality and quantity of clinical research personnel was previously recognized by NIH, and in response a number of new training initiatives (K awards) to enhance the numbers and quality of clinicians who are able to participate in clinical research were developed.<sup>14</sup> The Roadmap Initiative adds several more new training and curriculum development programs to those current K award programs, and introduces programs to enhance the efficiency of the clinical research enterprise through efforts to harmonize regulatory requirements and develop new clinical research networks, primarily among academic research centers and community-based primary care providers.

One novel approach to increasing the efficiency and efficacy of the clinical research enterprise is the concept of Clinical Research Networks (CRNs).<sup>15</sup> CRNs are defined as organizations of clinical field sites and investigators that conduct multiple research protocols in both academic and clinical care settings.<sup>16</sup> Implementing this goal will require an enhanced information technology infrastructure, the National Electronic Clinical Trials and Research (NECTAR) network, and a network of practitioners who will enroll and follow patients in clinical research projects. This network of practitioners, the National Clinical Research Associates Program (NCRA), will participate in clinical studies, assist in patient recruitment, administer experimental treatments, report data, and integrate new research findings into routine healthcare delivery. NCRA's are expected to be healthcare practitioners (i.e., physicians, dentists, nurse practitioners) who will function as clinical investigators by participating in clinical trials, recruiting patients, administering investigational drugs, and gathering and reporting data, while working in community practice and community hospital settings that are not affiliated with academic medical center.

Accompanying all three themes are initiatives to enhance the tools, instrumentation, methodologies, reagents, technologies, and information networks to increase the efficiency and effectiveness of research in their associated thematic areas.<sup>17</sup> These efforts are referred to as building a better “toolbox” for researchers throughout the three thematic areas. The toolbox efforts vary from supporting new quantitative technologies to measure multiple cellular metabolites to data collection, measurement, and analysis techniques in the social and behavioral sciences.<sup>18</sup> All of these themes have the goal of bringing new biomedical knowledge to the prevention, diagnosis, and treatment of human disease.

### **Translational Research**

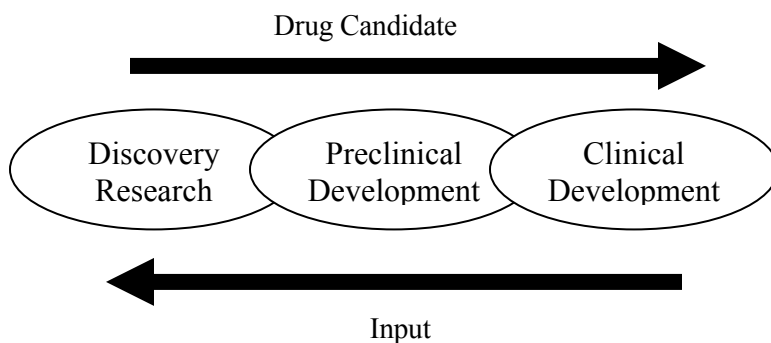
A concept that has come to symbolize the new research paradigm promoted by the Roadmap is translational research. Translational research has been defined in NIH publications as studies at the interface between the bench and bedside, with information flow at the interface being bidirectional, requiring close interaction between clinical and basic scientists.<sup>19</sup> However, slide presentations by NIH staff on the Roadmap Initiative expand the definition of translational research to include a Bedside to Practice step.<sup>20</sup> The following figure illustrating what is meant by translational research, with the vertical lines indicating barriers:



In translational research, information flow at these interfaces is bidirectional, between bench and clinical scientists, and between clinical scientists and practitioners. It is this bidirectionality of the arrows depicting information flow from Bench to Bedside and Bedside to Practice that distinguishes translational research from the current linear research paradigm. To complete the depiction of optimal translational research, a bidirectional arrow connecting Practice to Bench should be added to complete the circle and be consistent with the previous Zerhouni quote.<sup>10</sup>

The importance of bidirectional flow of information from Bench to Bedside to maximize drug development is not new to the pharmaceutical sciences. Dr. Ronald Borchardt of the University of Kansas School of Pharmacy and colleagues have been making the case for the necessity of improved two-way communication between drug discovery and drug development scientists to enhance the probability of developing new molecular entities with biological properties (promising drug leads) to molecules with “drug-like” properties that are suitable candidates for clinical

development.<sup>21</sup> The following figure is excerpted from one of Dr. Borchardt's presentations illustrating the need for increased two-way communication between drug discovery and drug development scientists, and mirrors the importance of translational research proposed in the NIH Roadmap to accelerate the pace of discovery of new drugs to treat human disease.



*Bedside to Practice:* Dr. Claude Lenfant, former Director of the National Heart, Lung, and Blood Institute (NHLBI) of the NIH, stated that much of what is learned in clinical research is often “Lost in Translation,” particularly the translation of effectiveness and efficacy data to the practice of medicine at the community level.<sup>22</sup> There are innumerable examples of the slowness of diffusion of innovative therapies into medical practice or alternatively, the retention of discredited or unproven therapies in practice. Additionally, reports of rare but significant adverse effects, dosing adjustments for specific patient populations, or drug-drug interactions, is not effectively communicated back through publication or standardized reporting mechanisms to other practitioners or the clinical researcher (Bedside). This individual and systemic failure to communicate in both directions, often results in suboptimal product use or even worse, a medical crises resulting in product withdrawal.

Translating bedside research into practice through the use of “best evidence,” and patient safety have been major Agency for Healthcare Research and Quality (AHRQ) goals.<sup>23</sup> Unfortunately, the extramural research budget of the agency is smaller than almost every NIH Institute budget, so it has not had the financial resources nor political support to generate needed studies to more significantly impact practice. A recent impetus for this new focus on translation of Bedside knowledge to Practice at the NIH originated from the Clinical Research Roundtable (CCR) of the Institute of Medicine.<sup>24</sup> The CCR has made a number of recommendations for improving the clinical research enterprise beyond the steps proposed by the Roadmap.<sup>25</sup>

### **Educating Graduate Students for Interdisciplinary Research**

In addition to its emphasis on translational research, another concept that permeates the Roadmap is the importance of an interdisciplinary research approach in solving the complex disease problems. Interdisciplinary research and training graduate students for increased breadth of experience is not a new idea to pharmacy.<sup>26,27</sup> In 1998, the Commission on the Future of Graduate Education in the Pharmaceutical Sciences made the following recommendation:<sup>28</sup>

“Pharmaceutical sciences faculty are encouraged to engage in multi- or interdisciplinary research and graduate training programs within their own institution and with other faculty within the university. Pharmaceutical sciences faculty need to be more proactive in proposing and organizing interdisciplinary institution-based and campus-wide

research programs, centers, or institutes, despite the possibility that the majority of faculty participants may not be from the college or school of pharmacy.”

While preparing future scientists to work across and at the boundaries of existing disciplines, improve their communication skills, inculcate ethical research practices, and if possible, provide opportunities to teach undergraduates, it is important to remember that the primary goal of graduate education is to prepare graduates to be “independent” researchers. PhD graduates are often hired into their initial industrial or academic position based on their mastery of a specific area of scientific or technical expertise.<sup>29</sup> This dichotomy of educating an independent investigator with specialized skills along with developing a person with breadth of knowledge and team research experience without adding a significant amount of time to the process is not lost on graduate students who generally view interdisciplinary research positively,<sup>30</sup> but also with concern that it could potentially have a negative impact on their long-term careers.<sup>30</sup>

### **Models of Interdisciplinary Research Training**

Promoting interdisciplinary research training was pervasive at NIH before the official launch of the Roadmap as indicated in the description of successful National Institutes of General Medical Sciences (NIGMS) Institutional Training Grants (T32) for predoctoral students.<sup>31</sup>

Successful applicants are expected to provide trainees with broad access to research opportunities across disciplinary and departmental lines and to maintain high standards for intellectual rigor and creativity. Collaborative involvement of faculty members who are from several different academic units and who conduct research programs in differing disciplines is essential. The students in these training programs should come from several academic units, and each student should participate in a variety of interdisciplinary training activities that broaden research skills and approaches.

The new Roadmap training grant program, “Training for a new interdisciplinary research workforce,” (RFA-RM-04-015) requested:<sup>13</sup>

“...a variety of new and innovative didactic and research activities designed to provide students with the necessary knowledge and research experience to apply interdisciplinary solutions to complex biomedical and health problems.”

A stated goal of the interdisciplinary research workforce training initiative is to enable development of these programs by “capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs.” Areas of interest for training include behavioral sciences, social sciences, economics, and ethics, in addition to the traditional biomedical sciences. Successful programs will have addressed the following:

- Scientific environment—expected to be strongly collaborative and interdisciplinary.
- Curriculum and degree requirements—should avoid extending time to degree.
- Program self-evaluation.
- Institutional commitment.

The training grant proposal also must address the following program features:

- Applicant pool—efforts must be made to increase ethnic diversity.

- Rotations and internships—highly encouraged and of sufficient length and rigor so that students in the program are conversant in two or more targeted fields.
- Mentoring—formal co-mentoring is highly encouraged.
- Student interactions—with other students and faculty so that they develop a sense of identify with their interdisciplinary field.
- Leadership and teambuilding skills—including building understanding of group dynamics
- Responsible conduct of research.
- Monitoring of students—with attention to retention and time to degree.
- Academic and career advice—including instruction on how to apply successfully for research funding.

Two other interdisciplinary training initiatives that are particularly germane to pharmacy have recently been announced by the Howard Hughes Medical Institute (HHMI). One which is particularly relevant to the laboratory-based pharmaceutical sciences is the HHMI-National Institute of Bioimaging and Bioengineering Institute (NIBIB) Initiative for Interdisciplinary Graduate Research Training (the Initiative).<sup>32</sup> The primary goal of this Initiative is to train a cadre of PhD scientists who possess the knowledge and skills to conduct interdisciplinary research at the interface between the biomedical sciences and the physical science, computational, engineering, or mathematical disciplines. These fields may include chemistry, imaging science, materials science, nanotechnology, and physics. All the laboratory-based pharmaceutical sciences fit into one or more of the fields that are the focus of the Initiative, so a further examination of the program may be illuminating as to what the members of these influential scientific organizations who designed this program believe might be effective in producing an interdisciplinary scientist.

In the area of curriculum and educational resources, the Initiative is looking to support development of unique courses, laboratories, and research experiences that bridge scientific disciplines and integrate the biomedical sciences with engineering, physical science (e.g., chemistry, physics), computational, or mathematical disciplines.

Curricular objectives include the following:

- Development of knowledge base and skill necessary to understand and use the approaches of other disciplines.
- Learning how other disciplines approach scientific problems.
- Development of an understanding of mathematical, computational, and problem-solving paradigms used by various disciplines.
- Learning the language, culture, technology, literature, and unique means of expression used by other scientific disciplines
- Learning the skills needed to work effectively in an interdisciplinary research team.

The second HHMI interdisciplinary training initiative has the goal of improving the understanding of clinical medicine and pathobiology by PhD scientists conducting biomedical research.<sup>33</sup> The program is not designed to facilitate the movement of biomedical science PhD students into medical school, but to provide PhD students with a better understanding of the human biology and disease. There are three possible approaches to achieving the goals of this training initiative. The first is the design of new courses coupled with a clinical experiential learning experience or physician-scientist mentoring. A second approach is the design of a supplemental certificate or master's degree program, similar to those for training a clinical scientist. A third approach is to support a portion of a graduate student's training in a clinical environment for a period of time, before they move back into a laboratory environment.

This HHMI program is based on an program initiated by Dr. Irwin Arias at Tufts University School of Medicine, who suggested in 1989 that in order to bridge the gap between biomedical science and clinical medicine, PhD students, postdoctoral fellows, and faculty receive training in pathobiology, visit patients, handle pathologic specimens, and receive exposure to hospital facilities.<sup>34</sup> The Lucille P. Markey Charitable Trust supported eight other programs which used different approaches to provide pathobiology and clinical exposure to PhD students from 1992-1996.<sup>35</sup> The outcomes from this Arias' inspired HHMI program could be obtained in a number of college/schools of pharmacy through either a designed PharmD/PhD program or through an exposure of pharmaceutical sciences graduate students to pathobiology and supervised patient contact under the supervision of a clinical pharmacy faculty co-mentor.

Colleges/schools of pharmacy with pharmaceutical science graduate programs routinely encourage graduate students to enroll in graduate courses taught in non-pharmacy disciplines, and promote their graduate programs as being multi- or interdisciplinary. Courses are often taught from a disciplinary perspective, and it cannot be assumed that students taking courses outside their major discipline will know how to apply what they have learned to their own disciplinary problems. In colleges/schools of pharmacy that have combined several pharmaceutical science disciplines into a single pharmaceutical sciences department, there is usually a set of "core" courses taken by incoming graduate student, but then students choose a track or "concentration," which appears very similar to that of free-standing disciplinary departments. Core courses are taught by department faculty within the college/school or by faculty outside the college/school, such as cellular or molecular biology to provide pharmaceutical sciences graduate students an introduction to these topic areas. Coursework can provide students the ability to learn the "vocabulary" of a discipline, which in turn assists them in understanding the literature and communicating with scientists within the discipline.

A significant difference between current pharmaceutical sciences graduate programs and the proposed interdisciplinary training program of the NIH and the new HHMI training programs is an attempt of the latter to educate the trainees from the beginning of their graduate education in how different disciplines approach solving problems through coursework that is presented from more than one disciplinary point-of-view, and also through multi-mentored experiences (i.e., research, clinical, industrial). Current graduate training programs expose the trainees to other disciplines with the idea that the trainee will absorb different disciplinary approaches to problem solving on their own through the interaction with others. This difference in approach may be significant or just a nuance. As most existing "interdisciplinary" scientists were initially educated and trained in a disciplinary environment, it will be difficult to tell what works and what does not work in preparing a person to be an interdisciplinary scientist.

There are few "benchmark" programs of excellence in interdisciplinary education and training of PhD scientists, so colleges/schools of pharmacy could use the NIH or HHMI training grant application guidelines to assist them in developing their own unique versions of interdisciplinary graduate education and training programs that utilize the strengths of all the institution's faculty. Colleges/schools of pharmacy are structurally similar to a pharmaceutical company with scientists involved in drug discovery from molecular synthesis to activity/toxicity determination, multiple aspects of drug product development, and clinical evaluation. Yet unlike companies which focus their research and development activities on bringing products to market, colleges/schools of pharmacy often operate with little research interaction among departments or divisions. There are some pharmaceutical science graduate programs that are interdisciplinary by design, however these

appear to be the exception.<sup>36,37</sup> Is it possible to utilize the inherent structure of academic pharmacy to produce interdisciplinary scientists in our graduate programs beyond coursework?

### **Postgraduate Education and Training for Interdisciplinary Research**

The postdoctoral fellowship, common to many disciplines, can provide more disciplinary breadth and team building skills, but this is often not the case. Postdoctoral positions are most often funded by individual investigator R01 grants, so the postdoctoral experience is often spent in developing additional expertise in a focused research area, and appears to do little towards fostering creativity and independence in developing the postdoctoral fellow's own research program.<sup>38</sup> Opportunities to explore new research areas or obtain classroom teaching experience are often denied to postdoctoral fellows because of the necessity of addressing the research requirements of the faculty member and agency funding their position.<sup>39</sup> In the pharmaceutical sciences, a majority of PhD graduates in pharmaceuticals and social and administrative sciences, do not find it necessary to complete a postdoctoral fellowship in order to find gainful employment, especially in the pharmaceutical industry. The lack of a postdoctoral experience due to high demand for recent graduates may initially disadvantage the graduates in these disciplines who accept academic positions in research-intensive universities located in colleges/schools of pharmacy where external funding is a primary consideration for promotion and tenure.

One final postgraduate venue for expanding the scientific breadth and communication skills of scientists is the workplace, through educational opportunities provided by employers, industrial or academic. Short courses which range in length from one-half day to a week are available to scientists in all the pharmaceutical sciences on a large variety of scientific topic areas. Scientific association meetings provide the interested scientist a plethora of opportunities to increase their breadth and depth of understanding of scientific issues. In academia, the year-long sabbatical or short leaves of absence can and have been utilized to broaden the knowledge base and sharpen technical skills that enhance an individual's ability to participate in interdisciplinary research and education.

### **Implications of the Roadmap Initiatives for Research in Colleges/Schools of Pharmacy**

It is the collective opinion of the RGAC that colleges/schools of pharmacy should pay particular attention to the NIH Roadmap themes in their strategic planning, particularly as to how they relate to their research missions. A pragmatic reason is that NIH grants and contracts provide the majority of external research funding to academic pharmacy institutions. Although Roadmap program funding is only about one percent of overall NIH extramural research budget, the Roadmap goals have had a spillover effect on non-Roadmap funded research initiatives from individual NIH institutes and even on the criteria used by study sections in evaluating new investigator-initiated research proposals.<sup>38</sup> The new criteria are specifically written to better accommodate interdisciplinary, translational, and clinical projects, focus areas for the NIH Roadmap. For example, under the Investigator criteria, rather than evaluating whether "the investigator is appropriately trained" the new criteria ask "are the investigators appropriately trained," and further, "Does the investigative *team* [italics added] bring complementary and integrated expertise to the project (if applicable)?" Thus, the Roadmap should not be viewed simply as "another" or add-on set of research initiatives, but as it was proposed, a roadmap of the future direction of biomedical/clinical research and training funded by the NIH.

The Roadmap's focus on interdisciplinary approaches to research is consonant with the potential strengths of academic pharmacy, and offer opportunities for increased research funding for all

pharmacy faculty, not just the laboratory-based pharmaceutical sciences. However, the presence of faculty with research expertise in disciplines ranging from chemistry to health economics, mirroring to some extent the structure of a pharmaceutical company, has not proven to be an effective catalyst for interdisciplinary, or even multi-disciplinary research within many colleges/schools of pharmacy.

Multi- and interdisciplinary research are collaborative activities, and the discipline-focused organization structure of many pharmacy colleges/schools may not be conducive to collaborative research. Additionally, the relatively small number of faculty within each discipline, and the diversity of faculty expertise within each discipline, often selected to “cover” required curricular topics in the professional degree program rather than needed research expertise, is not an optimal strategy to assemble a cohort of individuals with appropriate research expertise to plan, develop, and execute multi- or interdisciplinary research programs.

### **Roadmap Initiatives for Research in the Laboratory-based Pharmaceutical Sciences**

The Pathways to Discovery theme is primarily focused on improving methodologies and assays (e.g., toolbox) for characterizing the proteome and metabolome. Nanotechnology for biomedical application (e.g., nanomedicine), chemical library, and drug activity screening are also part of the Pathways theme. Within academic health center environments, pharmaceutical sciences faculty often possess the most expertise, and pharmacy colleges/schools often the best equipment to become involved in the type of research supported by Roadmap. Pharmacy faculty have been successful as Principal Investigators in these initiatives, and others are co-investigators or collaborators on other successful proposals.<sup>41</sup> Other than toolbox development, the research areas supported by the Pathways theme are also supported through other NIH award mechanisms, both individual, and Program Project awards.

### **Roadmap Initiatives for Social and Administrative Sciences (SADS) Research**

Two out of the three Roadmap themes address the education, training of clinical researchers and the conduct of clinical research, the Bedside to Patient activities in the translational research continuum. NIH defines clinical research to include 1) patient-oriented research, 2) epidemiologic and behavioral studies, and 3) outcomes research and health services research. This definition of clinical research encompasses almost all the research activities social and administrative faculty in colleges/schools of pharmacy.

The Roadmap proposed solutions for deficiencies in Bedside to Practice translational research are much the same approaches as those proposed for the Bench to Bedside deficiencies, with a focus on multi- and interdisciplinary workforce development, and research infrastructure improvement. Roadmap Background for an RFA supporting multidisciplinary clinical research career development states:<sup>42</sup>

“Clinical research is a complex endeavor that is ideally performed by a multidisciplinary team using an integrated approach.” “There is a well-recognized shortage of well-trained physicians and other health professionals (e.g., dentists, behavioral scientists, clinical pharmacologists, statisticians, nurses, study coordinators, and data managers) performing clinical research in a rigorous, highly collaborative, team-oriented environment.”

While there are social, organizational, and technical issues that must be dealt with in improving translational research between Bench to Bedside, there are extremely more complex “human subject” problems (e.g., psychological, sociological, economic, behavioral, cognitive, etc.) facing the scientists working in translational research at the Bedside to Patient boundary. Clinical research,

particularly patient-oriented research is difficult because control of the process and many of the measured outcomes are influenced by the subjects as much as by the treatment. Methodologies have been developed to minimize the influence of subjects on the results of clinical research through study design, but understanding the impact of behavioral and social factors on disease etiology and on the response of diseases to therapeutic interventions did not receive much attention or research support from NIH until the US Congress created the Office of Behavioral and Social Sciences.<sup>43,44</sup> One of the Roadmap Initiatives provides supplements to existing NIH grants to develop innovative methodologies in social and behavioral research.<sup>18</sup>

There is also a need for additional “biomarkers” to determine the efficacy of drug therapies, particularly with behavioral and cognitive changes as desirable therapy outcomes, especially in persons with chronic diseases. The Patient-Reported Outcomes Measurement Information System (PROMIS) will focus on the collection of self-reported data from a diverse population of chronic disease patients, including those from racial and ethnic minority groups.<sup>45</sup> These problems provide social and administrative pharmacy and clinical faculty opportunities to engage in multi- and interdisciplinary research both within the college/school of pharmacy and with colleagues within the university and among universities.

Involvement in multi- or interdisciplinary research on larger complex problems is not common for many of the faculty in the Social and Administrative Sciences, because most have been educated and trained in an environment where faculty funding for large research problems has been the exception, not the rule. A major factor impacting the discipline’s ability to engage in multi- or interdisciplinary research is the discipline’s demographics, specifically its small size. There were only 345 full-time faculty in the discipline of Social and Administrative Sciences in 2004-2005. Of these, approximately 30 percent were assistant professors, and another 15 percent were assistant, associate, or full deans.<sup>46</sup> In 2003-2004, 15 colleges/schools of pharmacy awarded 29 PhD degrees in Social and Administrative Sciences and 27 institutions enrolled 254 PhD students. Five programs enrolled more than 20 PhD students, while 10 enrolled five or fewer students.<sup>47</sup>

The small size of most graduate programs in the social and administrative sciences does have advantages in that most graduate coursework is taken outside the department which can provide breadth to the program and contributes to interdisciplinarity. The disadvantage of a small program is that the student’s research problem is often small project focused. Larger externally-funded research programs, where students can address parts of a large significant problem in depth and communicate their findings and develop research expertise with fellow graduate students are few in number. Some programs compensate for the relatively small numbers of faculty and graduate students by focusing the areas of departmental research or through formal or informal arrangements with other departments within the university, such as public health. These arrangements can provide opportunities for increased breadth of knowledge and multi- or interdisciplinary research.

The small numbers of graduates each year along with the increasing demand for program graduates in academic pharmacy and the pharmaceutical industry has inhibited the growth of postdoctoral positions in the discipline, although some graduates take postdoctoral fellowships in another non-pharmacy discipline. Postdoctoral fellows, who unlike graduate students devote the majority of their time to research, could contribute to increased research productivity in the discipline. One Roadmap postdoctoral training grant (T32) initiative is designed to support coursework and research in a new discipline to individuals already holding an advanced degree (i.e., PhD, PharmD). The initiative is interested in programs integrating behavioral/social sciences with a traditional biomedical science discipline.<sup>48</sup> The program recognizes that many disease processes are influenced by behavioral and social environment factors, in addition to biology. Colleges/schools of pharmacy with strong

research programs in both the biopharmaceutical sciences and behavioral sciences should consider application for this postdoctoral training grant. There is potential for a cooperative effort with the pharmaceutical industry in constructing the postdoctoral program experience.

### **Roadmap Initiatives for Clinical Research**

In 1995, former NIH Director Harold Varmus convened a NIH Director's Panel on Clinical Research (CRP), "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>14</sup> The CRP provided the definition of clinical research presently used by the NIH. Among its many recommendations was the initiation of training programs to produce more clinical researchers, or given that the panel was primarily physicians, physician researchers. Fortunately, this medicocentric view did not prevail and the training (K23, K24) and clinical education (K30) programs that resulted from the panel's recommendation were open to PharmD graduates, and the prior existing K08 program, previously for physicians only, available to and awarded to a very small number of PharmD-degreed full-time faculty.

Under the Re-engineering the Clinical Research Enterprise theme, an institutional postdoctoral training program (K12) was introduced. This "Multidisciplinary Clinical Research Career Development Program (MCRC)" provides financial support for individuals who have already obtained a doctoral-level professional degree (e.g., PhD, PharmD, etc.), who have the ability develop their expertise in clinical research.<sup>42</sup> The MCRC program includes both didactic and practical experiences in the design, conduct, and analysis of clinical research. The first year of the program must be dedicated to a core curriculum that must include a multi-disciplinary component to foster interactions between the participants and faculty from different disciplines. As of March 2005, four institutions with colleges/schools of pharmacy had received MCRC program grants; although there is no enrollment information on any of the programs.<sup>49</sup> Each of the funded programs mentioned the potential participation of faculty from their respective colleges/schools of pharmacy in the CRISP abstract. Each of the institutions with a funded K12 program also has a K30 Curriculum Development Award.

Currently there are a small number of NIH funded PharmD NIH principal investigators, and a potentially larger number of PharmD co-investigators or collaborators on NIH funded clinical research projects.<sup>50</sup> There are also a number of PharmD pharmacy faculty involved in several of the Centers for Education and Research on Therapeutics (CERTs) administered by AHRQ in cooperation with the FDA.<sup>51,52</sup> The majority of clinical faculty research appears to be funded by association foundations and the pharmaceutical industry. Clinical faculty are often involved in multidisciplinary or team-based research, but generally with other health professionals (e.g., MD, RN), not their pharmacy faculty colleagues. The hiring of clinical or therapeutic "experts" in order for the practice faculty to cover instruction in the pharmacotherapeutics curriculum works against developing a collaborative or team approach within the department to conducting research on significant clinical problems within more focused disease areas. This faculty diversity of expertise and interest might have instructional advantages, but it works against development of a multi- or interdisciplinary clinical research network within the college/school. The growth of graduate programs in clinical pharmacy, applied therapeutics, and clinical pharmacology should provide the discipline opportunities for more research productivity.

## Practice-based Pharmacy Clinical Research Networks

A Clinical Research Network (CRN) is an organization of clinical field sites and investigators that conduct multiple research protocols, often concurrently.<sup>16</sup> The organization of sites and investigators may be formal or informal. A group of investigators that is convened to conduct a single protocol and then disbanded, is not considered a network. Organized physician groups, consisting of medical school clinical faculty and community-based practitioners have been operating community-based CRNs for over twenty years, using the term Primary Care Practice-based Research Networks (PBRNs). PBRNs consist of a group of ambulatory practices devoted principally to the primary care of patients, affiliated with each other to investigate questions related to community-based practice.<sup>53</sup> The American Academy of Family Physicians (AAFP) has sponsored a National Research Network since 1999.<sup>54</sup> The AAFP PBRN has 290 primary clinician members in 45 states, the District of Columbia, and four Canadian provinces, eight ongoing studies as of March 2005, with funding from NIH, AHRQ, and the pharmaceutical industry. The AAFP PBRN also serves as secretariat for the Federation of Practice-Based Research Networks (FPBRN) which consists of 45 local, state, and regional based PBRNs, including an Advanced Practice Registered Nurse Research Network (APRNet).<sup>55</sup>

PBRN formation has received support from AHRQ through a small grant program (R03) and has been the focus of a joint National Cancer Institute/AHRQ Program Announcement to develop, improve, and/or validate research dissemination methods applicable to cancer control in primary care practice.<sup>56,57</sup> Fifteen FPBRN members were among 17 funded networks in the first round of the Robert Wood Johnson “Prescription for Health” Initiative in 2003.<sup>58</sup> The Clinical Research Roundtable of the Institute of Medicine identified the PBRN as an undervalued resource in improving the translation of clinical research (Bedside) into Practice, but recognized that these organizations need increased funding, training programs for health care providers, communications networks between providers, clinical researchers, and academic health centers, just the areas the Roadmap is addressing through its training grants, and NECTAR.<sup>59</sup>

Presently, the pharmacy profession does not appear to have any regional or national PBRNs or CRNs. The American Pharmacist’s Association Foundation’s Project ImPACT, which has supported two community-based pharmacy practice research projects is not a PBRN or CRN, although it does demonstrate that pharmacy-based and pharmacist staffed PBRNs could be developed both at a regional and national level.<sup>60</sup> There are several pharmacy faculty staffed Centers involved in research on, consulting with, or educating community practitioners, but none appear to meet the criteria of a PBRN or CRN. Is it time that academic pharmacy develop the infrastructure for establishing and supporting community pharmacy based research networks?

“...many have noted pharmacy’s underachievement in its participation in health services research. At last year’s Annual Meeting I spoke on our low profile in such activities; our studies have been too restricted in design, sample size, and tests of validation to have broad application. What is needed is a more expansive approach, involving more disciplines, and the application of more sophisticated techniques of research methodology and validation. The use of the multicenter concept is foreign to investigations in pharmacy, yet it offers an ideal opportunity for increasing the significance of our work, expanding the participation of our institutions, and enhancing the funding potential of our proposals.”<sup>61</sup>

Dr. Gerald Schumacher spoke those words at his incoming address in 1982 as AACP President and followed them up by appointing a Committee on Multicenter Research that was funded in part by a

grant from the American Foundation for Pharmaceutical Education (AFPE). In his outgoing address in 1983, Schumacher expressed disappointment that the committee work progressed more slowly than desired, although he reiterated the potential for such multidisciplinary efforts.<sup>62</sup>

In the twenty plus years since President Schumacher's call for multicenter and multidisciplinary work in health services research and what is now termed by the NIH as clinical research, innumerable funding opportunities for improving health outcomes have slipped past pharmacy due to a lack of a permanent research infrastructure to perform practice-based research. With several exceptions, the research to date on the efficacy of various community-based pharmacist services on health outcomes can best be described as pilot studies, the results of which generally presented to pharmacy-based audiences or published in pharmacy journals for a pharmacy audience, with little impact on the greater health care system.<sup>63-65</sup>

### **Implications of the Roadmap for Professional Degree (PharmD) Education**

One new Roadmap initiative is a predoctoral training grant program (T32) for health professions students, called the Predoctoral Clinical Research Training Programs (PCRTTP).<sup>66</sup> PCRTTP is designed to train individuals known as NIH Clinical Research Trainees, to become the next generation of clinical researchers performing clinical investigations in multi-disciplinary, collaborative clinical research settings. A PCRPT goal is to "expose" health professions students to clinical research, so that those going into clinical practice might become part of the Roadmap's NCRA Program. The NCRA Program is envisioned as a permanent nationwide clinical research network primarily consisting of non-academic center community practitioners.<sup>67</sup> The clinical network would be supported by another Roadmap Initiative, NECTAR, which is charged to develop common data standards, informatics, and software for protocol preparation, IRB management, and adverse event reporting.<sup>68</sup> NCRA would recruit and enroll patients and gather and report clinical data utilizing NECTAR, with again the goal of more rapidly translating Bedside results to Practice.

Eligibility of health professions students to participate in the PCRTTP is split into "primary targeted disciplines" and "secondary targeted disciplines." Medicine, dentistry, and nurse practitioners are primary targeted disciplines, while pharmacy, statistics, psychology, chiropractic, and naturopathic medicine are examples of secondary targeted disciplines. Those in the secondary targeted discipline category are eligible for short-term training and the clinical research Master's degree, but not eligible for a research doctoral program (i.e., PharmD/PhD).

The distinction of pharmacy from medicine, dentistry, and nursing students in this training effort to produce raises both questions and concerns about the perception of contemporary professional pharmacy education and pharmacy practice at the NIH. If this action is the result of a misperception or lack of understanding, then that must and should be corrected by AACP staff and members. However, there are several other questions that this decision raised that need to be addressed assuming that it is possible to have NIH change the Predoctoral Training Program guidelines and include pharmacy as a "primary targeted discipline."

- Would a significant number of PharmD students apply to participate in one or more the PCRTTP programs options designed to produce a clinical researcher?
- Does our present curricular content and structure create interest in our students to become clinical researchers?
- Do our member institutions have enough qualified pharmacy faculty clinical research mentors, particularly outside the academic health center environment?

- If pharmacy were recognized as a primary targeted discipline, pharmacy students would be eligible to receive support to participate in PharmD/PhD programs designed to educate and train clinical researchers. How many of our member institutions would be prepared to offer this dual degree option?

The 2003-2004 RGAC addressed the issue of the importance of faculty scholarship and an institutional culture of scholarship in educating students for the practice of pharmacy.<sup>1</sup> The committee addressed their importance in the context of the outcomes of professional pharmacy education, the provision of pharmaceutical care:

“If pharmaceutical care is successful, the outcomes of drug therapy in individuals or populations of patients will be significantly better than if the pharmacist did not undertake these actions. In essence, pharmacists practicing pharmaceutical care are performing what Boyer defines as the “scholarship of application.” If our graduates must practice the scholarship of application to provide pharmaceutical care (scholarly practice), then they must be educated within a culture of scholarship by scholars, particularly the practice faculty and the social, economic, and administrative sciences, as these disciplines, along with pharmaceuticals, are the “unique” components of a pharmacy education and practice.”

If we accept the view that practitioners must be scholars to provide pharmaceutical care, then it is not unreasonable to expect that those practitioners who engage in scholarly practice can participate in pharmacy-based practice research with the assistance and guidance of appropriate pharmacy faculty. The question to be asked is, do our professional educational programs produce scholarly clinician practitioners? And if they do not, why not?

### **Summary Suggestions and a Recommendation**

There is growing evidence that multi- and interdisciplinary research, conducted in a team environment, will increasingly be required to solve large, complex biomedical research problems. The present structure of most graduate programs in the biomedical and pharmaceutical sciences is not designed to produce an interdisciplinary scientist. That may be the result of but not restricted to the prescribed graduate curriculum, the research training environment including availability of space and instrumentation, the diversity of faculty expertise, and the number of graduate faculty. In some cases, the departmental or disciplinary organizational structure may work to discourage multi- or interdisciplinary graduate education and research, but even in those institutions where discipline-named graduate programs have disappeared and been replaced with graduate programs with names such as pharmaceutical or biopharmaceutical sciences, several core courses may be the only effort at interdisciplinarity, with students tracking into disciplinary focus research areas early in their graduate education. There is no organizational structure that can compensate for low levels of scientific diversity, strong discipline-focused departments, and a lack of visionary leadership in implementing an interdisciplinary research and graduate education environment, if that is what is deemed desirable by the institution.<sup>69</sup>

The RGAC can only make suggestions to its member colleges/schools of pharmacy based on the committee’s best judgment as a result of its discussion of the committee charges. In the area of interdisciplinary graduate education and research, the committee makes the following suggestions for colleges/schools of pharmacy:

- Each institution must strategically discuss and determine whether multi- and/or interdisciplinary research and graduate education is to be a major focus of its future mission.
- Each institution must determine whether they have the faculty with the appropriate diversity of expertise and interest to participate in collaborative multi- or interdisciplinary research, the facilities to conduct that type of research, and the organization and leadership required to coordinate the efforts necessary to successfully compete in the collaborative research environment of the future.
- If a more interdisciplinary research environment is a desirable goal for the future, the faculty should examine and modify if necessary, the evaluation metrics for individual faculty research productivity for promotion and tenure decisions. This must be done in the context of the university's requirements.<sup>70</sup>
- Institutions that do not have the appropriate resources to develop multi- or interdisciplinary research within the institution should develop desirable interdisciplinary research foci in partnership with other university academic units. In order to maintain college/school of pharmacy faculty identity within a multi-unit interdisciplinary effort, it is important that faculty bring strong research expertise into the partnership.

The Roadmap's NCRA proposal to expand clinical research from the academic health center and hospital to the community practice setting provides an opportunity for clinical faculty and ambulatory care pharmacy practitioners to interact for the improvement of patient care, faculty scholarship, and student learning. If pharmacy desires to take advantage of this opportunity, academic pharmacists and pharmacy practitioner must cooperatively design and develop a research infrastructure that can be utilized to conduct research in practice on practice activities that have the potential to influence patient care outcomes. This research infrastructure, a Clinical Research Network or Practice-based Research Network, including participants and participating sites must be made permanent and kept continually active with research projects.

**Recommendation:** The RGAC recommends that AACP convene a conference of academic pharmacy and pharmacy organizations to discuss the development of an infrastructure for supporting the formation of regional and a national Clinical Research Networks or Practice-based Research Network for the purpose of conducting research on practices and practice models that can lead to improved health through translation of clinical research to patient care.

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