

# ACCP POSITION STATEMENT

## The Research Agenda of the American College of Clinical Pharmacy

American College of Clinical Pharmacy

**Key Words:** American College of Clinical Pharmacy, ACCP, research agenda, clinical research, translational research, health services research.  
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In June 2005, the American College of Clinical Pharmacy (ACCP) Research Institute began the important task on behalf of the ACCP to articulate a research agenda. In this context, the ACCP research agenda is meant to define and describe those broad research domains and priority research themes that the ACCP advocates should be pursued through the Research Institute, governmental agencies, or other organizations that support health and/or drug therapy research.

This research agenda will provide critical guidance to many of the ACCP's advocacy, education, and research-related initiatives. This agenda will undergo regular review and update to ensure that its recommendations provide an appropriate level of guidance and that it reflects current and anticipated future needs and directions in clinical pharmacy practice and research.

### Background

Included within pharmacy's societal purpose is a responsibility to create and disseminate knowledge related to drug entities, products, therapy, and use—a research mission. Integral to the concept of pharmacy as an evidence-based practice is that the research enterprise produces the evidence on which practice is based.

The core purpose of the ACCP is to advance health and quality of life by helping pharmacists

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expand the frontiers of their practice and research. This core purpose is accomplished by providing leadership within pharmacy and health care, and through a variety of professional development (educational), advocacy, and research-related activities. This includes a mission, shared with the ACCP Research Institute, to advance clinical pharmacy and pharmacotherapy through support and promotion of research and research training. The ACCP Research Institute provides a framework and catalyst to advance the research endeavors of clinical pharmacists and the scientific bases that underpin the discipline of clinical pharmacy.

The vision of the ACCP is that pharmacists be recognized and valued as the preeminent health care professionals responsible for the use of medicines in the prevention or treatment of disease ([www.accp.com/plan2002.pdf](http://www.accp.com/plan2002.pdf)). The ACCP foresees the day when the following will occur:

- Pharmacists will commonly serve as principal investigators for pharmacotherapy research.
- Research led by pharmacists will generate a substantial portion of the new knowledge that guides drug therapy.
- A significant portion of ACCP's research-based members will compete successfully at a national level for funding of research that creates this new knowledge to guide drug therapy.

Certainly, some ACCP members and other pharmacists serve as principal investigators, generate new knowledge that guides drug therapy, and compete successfully for research funding at the current time. The above vision of the ACCP is meant to convey a quantitative

stretch in the prevalence of these indicators, as well as a societal expectation that this is an activity and responsibility of the profession.

The ACCP has been committed to extending the frontiers of clinical pharmacy practice and research since its founding more than 25 years ago. The ACCP's research mission is to "advance human health and quality of life by facilitating the generation, dissemination, and application of new knowledge that promotes the safe, effective, and cost-effective use of medications" (Appendix 1).<sup>1</sup> The ACCP is working to position the college and its members as highly influential contributors to rational pharmacotherapy. The ACCP Research Institute is striving to develop the resources and infrastructure to become a leading force for the advancement of research to achieve optimal drug use. A key initiative that will aid in achieving these goals is for both the ACCP and the ACCP Research Institute to proactively conceive and pursue a clinical, translational, and health services research agenda that advances optimal drug use.

### The ACCP Research Agenda

Development of a research agenda does not mean that the ACCP's research-related resources will be directed to support only those issues specifically contained within this document. However, conceiving and pursuing such an agenda will do the following:

- Help to solidify ACCP's and the Research Institute's leadership roles in achieving optimal drug use in patients.
- Add important guidance, clarity, and focus to many of the priorities and initiatives of the ACCP and the Research Institute.
- Define opportunities for the Research Institute to actively develop or solicit specific research initiatives that address questions of key relevance to clinical pharmacists and optimal drug use in patients.
- Guide the identification of other organizations with similar professional or research interests with whom ACCP and/or the Research Institute may wish to collaborate.
- Help to define the ACCP's research-related advocacy, professional affairs, and policy initiatives.
- Provide needed focus to the Research Institute's internal and external fund-raising efforts.

The process to craft a research agenda for the ACCP began with discussions among the

Research Institute's Board of Trustees. These discussions identified three broad research domains believed to be of particular importance to patients, society, and ACCP members:

- Ensuring medication effectiveness and patient safety
- Development and retention of an adequate clinical pharmacy practitioner and scientist workforce
- Translational pharmacotherapy research

Initial input to refine and validate these three domains was sought from the ACCP membership during the fall of 2005. Members of ACCP who represented a variety of practice, education, and research perspectives were invited to serve on one of three domain panels (Appendix 2). These panels were charged to confirm, define, and refine the broad research domains most appropriate to the ACCP at this time, and of sufficiently high societal priority to warrant inclusion on the ACCP's research agenda, as well as to identify a focused set of research themes pertinent to each domain that the ACCP should advocate be pursued.

### Ensuring Medication Effectiveness and Patient Safety

Drug therapy is integral to and inseparable from the modern provision of health care. As noted in the ACCP's Position Paper on collaborative drug therapy management, "effective and rational management of increasingly complex drug therapies is now essential both to the health and welfare of patients and to the efficient economic performance of health care systems and organizations of all types."<sup>2</sup>

Annual health care expenditures in the United States now total \$1.9 trillion and account for 16% of the country's gross domestic product. By 2015, spending on health care is projected to reach \$4 trillion and account for 20% of the gross domestic product. Annual spending for prescription drugs accounts for about 11% of health care costs (about \$200 billion). In addition to the direct costs of these drugs, an additional \$76.6 billion is estimated to be spent each year because of drug-related morbidity and mortality among ambulatory patients.<sup>3</sup> Also, an estimated \$1.33 is spent in the management of drug-related problems for every dollar spent on drugs in nursing facilities.<sup>3</sup> Clearly, the costs of prescription drug therapy in the United States well exceed the monetary costs of the drugs themselves.

The ACCP has defined clinical pharmacy as “patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.”<sup>4</sup> In crafting its 2015 vision for pharmacy, the Joint Commission of Pharmacy Practitioners stated that “pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.”<sup>5</sup>

The concept of optimal drug therapy implies the use of drugs to achieve targeted clinical, humanistic, and economic outcomes; drug use that is safe, effective, appropriate, affordable, cost-effective, efficient, and specific to the needs of a given patient; and therapy that is chosen in partnership with the patient. The concept of optimal drug therapy also implies that it occurs within a drug-use system that has the necessary structure and processes in place to both evaluate and manage drug therapy. That is, to ensure that drug use is associated with the highest likelihood of achieving the desired health and economic outcomes.

Considerable evidence indicates that significant gaps exist between the goal of optimal drug therapy and the current state of drug use in the U.S. health care system. For example, a meta-analysis of 39 prospective studies conducted in U.S. hospitals reported that approximately 11% of hospitalized patients experience an adverse drug event (ADE), 2% experience a serious ADE, and 0.2% experience a fatal ADE.<sup>6</sup> This report estimated that nearly 5% of hospital admissions are due to a serious ADE and that 2.7% of these prove fatal. Using the total number of U.S. hospital admissions in 1994 as an example, these investigators estimated that more than 1.5 million patients were admitted to the hospital because of serious ADEs (43,000 of which proved fatal) and an additional 702,000 patients experienced serious ADEs while in the hospital (63,000 of which proved fatal).

The frequency of ADEs in the ambulatory care setting is less well described. In a relatively small study of 661 outpatients, the authors observed that the rate of ADEs may be as much as 4 times higher among ambulatory patients than is usually noted in hospital-based studies.<sup>7</sup> Of note, 13% of the ADEs were considered serious, and 39% were either preventable or ameliorable. All ADEs thought to have been preventable were due to prescribing errors (known allergy, inappropriate drug, or incorrect dosage regimen). Of the ameliorable ADEs, two thirds were attributed to a failure on the part of the physician to respond

appropriately to drug-related symptoms, whereas one third were attributed to the patient's failure to inform the physician of the problem.

In addition to hospitalized and ambulatory patients, an estimated 350,000 ADEs occur each year among the 1.6 million people who reside in U.S. nursing homes. Of these ADEs, more than half may be preventable. Also, an estimated 20,000 life-threatening or fatal ADEs occur annually in these nursing home residents, of which as many as 80% may be preventable.<sup>8</sup>

Although a theme within the pharmacy literature for many years, the issue of patient safety related to medication errors received much needed emphasis with publication of the 1999 report from the Institute of Medicine, “To Err is Human: Building a Safer Health System.”<sup>9</sup> This report estimated that more than 7000 deaths occur each year as a result of medication errors in the hospital and outpatient settings. Stimulated by this and other reports, Congress mandated through the Medicare Modernization Act of 2003 that the Institute of Medicine perform a comprehensive study of drug safety and quality issues in order to provide a blueprint for system-wide change. In constructing its work plan, the Institute of Medicine Committee on Identifying and Preventing Medication Errors defined drug safety and quality to mean issues relating to the safe, effective, appropriate, and efficient use of drugs.<sup>10</sup> The committee noted that errors occur all too commonly during all steps of the drug use system: selecting and procuring the drug by the pharmacy, prescribing and selecting the drug for the patient, preparing and dispensing it, administering it, and monitoring the patient for effect.<sup>11</sup>

As clinical pharmacists, our perspective regarding the safe use of drugs must extend beyond enhancements to the system for preparing, delivering, and administering drugs—the usual targets for the patient safety initiative—to include the process by which therapeutic decisions are made, implemented, and monitored for effectiveness. It could be argued that the greatest risk to patient safety occurs when a particular drug is prescribed, dosed, taken, or monitored inappropriately. Knowledge derived from clinical and health services research must guide decisions regarding which drug is chosen, what dose is administered, how therapy is monitored, and how patient adherence is ensured.

It has been suggested that the considerable attention paid to the adverse consequences of drug therapy may have distracted attention from

what may be an even larger problem: the underuse of beneficial drugs when truly needed.<sup>8,12</sup> This underuse may be especially pertinent in the management of chronic conditions such as cardiovascular disease, hypertension, stroke prevention, osteoporosis prevention, pain management, and depression that occur commonly in the elderly.

Our health care system does a relatively poor job of translating the considerable knowledge gained from the country's research enterprise into safe and effective practice. Significant gaps in the treatment of many acute and chronic conditions in essentially all patient groups have been noted when one compares the optimal efficacy of a given drug therapy as measured in a typical randomized clinical trial with the real-world effectiveness seen in routine practice.<sup>13-16</sup>

Experimental clinical trials (most often conducted as randomized clinical trials) are designed to determine how and why a particular treatment works in a controlled study environment with inclusion of carefully selected subjects. Such studies assess the efficacy of the treatment. However, they often provide a relatively poor indication of the actual effectiveness of the treatment when used in real-world conditions (i.e., in different patient populations or care settings from those originally studied; in special populations such as children, the elderly, or pregnant women; in larger numbers of patients; or in combination with other drugs or therapies). Determination of effectiveness requires the conduct of clinical trials designed specifically to address practical questions about benefits, risks, and costs as they would occur in routine clinical practice. Such studies have been referred to as pragmatic or practical clinical trials. Key features of practical clinical trials are that they compare clinically relevant interventions, include a diverse population of patients from a variety of care settings, and assess data on a broad range of clinical, humanistic, and economic outcomes.<sup>17</sup>

Despite an overall increase in public and private funding, the current clinical research enterprise in the United States generally does not produce the type of information most helpful to and needed by clinicians and health policy decision makers.<sup>17</sup> For example, the research missions of the National Institutes of Health (NIH) and the pharmaceutical industry—the most notable funding sources for clinical research in the United States—concentrate mainly on either basic discovery or determining the efficacy

of new treatments. Relatively little attention is placed on determining the comparative effectiveness of different treatments.

The volume of new information available to health care practitioners is overwhelming and can understandably result in paralysis of the clinician. Development and distribution of clinical practice guidelines is one way that a variety of organizations and governmental agencies have attempted to synthesize this new knowledge and encourage its application in patient care. However, existing research suggests that practice guidelines have had a limited impact on changing clinician behavior.<sup>18</sup> Barriers to guideline adherence by clinicians include unawareness of their existence, unfamiliarity with their specific recommendations, disagreement with the guideline's recommendations, failure to believe the recommended treatment will yield the desired outcome, and resistance to changing established practices.

The *raison d'être* for clinical pharmacists is to optimize drug therapy that promotes health, wellness, and disease prevention. The clinical and economic impact of pharmacy services directed toward this goal have been summarized.<sup>19-21</sup> Despite the volume of this previous work, it has been suggested that a specific research agenda be created to ensure that studies are conducted in practice sites and address the types of pharmacy services for which data are lacking.<sup>21</sup>

#### ACCP's Research Agenda: Ensuring Medication Effectiveness and Patient Safety

The above discussion of the gaps that exist between the definition of optimal drug therapy and the current state of drug use in the United States identifies six high-priority areas in which the ACCP believes additional research is needed:

- Identify and evaluate patient, clinician, and system factors that contribute to the safe and effective use of drugs in clinical practice.
- Evaluate the effects of drugs on patient clinical, humanistic, and economic outcomes in settings typical of routine clinical practice.
- Develop and use data repositories and novel population-based methods to identify new indications or uses of drugs, and for the identification or confirmation of new adverse events.
- Characterize general patterns of drug use, and their use in populations not previously studied, to determine their effect on clinical,

humanistic, and economic outcomes.

- Identify and evaluate patient, clinician, and system factors that influence the provision and effectiveness of care provided by clinical pharmacists.
- Evaluate the effect of pharmaceutical care delivery models and other pharmacy services on patient clinical, humanistic, and economic outcomes.

### Development and Retention of an Adequate Clinical Pharmacy Practitioner and Scientist Workforce

#### Practitioner Workforce

Pharmacy has responded to society's need and call for a better drug use system with efforts to qualitatively and quantitatively enhance the capabilities and capacity of its practitioner and researcher workforce. This response has included changes in educational curricula, growth of postgraduate residency and fellowship training, development of mechanisms for practitioner credentialing, reengineering of the practice setting, and development of payment systems that recognize and value pharmacy's role and responsibility to ensure optimal drug use.

As noted earlier, it is ACCP's vision that pharmacists be the preeminent health care professionals responsible for the use of medicines in the prevention and treatment of disease. Saying essentially the same thing, the Joint Commission of Pharmacy Practitioners has stated as its vision for the profession that "pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."<sup>5</sup> Fulfilling this societal mission will require a substantial qualitative and quantitative change in the practitioner workforce from that which exists today.

But how many practitioners? Of what types? With what education, training, and credentials? Deployed in what way? It has been suggested that only about 19,000 additional pharmacist full-time equivalents would be needed to fully implement for all patients in all U.S. hospitals what the authors have identified as five core clinical services (drug information, ADE management, drug protocol management, medical rounds participation, and admission drug histories) most strongly associated with improved outcomes in patient mortality rates, drug costs, total cost of care, length of hospital stay, and medication errors.<sup>22</sup> However, an

invitational conference convened by the Pharmacy Manpower Project has suggested that we may need as many as 165,000 primary care pharmacists (defined as those who provide the pharmaceutical care necessary to manage simple and complex drug use in ambulatory patients including patient assessment, advice to providers and patients on elements of the drug use process, patient counseling, and surveillance or monitoring for appropriate therapeutic response) and 130,000 secondary and tertiary care pharmacists (defined as those who provide mainly hospital-based services such as patient assessment; selection, monitoring, and adjustment of therapy; and establishment and oversight of drug safety systems and drug policy issues) by 2020.<sup>23</sup> Given that about 200,000 pharmacists currently practice in the United States, these widely disparate projections of future need render difficult the development of responsible plans to meet future professional workforce requirements.

Apart from the number of practitioners required in the future, the levels of knowledge, skill, experience, and clinical maturity required to manage complex drug therapies and patient problems—and to improve upon the current state of drug use in the United States—should not be underestimated.<sup>24</sup> Although not proved through definitive research, many believe that these professional knowledge, skills, attitudes, and beliefs are best and most efficiently gained through formal postgraduate residency training.<sup>25</sup>

In that regard, ACCP has set a short-term goal to at least double the number of students that pursue residency training. Currently, about 20% of the approximately 8500 students who graduate each year from pharmacy schools enter residency training. As part of its vision for pharmacy, ACCP believes that formal postgraduate residency training will become mandatory before a pharmacist will be able to enter practice.

The American Association of Colleges of Pharmacy (AACCP) has examined the role of schools of pharmacy in residency training. Noting the important role that these programs play in educating and training both practitioners and faculty, the AACCP task force recommended that studies be done "to document the value of (post)graduate pharmacy education programs in terms of career laddering, job promotions, and salary increases," and "to facilitate federal and state funding for all (post)graduate pharmacy education programs."<sup>26</sup>

A conference of concerned stakeholders, including ACCP, was convened in January 2005

to create a shared vision for the future of post-graduate residency training in the United States.<sup>27</sup> It was noted that more work needs to be done to demonstrate the value of residency training to training sites, prospective residents, health care providers, patients, employers, and payers. The conference report specifically recommended that more research on the effect of residencies on patient care and safety be conducted.

The 2004 ACCP Task Force on Residencies also recommended that advocacy efforts work to increase government financial support of residency training.<sup>25</sup> While pointing out the essential absence of data regarding the benefits of residency training in any of the other health professions on patient outcomes, the task force noted, "The evidence supporting our position that residency training is a necessary prerequisite for pharmacists engaged in direct patient care is limited, and minimal data are available from pharmacy-specific sources. Convincing evidence supporting the value of pharmacy residency training in achieving improved patient outcomes would certainly be helpful in making this case."<sup>25</sup>

Crafting successful strategies to increase the number of students who pursue residency training is best accomplished if one fully understands the factors that influence students' career choices. The most recent study in this area was published in 1995.<sup>28</sup> The 2004 National Pharmacist Workforce Study noted that 38% of pharmacists working in supermarket outlets intended to leave their job within the next year, compared with 15% of hospital pharmacists.<sup>29</sup> These data could be interpreted to indicate that supermarket practitioners are much less satisfied with their positions. No data are available to evaluate job satisfaction and stress among pharmacists practicing as clinical pharmacists (regardless of setting) compared with those who practice primarily in a drug distribution role. Given the evolving dynamics of pharmacy education and practice, contemporary information about and a means to regularly reexamine the factors that influence pharmacy students' career choices are needed. Such knowledge would allow more informed career guidance of students or suggest problems related to quality of work life that need to be addressed.

The issue of developing and retaining an adequate clinical pharmacy practitioner workforce involves more than the issues described above. It also includes the means to ensure the quality of care provided by pharmacists. One way that health and other professions have addressed this

issue of quality assurance is through board certification of their practitioners.<sup>30</sup> Fully 85% of licensed physicians hold some form of board certification,<sup>30</sup> and the majority of hospitals require board certification as part of their privileging process.<sup>31</sup> More than 5000 pharmacists hold certification in one or more of the five specialty practice areas recognized by the Board of Pharmaceutical Specialties (nuclear pharmacy, nutrition support, oncology, pharmacotherapy, psychiatry). Part of ACCP's envisioned future for pharmacy is that the majority of pharmacists will be board-certified specialists.

Attempts have been made to examine the link between board certification of physicians and clinical outcomes.<sup>32</sup> Perhaps not surprisingly, it has been observed that most of these studies used research methods inappropriate for assessing the research question in mind. As one group noted, "Although the evidence on clinical outcomes is mixed, it is nonetheless promising that better outcomes are associated with physician certification and recertification in many studies."<sup>30</sup> No studies have been done to examine the relationship between specialty certification in pharmacy and any measures of patient outcomes or quality of care. The ACCP Certification Affairs Committee has recommended a collaborative effort to evaluate the potential benefits of specialty board certification on patient care and the delivery of health care.

#### Faculty Workforce

Responding to the noted pharmacist shortage in the United States, several new schools and colleges of pharmacy have opened within the past few years or will do so in the near future. Existing schools have increased their enrollments. As part of implementing the entry-level doctor of pharmacy (Pharm.D.) curriculum now required of all schools of pharmacy, schools and colleges have had to markedly increase the amount of experiential and other clinically oriented education provided. This has created a dramatic need for new faculty at a time when competition for pharmacy graduates is keen.

Virtually all pharmacy educators agree that there are not enough appropriately educated and trained candidates for the tenure-track and non-tenure-track clinical faculty positions currently needed. The problem is of such magnitude that AACP has begun to collect information on the number of vacant pharmacy faculty positions in the United States. During the 2004–2005 academic year, 76 schools of pharmacy that responded to

the AACP request for information reported a total of 396 vacant faculty positions (5.2/school).<sup>33</sup> The vacancy rate/school is essentially unchanged from that noted during the 2002–2003 academic year (4.9/school), the first year in which the data were compiled.<sup>34</sup>

Of all vacant faculty positions, essentially half (49.3%) during 2004–2005 were in clinical science or pharmacy practice. More than half (55.7%) of the vacant positions remained so because there were not enough qualified candidates. Clearly, more needs to be done to encourage pharmacy students to pursue a career in academia. Contemporary information about, as well as a means to regularly reexamine, the factors that influence career choices made by students, residents, and fellows are needed and would help to make these efforts more effective.

Educators also report difficulties with retaining faculty. Of interest, the most common reason noted for faculty vacancies in the 2004–2005 AACP survey was that the individual previously in the position moved to a faculty or administrative position at another pharmacy school (27.4%). However, at least another 24% of vacancies occurred because the previous occupant moved to a position in the private sector (14%) or pharmaceutical industry (10%). Although certainly not the only factors involved in job turnover, the most recent studies of career burnout among pharmacy faculty and job satisfaction among junior pharmacy faculty were published in 1993 and 1995, respectively.<sup>35, 36</sup> Other than speculation about “more pay” and “not having to work so hard,” little is known about the factors that drive these changes in career direction. Objective 6.3.2 of the ACCP strategic plan calls for a study of issues surrounding faculty development and retention.

On the positive side, this crisis in faculty recruitment and retention has forced pharmacy academia and organizations such as ACCP to examine what they must do to encourage students toward a career in academia, prepare residents and fellows to assume faculty positions and responsibilities, and mentor the professional, scientific, and career development of junior faculty.<sup>37</sup> Simply encouraging more individuals to enter a career in academia will not provide a true remedy for this problem unless those individuals also are well prepared for the unique aspects of academic life, including an important commitment to faculty scholarship and research productivity. The current effort to articulate a research agenda for the ACCP will provide vital

direction to help shape the ACCP's future research, education, and advocacy initiatives. However, efforts to operationalize this agenda will be hampered if the discipline of clinical pharmacy lacks the critical mass of clinical, translational, and health services researchers with the scientific development and competitiveness needed to pursue its recommendations. This concern is real and deserves the attention of ACCP and others.

Competitive funding awarded by the NIH can be used as one measure of faculty scholarship. According to data compiled by AACP, competitive NIH funding to schools of pharmacy in 2005 totaled \$232 million. In contrast, schools of medicine received approximately \$10 billion.<sup>38</sup> Table 1, compiled by AACP, suggests, however, that pharmacy faculty as a whole are more competitive than simply looking at total funding would imply.

It must be noted, however, that the distribution of NIH grants and contracts received by pharmacy faculty is not uniform across the disciplines. Approximately 30% of medicinal chemistry faculty hold NIH funding compared with slightly more than 1% of full-time pharmacy practice faculty. Anecdotal evidence suggests that pharmacy practice (Pharm.D.) faculty fare as well on average as their doctor of philosophy and doctor of medicine counterparts when they submit for competitive NIH funding, but that relatively few are making application. Even though pharmacy practice faculty now account for about half of all pharmacy faculty, many of these individuals occupy clinical-track positions. Scholarship in the form of original research supported by extramural funding is not usually expected of these individuals. Nonetheless, all available evidence indicates that the majority of those tenure-track pharmacy practice faculty who are expected to possess a research mission have not yet submitted for, much less received, NIH funding. This failure to pursue funding may indicate simply a relatively young discipline in development, a failure of mentorship, the primacy given to practice and teaching responsibilities (i.e., no time to pursue research), or a systemic shortfall in the scientific development and competitiveness of these faculty.

#### ACCP's Research Agenda: Development and Retention of an Adequate Clinical Pharmacy Practitioner and Faculty Workforce

The above discussion regarding development and retention of an adequate clinical pharmacy

**Table 1. Comparative Research and Teaching Productivity Among Selected Health Professions Schools<sup>38</sup>**

Variable	Pharmacy	Dentistry	Veterinary	Medicine
Programs (no.)	83	56	27	125
Professional students enrolled (no.)	43,000	17,500	9360	66,680
Full-time faculty (no.)	3780	4760	2631	109,525
Professional students/full-time faculty	11.4	3.7	3.6	0.6
NIH grant funding, fiscal year 2003 (\$, M)	189.2	170.6	154.6	9610
NIH grant funding/full-time faculty (\$)	50,500	35,860	58,730	87,740
Institutions with funding (%)	77	86	100	98

NIH = National Institutes of Health.

practitioner and faculty workforce identifies four high-priority areas in which the ACCP believes additional research is needed:

- Defining and assessing the adequacy of the pharmacy workforce.
- Assessing the value of residency training.
- Evaluating the value of board certification in pharmacy.
- Evaluating methods to educate, train, and increase the number and preparedness of clinical faculty and scientists.

#### Translational Pharmacotherapy Research

For clinical pharmacists to fulfill their professional mission, they must apply evidence-based therapeutic guidelines, knowledge from the evolving sciences, emerging technologies, and relevant legal, ethical, social, cultural, economic, and professional principles to the care of their patients. This emphasis on the application of evidence and the evolving sciences points out that clinical pharmacy is a scientifically rooted discipline. As such, part of pharmacy's societal responsibility is to generate and disseminate new knowledge about drug entities, products, therapy, and use. This research mission includes the conduct of translational and clinical research, and the transference of research results into practical clinical applications.

The ability to provide patients with optimal pharmacotherapy—that is, drug therapy most likely to achieve the desired clinical, humanistic, and economic outcomes—is based in part on the practitioner's knowledge of pharmacokinetics, pharmacodynamics, and now pharmacogenomics. Clinical pharmacist researchers have contributed substantially to the generation and dissemination of basic knowledge in these three areas. However, to improve human health, scientific discoveries must be translated into practical applications usable by clinicians in their routine delivery of

patient care.

The concept of translational research is thus meant to convey the transfer of knowledge gained from laboratory-based research to new and improved methods of preventing, diagnosing, and treating disease, as well as the transfer of clinical insights gained through the care of patients into hypotheses that can be tested and validated in the laboratory. By its very nature, the conduct of translational research usually involves collaboration among a multidisciplinary and interdisciplinary team of laboratory-based and clinical investigators. As part of the NIH Roadmap, the NIH is working to reengineer its clinical research enterprise. This includes initiatives to strengthen and accelerate translational research.<sup>39</sup>

The ACCP has no desire (nor the resources) to duplicate the NIH efforts in this area. However, there are many examples where the further application of basic knowledge in pharmacogenomics, pharmacokinetics, and pharmacodynamics can yield substantial gains in the quest to optimize patient outcomes from drug therapy. As space does not allow an exhaustive review of this literature, a few representative examples follow.

Concern has been voiced that the weak pipeline for development of new antimicrobials, coupled with the ever-increasing development of microbial resistance to current anti-infectives, may result in a significant public health problem.<sup>40</sup> Although increased efforts to identify and develop new antimicrobials are clearly needed, an additional solution to this problem is to maximize the benefits from current agents through improved dosing strategies based on the application of pharmacogenomic, pharmacokinetic, and pharmacodynamic knowledge gained in the laboratory. One way to lessen the emergence of resistant organisms is to reduce their overall exposure to a given antibiotic by shortening the duration of therapy.<sup>41</sup> To do so requires that

dosage regimens able to achieve needed drug concentrations at the site of infection be based on pharmacokinetic and pharmacodynamic data, and then tested in the clinical setting to determine their comparative efficacy.<sup>42, 43</sup>

A critical issue in the treatment of many psychiatric, neurologic, and other disorders of the central nervous system (e.g., cancer, human immunodeficiency virus [HIV]) is that the drugs used to treat these diseases must be able to achieve an effective concentration at their site of action. Drug uptake into the brain is governed by a number of factors, including the agent's affinity for specific drug efflux transport systems such as P-glycoprotein located at both the blood-brain and blood-cerebrospinal fluid barriers.<sup>44</sup> It has been proposed that genetic polymorphisms in the expression and functionality of these drug transporters may be involved in the drug resistance observed in some patients with brain tumors, central nervous system HIV, or epilepsy. This suggests that efforts identified in the laboratory to bypass these efflux transporters or modulate their activity through specific inhibitors, functional modulation, or transcriptional modulation could lead to new clinical strategies and improved patient outcomes.

The metabolism of many antidepressants and antipsychotics is governed by the cytochrome P450 (CYP) enzyme CYP2D6, and CYP2C19 is important for the metabolism of some antidepressants. Commercial testing to genotype patients for the genes that regulate these two enzymes is now possible. This means that clinicians can determine whether their patients are poor or ultrarapid metabolizers; this knowledge allows clinicians to potentially modify the patient's drug regimen accordingly to minimize adverse effects and maximize therapeutic benefit. However, how this new knowledge should be applied in clinical practice is not yet known.<sup>45</sup>

Polymorphisms in the CYP2C9 enzyme are known to reduce the clearance of warfarin, prolong the time required to achieve a stable dosage regimen, and increase the risk of bleeding in patients treated with this drug. The anticoagulant effects of warfarin result from its inhibition of the enzyme vitamin K epoxide reductase (VKOR). Patients with polymorphisms in the gene that encodes for the VKOR protein (VKORC1) require doses of warfarin only 30–50% of that of patients with the wild-type genotype to achieve therapeutically appropriate anticoagulation.<sup>46</sup> An algorithm that incorporates

CYP2C9 genotype and other nongenetic patient factors to determine the warfarin dosage has been developed.<sup>47</sup> However, whether using information from prospective testing of patient genotype for CYP2C9 and VKORC1 can enhance the effectiveness of warfarin therapy, improve patient outcomes, and lessen the occurrence of adverse effects remains to be determined.

Polymorphisms in the CYP2D6 enzyme can affect the rate with which patients metabolize the  $\beta$ -blockers carvedilol, metoprolol, propranolol, and timolol. Also, polymorphisms in the gene that encodes the  $\beta_1$ -receptor can influence the antihypertensive response after  $\beta$ -blocker administration and may be associated with the degree of hemodynamic improvement seen when these drugs are used in patients with heart failure.<sup>48</sup> Although promising, whether genomic screening will allow clinicians to individualize pharmacotherapy based on the patient's genotype is unknown.

A sizable body of literature is emerging to describe the application of pharmacogenomic and pharmacokinetic principles in patients with cancer. It has been previously noted that children may vary widely in their ability to clear some anticancer drugs, and that the therapeutic benefit was significantly less in children with rapid clearance.<sup>49, 50</sup> In 1998, a study reported that children with acute lymphoblastic leukemia who received an individualized dosage of methotrexate, teniposide, and cytarabine based on blood drug level measurement and calculation of clearance had significantly improved clinical benefits compared with those whose dosage was based simply on body surface area.<sup>51</sup>

The drug 6-mercaptopurine is commonly used to treat leukemia in children. Genetically controlled variability in the activity of the enzyme that metabolizes 6-mercaptopurine, thiopurine methyltransferase (TPMT), causes a small number of patients to have very low or no TPMT activity.<sup>52</sup> These children will experience severe or fatal toxicity when given standard doses of 6-mercaptopurine because of their inability to eliminate the drug.<sup>52</sup> It is thus now recommended that clinicians screen patients for polymorphisms of the TPMT gene before treatment with 6-mercaptopurine and adjust the dosage regimen in those patients whose genotype is associated with TPMT deficiency.

More recently, the product label for irinotecan hydrochloride injection was changed to reflect the increased risk of neutropenia in patients with reduced activity of the drug metabolizing enzyme

uridine diphosphate glucuronosyltransferase (UGT)1A1. It is now possible to screen patients for the genetic polymorphism associated with reduced UGT1A1 activity, and potentially modify irinotecan dosage or select an alternative therapeutic regimen. However, additional research is needed to elucidate the optimal approach in such patients (J. M. Kolesar, written communication, May 2, 2006).

It has been speculated that “the potential is enormous for pharmacogenomics to yield a powerful set of molecular diagnostic methods that will become routine tools with which clinicians will select medications and drug doses for individual patients.”<sup>53</sup> Translation of new knowledge and technology in pharmacogenomics, pharmacokinetics, and pharmacodynamics to routine clinical practice for high-risk drugs or patients provides fertile ground for those involved in translational pharmacotherapy research.

#### ACCP's Research Agenda: Translational Pharmacotherapy Research

The above discussion regarding the application of basic knowledge in pharmacogenomics, pharmacokinetics, and pharmacodynamics to optimize patient outcomes and the clinical benefits from drug therapy identifies four high-priority areas in which the ACCP believes additional translational pharmacotherapy research is needed:

- Assessing the effects on patient outcomes that result from translating basic knowledge in pharmacogenomics, kinetics, and dynamics to practical clinical applications.
- Improving drug dosing strategies and testing drug formulations.
- Developing, enhancing, and testing models to predict patient response to drug therapy.
- Evaluating new technology and biomarkers that predict drug efficacy or toxicity.

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### Appendix 1. The Research Mission of the American College of Clinical Pharmacy<sup>a</sup>

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Professions exist to serve society. In fulfilling its societal role, pharmacy has been defined as a knowledge system that “generates or integrates knowledge about man in sickness and in health; takes knowledge from other sciences and arts; criticizes and organizes that knowledge; translates knowledge into technology; uses some knowledge to create products, devices, and instruments; [and] transmits the knowledge through the education of practitioners and dissemination to others, to the end that an individual known as a patient may benefit...”<sup>1</sup>

Included within pharmacy’s societal purpose is a responsibility to create and disseminate knowledge related to drug entities, products, therapy, and use—a research mission. Integral to the concept of pharmacy as an evidence-based practice is that the research enterprise produces the “evidence” on which practice is based.

The American College of Clinical Pharmacy (ACCP) has long valued its commitment to extending the frontiers of clinical pharmacy practice and research. It is logical that any attempt to articulate ACCP’s research mission must be done within the broader context of the research mission of the profession of pharmacy.

The ACCP believes that the research mission of the profession of pharmacy is to advance human health and quality of life through the generation, dissemination, and application of new knowledge about drug discovery and use. This mission is accomplished by:

- Developing individuals and programs to conduct research
- Funding and conducting basic, translational, clinical, health services, and educational research
- Communicating research results to the health professions, policy makers, and consumers
- Translating research results into practical applications
- Advocating policies that advance research.

The research mission of the ACCP is to advance human health and quality of life by facilitating the generation, dissemination, and application of new knowledge that promotes the safe, effective, and cost-effective use of drugs. This mission is accomplished by:

- Supporting the training and development of clinical scientists
- Funding translational, clinical, and health services research
- Communicating research results to the health professions, policy makers, and consumers
- Providing educational programs and publications that help health care practitioners translate research results into enhanced patient care
- Advocating policies that support translational, clinical, and health services research

#### Definitions

Basic research: advances fundamental scientific knowledge. Although basic research may be in fields with current or future commercial interest, it does not have specific immediate applications toward processes or products in mind.

Clinical research: research conducted in humans (or with human tissues) to study the mechanisms, epidemiology, or prevention of disease; test therapeutic interventions; or develop new technologies.

Educational research: assesses the role of content, delivery methods, evaluation techniques, and management on the outcomes of teaching and learning.

Health-services research: examines the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services (including pharmacy services).

Translational research: transfer of knowledge gained from basic research to new and improved methods of preventing, diagnosing, and treating disease, as well as the transfer of clinical insights into hypotheses that can be tested and validated in the basic research laboratory.

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<sup>a</sup>Endorsed by the ACCP Board of Regents April 25, 2003, and the ACCP Research Institute Board of Trustees April 16, 2000.

**Appendix 2. Domain Panel Members**

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## Panel I: Ensuring Medication Effectiveness and Patient Safety

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## Panel III: Translational Pharmacotherapy Research

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