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AACP REPORTS AND MINUTES

The Future of the Pharmaceutical Sciences and Graduate Education: Recommendations from the AACP Graduate Education Special Interest Group

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Despite pharma's recent sea change in approach to drug discovery and development, U.S. pharmaceutical sciences graduate programs are currently maintaining traditional methods for master's and doctoral student education. The literature on graduate education in the biomedical sciences has long been advocating educating students to hone soft skills like communication and teamwork, in addition to maintaining excellent basic skills in research. However, recommendations to date have not taken into account the future trends in the pharmaceutical industry. The AACP Graduate Education Special Interest Group has completed a literature survey of the trends in the pharmaceutical industry and graduate education in order to determine whether our graduate programs are strategically positioned to prepare our graduates for successful careers in the next few decades. We recommend that our pharmaceutical sciences graduate programs take a proactive leadership role in meeting the needs of our future graduates and employers. Our graduate programs should bring to education the innovation and collaboration that our industry also requires to be successful and relevant in this century.

Keywords: pharmacy, education, graduate, pharmaceutical industry, future, pharmaceutical sciences, jobs, career, skills, preparation, higher education

BACKGROUND

The report compiled by the US Commission on the Future of Graduate Education entitled "The Path Forward: The Future of Graduate Education in the U.S."[1] was a joint effort between the Educational Testing Service and the Council on Graduate Schools. The report listed areas where the U.S. demonstrated vulnerability in our predominance in graduate education, including among other things, competition from graduate programs abroad, changing demographics in the U.S., attrition rates, time to complete graduate degrees, and the job market for graduates.

In 2010-11 the AACP Research and Graduate Affairs Committee (RGAC) was charged to evaluate the Path Forward Report as it pertained to pharmaceutical sciences and to recommend how AACP and its member graduate programs can prosper given the present and future described by the Report. In their 2010-2011 recommendations,[1] RGAC identified some threats specifically to pharmaceutical sciences graduate programs including the declining percentage of students with U.S. Pharmacy degrees pursuing graduate education, shrinking resources for funding graduate education, and changing career pathways for graduates. The RGAC also examined the National Research Council Assessment of Graduate Education (2006) and several other reports over the past decade including RGAC past reports that focused on graduate education in the pharmaceutical sciences.

The Committee created a SWOT (strengths, weaknesses, opportunities, and threat) analysis using this data, and identified priority recommendations:

- Support dual degree programs
- Adopt and support interdisciplinary research and doctoral education programs in experimental pharmacotherapeutics

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- AACP should lead in the promotion of pharmaceutical science research and graduate education as well as integrating the goals of professional and graduate pharmacy education
- Increase funding for post-Pharm.D. clinical research
- Pharmacy faculty should be developed and supported to lead and contribute significantly to fields such as cell and systems biology, genomics, proteomics and nanotechnology

Concurrently during the 2010-2011 RGAC's tenure, AACP created a new special interest group (SIG) focusing on graduate education. The objective of the Graduate Education SIG's newly formed Planning Committee (GEPC) was to plan initiatives for the SIG and to work with AACP in their planning process in the area of graduate education. To this end, the GEPC has studied the RGAC Report (2010-2011) and others, but also the literature pertaining to trends in pharmaceutical research and graduate education to inform our recommendations of how the future of our discipline might impact the strategic course for strengthening graduate education across all AACP and its member schools. These recommendations from the GEPC report have the support of the American Association of Pharmaceutical Scientists (AAPS).

PHARMACEUTICAL INDUSTRY TODAY

Pharmacy faculty hear anecdotal information that the pharmaceutical industry has been undergoing significant change but few academics have direct and broad-based knowledge of its future trends.

A recent analysis from PricewaterhouseCoopers entitled "Pharma 2020:Virtual R&D – Which Path Will You Take"[2] explored current trends and the future of the pharmaceutical industry. The article described current trends in the industry to include:

- Declining productivity in research and development
- Decreasing revenues due to generic drugs
- Expiring patents that are not being replaced by innovative new drugs

The scientific literature and community also have spoken to the need to become more efficient, innovative, and collaborative in science. Several reports or articles concurred with the description of pharma's decreasing innovation,[3,4] falling profits[5] accompanying increased costs.[4-7]

Some concur with PWC that pharma's productivity has been declining[4,7] though Kaitin asserted that industry productivity has been constant since 1980 except for a temporary spike in new drugs due to the Prescription Drug Users Act in 1992 that caused the ensuing apparent decline.[8]

Other factors contributing to diminishing productivity and revenues have included less equity available for investment,[9] a plateau in investment in R&D since 2007[6] and projected cutbacks in R&D investment in the future.[10] Additional contributing factors include high candidate failure rate due to poor portfolio management and candidate advancement,[11] more international and domestic outsourcing of activities to contract research organizations (CROs),[4,12-14] and increased regulation.[3,5,6] Research and development in pharma is becoming more streamlined, thus many more graduates in the future will be working in small companies where the responsibilities are integrated.[14]

In a recent *Economist* summit on pharma, Chief Strategy Officer for GlaxoSmithKline David Redfern discussed the imperative for pharma to change.[10] According to Redfern, "the (current challenges) have the capacity. . .to fundamentally change and almost destroy the entire industry. . . if your business model isn't any good you have to change everything you do." Additionally he stated that this might be the last generation of R&D spending using the blockbuster drug funding model currently in use. The principles infused in his vision of the future include extensive strategic program eliminations, globalization of markets and R&D, accountability, more innovation and risk, transparency, philanthropy, and investment in pharma's stakeholders (e.g. developing countries' infrastructures, green initiatives, orphan drugs, etc.).

Despite these overall trends, some parts of the industry have been thriving. Biologics have been the fastest growing class of new drugs and have accounted for 33% of all new drug applications (NDAs).[15,16] Pharma has continued to acquire biotechnology to feed their pipeline, and even modifying the large corporation into smaller, more flexible, mobile divisions in the spirit of the startup to increase competitiveness and creativity.

Recently, an approval pathway for biosimilars has become available which will further fuel the growth of biological drug approval[15,17] resulting in a growing need for appropriately trained graduates.[13] Personalized medicine is also accounting for a growing number of drugs in the pipeline, estimated to between 12-50% and will enjoy an estimated 53% increase in spending from 2011-2015. Ninety-four percent of companies surveyed are investing in new technologies in personalized medicine, and 100% are using biomarkers in drug discovery research.[6]

THE FUTURE OF PHARMA

One of the resources considered by PWC in their Pharma2020 report was the FDA's Critical Path Initiative

(CPI) 2004.[18] The CPI's goal was to redefine how drugs will be developed, evaluated and manufactured. They identified several key areas that will be essential to realize this new path including biomarkers, bioinformatics, nanotechnology, and imaging. The Critical Path will require collaboration of existing stakeholders to enable this vision. Since 2004, progress towards CPI has included the Predictive Safety Testing Consortium whose goal was to establish new biomarkers, Clinical Trials Transformation Initiative to transform clinical trials, drug safety surveillance projects, and collaborations by FDA with other government and non-government agencies such as the NIH to increase research and funding in regulatory sciences.

In addition to examining current trends, PWC also made several recommendations for the industry regarding the research areas that are becoming increasingly important for the industry:

- Need better virtual predictive models and simulation programs, including virtual organs, animal and human models to discover and test new drugs, a recommendation echoed by others.[19,20] Some estimate that model and simulation sciences can reduce development costs by 50%[20]
- Use semantic technology to both aggregate like and separate unlike data despite overlapping or disparate nomenclature
- Develop innovative technologies in areas such as drug delivery and therapeutic cells/tissues, clinical biomarkers, biochips for real-time and remote monitoring or drug delivery
- Creation and use of criteria for developing drugs that are cost-effective; development and licensing of cost-effective and efficacious drugs should become an ongoing and iterative process involving regulators throughout the development process, a position also advocated by others[5,21,22]

Predictive methods are a growing research area called comparative effectiveness research. Comparative effectiveness research (CER) has used retrospective studies of large populations to make predictions about drug use.[21] CER has also been an important new area for demonstrating the cost effectiveness of new drugs relative to their competitor brands during the drug development process instead of after approval.[2,5,21] For example, information technology tools are being used to mine pre-existing data as an alternative to prospective large-scale clinical trials. The concomitant growth of electronic medical records is making this kind of large-scale database research more feasible. This has been done in such areas of hypertension, diabetes, macular degeneration, and drug safety.[21]

The growing inefficiency and cost of research and development has spawned research in other predictive sciences, such as quantitative risk analysis and risk management. This new field has been increasingly used as a statistical tool involving probability theory to model outcomes, and to estimate risk/benefit for decision making in drug development.[23] Multiscale systems models, such as those that might include biology/physiology/pharmacology/pathophysicology elements concurrently, are also more commonly used to predict clinical success with experimental data. Multiscale models have already been applied to areas such as cardiovascular, diabetes, and osteoporosis.[19] Recently, the NIH published a white paper[24] recommending support for quantitative systems pharmacology (QSP) to aid in developing precision medicines through a combination of computational and experimental research.

In summary, many of these emerging research areas have been designed to improve prediction of drug safety, clinical efficacy or cost-effectiveness at lower cost and more efficiently. Predictive sciences, including database management, biostatistics, programming and modeling are likely to become increasingly important components of drug discovery and development as a means to offset rising costs and lengthy studies.

Other PWC recommendations were made regarding the business practices of pharma:

- Encourage innovation based on individual performance, not candidate drug fate
- Develop and use clinical trial supercenters instead of decentralized multi-center trials facilitated by electronic data interchange and electronic records using common data formats
- Industry must work more closely with regulators and be willing to adapt based on their input
- Drug companies must decide whether to focus on mass market versus specialty medicines, outsource versus in-house R&D; this decision will affect the mix of skills needed in the workforce
- Change the way staff are remunerated and rewarded
- *Be more innovative, collaborative/inclusive and cost-effective*

The need to be more interdisciplinary and innovative has by necessity resulted in novel ways for pharma to collaborate with each other and academia. For example, open innovation models have allowed shared risk and cost between collaborators that has been enabled by shared data and intellectual property.[25]

The authors describe open innovation as a flexible business model where intellectual property from both internal and external sources is used to fuel innovation.

Proctor & Gamble reorganized their R&D model in 2000 in attempt to be more innovative, and reportedly increased product success rate by 50% and R&D efficiency by 60%. Lilly, Merck, GlaxoSmithKline, Alynlam, and Pfizer have also begun to make their technology, expertise and compounds more openly available.

Partnerships (with other private and academic organizations) and innovation networks (network of stakeholders who share in risk and reward of innovation)[8,14] have been another mechanism by which industry has been trying to become more competitive. Several have stressed that underlying the new collaborative models and all else must be quality science[9].

The future as described above will require graduates with additional skills beyond those taught in the lab. To be successful and to thrive with this dynamic landscape will require a range of skills in business, communication, teamwork, and leadership, among others (Table 1). The value of a broad education has also been cited by the AAPS Big Pharma/Small Pharma Task Force. The Task Force observed that 48% of members now come from small companies where it traditionally has focused members from large companies.[14]

Table 1. Summary of Skills Needed by Scientists in the Pharmaceutical Industry

Skill	Reference Number(s)
Business skills	9,24,26-28
Marketing	
Management	
Writing business plans	
Venture capital education	
Negotiation	
Interdisciplinary	7,12,24,26,27,29,30
Flexible	13
Creative	4
Globalism/diversity	14,18,31
Advocacy	18
Leadership	12,14,27,32
Cost – research and patient cost-benefit	11
Communication skills	7,18,24,27,28,32
Teamwork/collaboration	7,18,26,31
Mentoring	24,26,28,32
Grantsmanship	18
Career development – including exposure to careers in industry and government	1,18,24,28
Networking	32
Ethics	33
Multitasking/prioritization	34
Being entrepreneurial	14

ACADEMIA TODAY

On one hand, since the pharmaceutical industry has been rapidly changing, the skills needed in scientists entering this field have also been changing. However, pharmaceutical science graduate programs have been still primarily designed to train students to conduct academic research much in the same manner as it has for decades. Students have been trained in the image of their professors: scientists who conduct NIH-style research in an academic setting.[35] While this approach has been logical if the primary goal has been to fill the pipeline for future faculty, only 14% of postdoctorals in the UCSF pharmaceutical sciences have gone to tenure track positions in academia while 33% have entered into non-research careers.[32] In addition, the NIH funding mechanism has been inherently unstable and has perpetuated an overproduction of scientists.[35]

However, faculty have no control over the job market, so the traditional educational approach has been failing to prepare the remaining 86% of our graduates who enter non-academic careers.[32] Others have gone further to say that the academia has lacked both efficiency and interdisciplinarity,[30] both important characteristics that are needed to create a viable future for the pharmaceutical sciences and industry.[29]

The current funding mechanism for many of academic pharmaceutical scientists perpetuates the NIH-emphasized research. The large overhead funds that accompany NIH grants provide resources to the institution. Federal grants in general bring prestige to the institution. In addition, students often choose their research mentors based on their NIH-funding success. For these reasons, schools have many incentives to continue the current funding model.

Other threats to our graduate programs that have been identified include foreign graduate programs providing competition, releasing into a crowded and uncertain marketplace more graduates of mixed quality.[18,27] decreased funding for graduate programs, insufficient advocacy by faculty for our graduate programs, and decreasing number of faculty with Pharmacy backgrounds.[18]

GRADUATE PROGRAMS OF THE FUTURE

Pharmaceutical sciences graduate programs are now facing a potential crisis in terms of being able to sustain viable, yet relevant, graduate programs that produce scientists who are ready to contribute in academia, industry or non-research areas in our rapidly changing environment. The Academy should have as a primary goal to make our graduate programs more relevant for the graduates and all employers of the future.

To fully inform a strategic path to secure the relevance of our field, our discipline requires a needs analysis: our graduate programs should be responsive to current and future job needs, both in academia, industry and non-research positions.[18,27] This analysis also requires we determine whether we are graduating an appropriate or excess number of doctoral or masters students for the market[18,27,30] and whether our graduates have the knowledge, skills and attitudes to be competitive for the jobs of the future or even lead the way into the new era of drug discovery and development.

Such a needs assessment and self examination is a priority also according to those who responded to a recent NIH Request for Information.[28] The NIH Advisory Committee to the NIH Working Group on the Future of Biomedical Research Workforce submitted a RFI identifying eight issues that might be relevant toward creation of a new model for the future biomedical workforce. The RFI elicited comments from 219 individuals, who identified the PhD supply and demand, followed by PhD characteristics issues as the most important issues on the list. Commenters stated that because of the overabundance of graduates, excellent candidates cannot find jobs in academia and those that do have unacceptably low salaries. The characteristics of PhD graduates were also of concern to responders. Responders recommended that career counseling, alternative career pathways, career development, and more structure in graduate programs would help students find employment after their postdoctoral training. Others agree that programs should do more to help students clarify their career pathways.[18,32,36]

How we educate our students and in what areas remain key questions. As discussed above, emerging and growing scientific areas in the pharmaceutical sciences such as modeling and simulation sciences, biologics, clinical and translational science and nanotechnologies should become more widely available for both basic and advanced training throughout the Academy. Soft skills (Table 1) should also become available to students as foundational courses. Other suggestions to enhance graduate education include improve degree completion rates,[18,32,36] shorten time to degree,[18,32,36] employers and policymakers should support graduate education including the provision of internships,[18,24,28] increase advocacy efforts and possibly increase exposure of clinical and translational research to Pharmacy students.[1] The manner in which NIH, NRC and other funding organizations measure success for graduate programs should include evaluation for non-research pathway.[32] Others[37] recommend adding clinical training elements, such as patient simulations, to training in basic biomedical research to enhance the translational science education.

In this era of diminishing resources for higher education and basic research, how can an organization like AACP help meet the rapidly changing needs of the discipline? It is essential that AACP provide the leadership and support to enable the creation of a new future for our graduate programs. Indeed, for the creation and provision of high quality courses and degree programs in newly emerging areas, the time and resources needed to create the necessary core of faculty expertise can take years or decades for a given institution if acting alone. However, if one removes institutional and distance barriers to new program development, the speed, cost minimization and quality of program creation can be greatly enhanced.

Our programs must apply innovation and technology to enable both educational quality and efficiency simultaneously. In addition, the traditional silo and classroom approaches to graduate education are hindering our ability to be efficient and responsive to the needs of our profession. Efforts to increase professionalism, soft skills, and enhance career development also need not be repeatedly replicated within each School of Pharmacy. Shared workshops, courses and webinars could be offered through AACP or collaboratively between a network of Schools to avoid repeatedly having to develop and teach programs to a small number of students.

New strategies to effectively train students for the future include collaborative education models.[26,38] Such collaborations typically occur between academic institutions but partnerships with industry and government can also provide mutual benefit in terms of increasing the pool of available expertise, and focus on topics and approaches that are relevant to employers. For example, the NIH Biomedical Workforce[28] suggest industrial partnerships and fellowships could be used to train students in non-academic careers.

Collaborative models may be designed where some subjects are outsourced to other institutions, and/or certain faculty are shared between institutions. Online technology could be a useful tool to facilitate such collaborations, though online education seems to be slow to permeate graduate programs. Sanders[38] provides a model for online graduate education using an inter-institutional collaborative model for distance education.

The feasibility of such an approach has already been demonstrated by NIPTE (National Institute for Pharmaceutical Technology and Education; nipte.org) which offers training programs in pharmaceutical technology by using a network of collaborative schools who participate in teaching the course. Such a collaborative effort could potentially address the concern of some faculty that soft skill development is a low priority, if such programs can be offered efficiently and for low cost.

The rising costs and demands of bringing transformative therapeutics to patients are also driving the collaborations between pharmaceutical and life science industry and academia to stimulate innovations. Despite the several opportunities afforded by collaborations, companies and universities lack a systematic approach for capturing the full potential of such relationships. Cultures, values and norms differ significantly between academia and industry. While pharmaceutical companies typically define the goals, objectives and timelines for their researchers, in academia, researchers have the freedom to define their own goals, objectives and timelines. Despite the surfeit of collaborative models, many of the most successful models fail to provide open access to data or resource sharing.[39] This protective and conservative approach to data management limits innovation. The traditional competitive business models practiced by most companies do not fit the mission and culture of universities where data sharing plays a major role.[39] However, the emerging examples ofnew open business models, as described earlier, will support the concept of open innovation.[25,40] The continued development of such open innovation models is necessary to sustain the highly innovative collaborative structures between industry and academia. So, it is imperative that future graduate programs understand these differences and develop relationships with industry that provide opportunities for investigators and companies to pursue research interests and goals that naturally overlap.

RECOMMENDATIONS

Because the future of the pharmaceutical sciences is changing and has changed so dramatically in recent years, strong leadership will be required to steer the Academy through a period of transition. Asking Schools to organize this transition at the grass roots level will result in delays and inefficiencies.

Therefore, we concur with the RGAC 2010-2011 report that AACP should take a central role in leading this effort at the national level, calling upon participation by Schools across the membership. Centralized, organizational leadership will not only be needed for new curriculum identification, creation, sharing, and offering, but also to help identify and secure funding for initiatives, survey research, creation of partnerships with stakeholders, creation of faculty and institutional development for the transition, best practices for intellectual property generated by these innovative collaborations, and assistance with the cultural change that will be needed to realize these changes, not only in the graduate programs but the Schools themselves. The Academy should also take a data-driven and scholarly approach to implementing and evaluating change: new programs and initiatives should demonstrate their value and efficacy.

The consequences of inaction could lead to an increasing irrelevance of the pharmaceutical sciences to any place other than academia. The benefit of retooling our graduate programs can potentially be to revitalize and energize our students and alumni to find and create jobs that continue to make a meaningful contribution in health care.

Curriculum

- Create a Task Force (with input from stakeholders) to determine the need for specific core and specialty curriculum that will involve Schools and Colleges across the Academy to collaboratively create and offer these curricula. Both key scientific areas of importance to the future of pharmaceutical sciences, such as clinical and translational sciences, bioinformatics, decision-making sciences, and in non-scientific areas such as career pathways, career development, soft and leadership skills, and how to best prepare and advise graduates for non-academic and non-research careers should be considered.**
- *Create and make widely available across the Academy, core curriculum in these areas at the basic and/or advanced levels by involving graduate programs across the Academy and collaborations/partnerships with stakeholders such as industry and the FDA. Course delivery and pricing should be designed to be accessible to the Schools in the Academy*.*

Funding

- Conduct surveys on a regular basis to determine what the long and short term hiring needs are for academia and pharmaceutical industry in terms of numbers of graduates and skills needed, and stipends in the pharmaceutical and biomedical sciences.**
- Re-evaluate across the Academy the number of MS and PhD graduates by discipline, including consideration of the impact of creation or enhancement of new or existing disciplines within pharmaceutical sciences, and how to help programs transition to include more research areas that make our graduates more marketable and relevant to employers.** A recent report by Chmura Economics & Analytics estimates that the annual demand for PhD's in pharmaceutical sciences is 497[41].

- *Foster research in emerging areas by offering small grants, recognizing excellence in the fields, and providing graduate student support**
- Facilitate fundraising for these new programs and curriculum by coordinating grants to NSF, advocacy and fundraising from stakeholders
- Increase the number and amount of new investigator funding available, especially in emerging disciplines
- *Encourage schools to prioritize new faculty hires in emerging areas**
- Foster open innovation models between academia and pharma

Development

- Provide and/ or organize student development programs via online or national/regional courses or workshops at low cost to programs and students**
- Develop faculty to enable the effective creation and implementation of emerging disciplines by providing exposure to and collaborative opportunities with scientists currently working in those disciplines, as well as protected time to pursue these new areas**
- Create a central location for advertising student internships; foster the creation of internships for pharmaceutical science graduate students in scientific and non-scientific areas
- Include in graduate training exposure to alternative career opportunities (i.e. scientific writing, patent law, leadership, financial management, etc.)**

Recruitment/Admissions/Pipeline

- Create tools (videos, website content, national effort to promote graduate education, centralized application process, etc.) for schools to use for recruitment and admission of applicants into graduate programs, especially PharmD students
- *Create scholarships specifically for PharmD students entering graduate school**
- Consider revising or expanding the graduate program admissions criteria to include key skills assessment

Advocacy

- *We concur with Fuhrmann et al.[32] that we should advocate for changes from funding agencies and review committees as to the definition for "success" of doctoral training programs to include measures for contribution to the scientific enterprise more generally, rather than primarily movement into academic positions.**

Indicates priority recommendations over the next 2* (*italics*) or 5** years.

Implicit in this proposal is the need for the Academy to agree upon a shared vision for the future. Each school will have their own implementation needs and obstacles, so implementation will likely evolve in different ways to various endpoints for each institution. This agreement of the shared vision within the Academy and individual schools will be key to overcoming resistance to change. A realistic expectation should be maintained of the change timeline and amount of faculty time available for change. It is also neither realistic nor desirable to expect faculty to completely change their research or teaching areas; new areas of emphasis will likely begin and evolve as collaborations with existing scientists and so access to these scientists should be facilitated and encouraged.

In addition, the use of carrots rather than sticks is more likely to be effective in encouraging change. For example, the recommendations include providing resources, recognition, access to experts, and leadership to enable the change. Without those critical elements, the faculty will likely and rightfully feel this evolution is yet another unfunded mandate. In contrast, with the right vision and leadership, the faculty may even take ownership of the change process in their institution, and find ways to creatively contribute and enhance the process for the Academy.

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