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Commentary

Education in Pharmaceutical Sciences Needs a Brand New Direction to Meet the Challenges of Drug Research and Development

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In two recent *Pharmaceutical Research* editorials, Prof. Ronald T. Borchardt of the Department of Pharmaceutical Chemistry at the University of Kansas (1) and Dr. Alice E. Till of the Generic Pharmaceutical Industry Association (2) discussed how graduate education in pharmaceutical sciences can meet some of the challenges of drug research and development in the pharmaceutical industry. As a research scientist who has spent the past 21 years in R&D in major US pharmaceutical companies, I would like to provide one additional perspective of the issue. In my opinion, the current focus of US pharmaceutical education may not be conducive to major positive changes in pharmaceutical science education. Despite all the talk about downsizing in the pharmaceutical industry, there is a great unmet need for well-educated and well-trained pharmaceutical scientists both within and outside the industry. The entire education system in pharmaceutical sciences—both undergraduate and graduate—needs a brand new direction in order to meet the challenges of drug research and development.

SHIFT IN EDUCATIONAL FOCUS

To meet the needs of patient care end of pharmacy, the focus of pharmaceutical education in the USA has gradually changed during the past three decades from basic science to clinical practice. The study of basic science courses and the related laboratory training have been de-emphasized, while more and more clinical pharmacy courses have been introduced in the curricula. Indeed, the 1996–1997 Academic Affairs Committee of the American Association of the Colleges of Pharmacy (AACP) "recognized and agreed that pharmacy students and graduates of professional degree programs are not scientists and should not be expected to be scientists. Rather, they are professionals—pharmacists who use science, its findings and processes, in their practice to solve problems" (3). Dr. D. Eric Wurster of the University of Iowa recently summarized the situation (4): "From the moments that students enter a college or school of pharmacy, they are being indoctrinated about the importance of patient-pharmacist relationship. This is not an environment in which a mild curiosity about laboratory science is likely to be intensified to a serious interest."

DEMAND FOR PHARMACEUTICAL SCIENTISTS

While the focus of pharmacy education has been shifting away from basic sciences, the demand for pharmaceutical scientists in industry, academia, regulatory agencies, and government and independent research institutions has grown greatly. In 1995, the research-based US pharmaceutical companies had a professional and scientific staff of 34,784 in R&D alone (5), and the total number would be much higher if all scientific disciplines and all sectors of the industry were taken into account. Along with the scientific staff, the R&D expenditure of the research-based companies has grown to 15.1 billion in 1997 (5). As far as the research institutions are concerned, National Institutes of Health (NIH), which to a large extent is responsible for basic research leading to drug discovery and development, has a 1997 budget of 12.4 billion dollars, with 19,000 intramural employees and 35,000 extramural principal investigators (6).

The current US pharmaceutical education system has been unable to meet such a demand for pharmaceutical scientists. Instead of strengthening the existing programs and introducing new programs in emerging pharmaceutical fields, the support for both undergraduate and graduate education in pharmaceutical sciences in pharmacy schools has continuously been decreasing. In the absence of qualified and interested pharmacists for careers in drug research and development, the drug industry has been forced to recruit scientists educated in other disciplines of science and train them in pharmaceutical sciences. Out of the 34,784 R&D scientists of the research-based pharmaceutical companies mentioned above, the majority (23,460) are at the B.S./M.S. level. Although there is no detailed survey, it is estimated that less than 2% of them have an undergraduate pharmacy degree. Among the 9,972 Ph.D. level R&D scientists, pharmacists have a visible presence only in pharmaceutics, drug metabolism and pharmacokinetics.

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CALLS FOR CHANGES

There are many reports on how the demand for pharmaceutically trained personnel in drug research and development can be met (3,4,7–10). However, most suggestions focussed on increasing the scientific base of undergraduate pharmacy curricula and upgrading of graduate programs. They centered around initiatives that must be taken by the schools of pharmacy. As an example, the recommendations of the AAPS Task Force on Academic Pharmaceutics (10) is worth noting. According to the Task Force report, "to fulfill their role as an academic institution, schools of pharmacy are obligated to offer high-quality educational programs in the pharmaceutical sciences that prepare qualified students for a research career". Therefore, "most of the recommendations of this Task Force call for actions that must be initiated by chairpersons or deans", which included hiring of a critical mass of faculty in basic sciences, providing junior faculty with full research support, development of four-year baccalaureate programs in pharmaceutical sciences and the development of integrated Pharm.D.-Ph.D. programs.

As the latest attempt to address the present crisis, the 1995–96 AACP Research and Graduate Affairs Committee recommended the establishment of a "Commission on the Future of Graduate Education in Schools of Pharmacy" with a broad-based representation (11), which has recently been formed. It is the second such AACP commission during the past decade (12). However, as the name implies, the commission is entrusted to address only the 'graduate education' and the 'schools of pharmacy' should be able to implement its recommendations.

WORSENING SITUATION

The chance of implementing recommendations which call for "actions" by pharmacy schools, however, does not appear promising. For example, since the publication of the AAPS Task Force recommendations in 1990, the focus of pharmaceutical education has shifted even further away from basic science. The American Council on Pharmaceutical Education (ACPE), which is responsible for accrediting pharmacy education programs in the USA, declared that, effective from the year 2000, Doctor of Pharmacy (Pharm.D.) with a minimum six years of education at the post-high school level will be the only accredited entry-level pharmacy program. The addition of an extra year to the pharmacy program for this B.S.-to-Pharm.D. switch and the accompanied increase in clinical pharmacy faculty are occurring in most schools at the expense of possible expansion or upgrading of pharmaceutical science programs. In most cases, the schools are setting new priorities to conform with recent changes and initiatives in the health care field. Just to name two of these changes and initiatives, the APhA has changed the mission of pharmacy to "the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes" (13), and the Third Report of the Pew Health Professions Commission recommended that the professional training should focus "even more on issues of clinical pharmacy" (14). There is no indication that this trend will be reversed.

The graduate enrollment in pharmacy schools has also been affected by the above change in undergraduate education. While the enrollment in Ph.D. programs remained almost steady between 1989 and 1996, the percentage of US-educated pharmacists dropped from 28 per cent of the total number of Ph.D. students in 1989–90 to less than 16 percent of the total in 1996–97 (15). Only 337 US-educated pharmacists were pursuing full-time Ph.D. studies during the fall of 1996, which is only about 1 percent of the undergraduate enrollment of 33,059. Even out of this small number of 337, about 30 percent (101) were specializing in areas of pharmacy practice, social and administrative sciences, etc., thus making the number interested in drug research and development even smaller. Assuming that there will be no further erosion in the enrollment of US-educated pharmacists in graduate programs and the average time required for the Ph.D. degree will be 4 to 5 years, we can expect that only about 50 Ph.D. degrees will be conferred annually to the US-educated pharmacists in such disciplines as pharmaceutical chemistry, pharmaceutics, pharmacology, etc. Even this number, which is very small as compared to the total demand in the industry, academia, regulatory agencies, and research institutions, may not be guaranteed in the future. This is because the incentive for U.S.-educated pharmacists to spend additional four to five years for a Ph.D. degree in pharmaceutical sciences may further decrease with the full implementation of six-year Pharm.D. programs by the year 2000.

NEW DIRECTION

It is evident from the above analysis that the practice-oriented education in US pharmacy schools has diverged from that in pharmaceutical sciences, the pharmacy schools are no longer committed to teaching pharmaceutical sciences at the undergraduate level to meet the demands of drug research and development, and the interest of US-educated pharmacists in graduate education in this area is low. The first step in changing the situation could be the separation of education in pharmaceutical sciences from that in pharmacy practice by introducing undergraduate and graduate degree programs in pharmaceutical sciences which would be independent of pharmacy schools. There are several advantages to this approach. First, the existing pharmaceutical science programs of many pharmacy schools may serve as the nuclei and be combined with other complementary disciplines within an university to develop these new programs, without being restricted by the goals and objectives of the schools of pharmacy. Second, the teaching of pharmaceutical sciences will not have to be limited to the universities currently having schools of pharmacy. Universities with strong biomedical education and research programs, including many Ivy League universities as well as such educational institutions as John's Hopkins University, Stanford University, etc., may be encouraged to initiate undergraduate and graduate degree programs in pharmaceutical sciences, since such programs will be complementary to their existing biomedical programs. Third, undergraduate students with career goals in pharmaceutical and biomedical areas, including many who currently study chemistry, pre-medical biology, chemical engineering, etc., in universities both with and without pharmacy schools, can be attracted to the new focussed and specialized programs in pharmaceutical sciences. Fourth, since separate programs in pharmaceutical sciences will free the faculty members from involvement in professional pharmacy education, the recruitment of established scientists with interests in basic pharmaceutical and biomedical sciences only will be easier.

The structure of educational programs in pharmaceutical sciences should be the subject of discussions among educators,

pharmaceutical researchers, and industry representatives. Only some preliminary outlines may be presented here. Pharmaceutical research is interdisciplinary in nature and encompasses many scientific disciplines, including medicinal chemistry, biochemistry, biotechnology, pharmacology, toxicology, drug metabolism, pharmacokinetics, physical and analytical chemistry, pharmaceutics, chemical and pharmaceutical engineering, clinical sciences, regulatory affairs, etc. For the efficient and accelerated discovery and development of drugs, scientists must work as members of teams, where a broad scientific background outside of one's immediate area of specialization is very important. Therefore, students enrolled in undergraduate programs can major in certain disciplines of pharmaceutical sciences, while minoring or taking electives in other disciplines. The majors may include: pharmaceutical chemistry, with emphasis in medicinal chemistry, drug screening, and analytical chemistry; biopharmaceutical sciences, with emphasis in biochemistry, pharmacology, toxicology and drug metabolism; biotechnological sciences, with emphasis in the discovery and the development of macromolecular drugs such as peptides, proteins, and oligonucleotides; and pharmaceutics, with emphasis in physical pharmacy, dosage form design, pharmacokinetics, drug stability testing, pharmaceutical engineering, regulatory affairs, etc. Adequate emphasis should be given to inculcate laboratory skills to the students, which is deficient in the current system. The support for such approaches may be obtained in a recent proposal by Dr. D. Eric Wurster for a B.S. in Pharmaceutical Chemistry program that would incorporate pharmaceutics, medicinal chemistry, and pharmacology (4).

The graduate education in pharmaceutical sciences will be the continuation of undergraduate studies where the students will be able to specialize further. With the undergraduate programs to support the graduate education, the concerns about the shortage of talented students for graduate studies (12) will also be diminished.

The AAPS may be able to pave the path towards the new direction of education in pharmaceutical sciences. The Association was established when it was evident that the APhA was no longer able to satisfy the aspirations of pharmaceutical scientists. Now that the pharmacy schools are not being able to meet the demands of pharmaceutical research and development, it might be the responsibility of the AAPS to lead us to the new direction. The active support and collaboration of pharmaceutical industry is also necessary.

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