



The University of Georgia

University Council
Athens, Georgia 30602

February 6, 2015

UNIVERSITY CURRICULUM COMMITTEE – 2014-2015

Dr. William K. Vencill, Chair

Agricultural and Environmental Sciences - Dr. Robert B. Beckstead

Arts and Sciences - Dr. Roxanne Eberle (Arts)

Dr. Rodney Mauricio (Sciences)

Business - Dr. Myra L. Moore

Ecology - Dr. James W. Porter

Education - Dr. Seock-Ho Kim

Engineering - Dr. Sidney Thompson

Environment and Design - Mr. David Spooner

Family and Consumer Sciences - Dr. Silvia Giraud

Forestry and Natural Resources - Dr. John C. Maerz

Journalism and Mass Communication - Dr. Alison F. Alexander

Law - Ms. Elizabeth Weeks Leonard

Pharmacy - Dr. Cory Momany

Public and International Affairs - Dr. Robert Grafstein

Public Health - Dr. Katie D. Hein

Social Work - Dr. Kristina Jaskyte

Veterinary Medicine - Dr. Scott A. Brown

Graduate School - Dr. Timothy L. Foutz

Ex-Officio - Provost Pamela S. Whitten

Undergraduate Student Representative - Mr. William Heaton

Graduate Student Representative - Ms. Lauren E. Mullenbach

Dear Colleagues:

The attached proposal for a new dual degree in Pharmaceutical Sciences (B.S.) and Pharmacy (M.S.) will be an agenda item for the February 13, 2015, Full University Curriculum Committee meeting.

Sincerely,

William K. Vencill, Chair
University Curriculum Committee

cc: Provost Pamela S. Whitten
Dr. Laura D. Jolly

The University System of Georgia
Format for Dual Degree Program Proposal

Dual degree program proposals include more than one degree. Please provide the following information for each unit involved.

1. Institution(s): University of Georgia
2. Date: August 15, 2014
3. School(s)/College(s)/Division(s)/Institution(s): College of Pharmacy
4. Departments: Pharmaceutical and Biomedical Sciences
5. Degrees to be offered: Bachelor of Science and Master of Science
6. Majors to be offered: Pharmaceutical Sciences (B.S.) and Pharmacy (M.S.)
7. Starting date: Fall 2015

8. Program abstract

Provide a summary of the proposed program. This section should include advantages to each respective degree program and impact on the University of Georgia. If a dual degree program is with another University System institution, describe the advantages to the University of Georgia.

We propose to create a unique dual degree program between the existing B.S. in Pharmaceutical Sciences and the M.S. Program of the College of Pharmacy. This degree will have two areas of emphasis, one in Pharmaceutical and Biomedical Regulatory Affairs and one in Pharmaceutical and Biomedical Sciences. These graduate programs both currently exist as areas of emphasis within the M.S. in Pharmacy. The B.S. Program is off to a tremendous start, with enrollment already exceeding second year projections of 20 students per class. Half of our existing majors are planning to continue on to graduate school, which is in agreement with data we have from the Pharmaceutical Sciences program at Purdue University.

The College of Pharmacy strategic plan Goal 1-5 is to expand educational opportunities through new undergraduate and graduate offerings to meet the health care and workforce needs of the state and the nation. As part of this goal there is a special emphasis on joint degree programs. Therefore, combining these two well aligned programs is a logical step toward meeting this goal. Goal 2-2 is to recruit and graduate outstanding graduate students. UGA has some of the highest quality undergraduate students in the nation (incoming freshmen 2014 GPA 3.9). By focusing on bringing the most academically qualified students into this program, we will build a recruiting pipeline for our master's degree programs. This option also increases the likelihood that top UGA undergraduates will continue their graduate work here because of the compressed timeline to complete the M.S. degree. Combined, these programs will help the college attain its goal of increasing both the quality and quantity of students in our graduate programs.

Finally, this B.S./M.S. would be a unique program that matches a need for industry. When the B.S. program was approved, we had strong letters of support from senior management from pharmaceutical companies throughout Georgia and the United States (See attached letters in Appendix A). The design of this program will allow us to enhance two of the items most frequently cited as valuable by industry:

(1) increased knowledge of the regulatory sciences and (2) greater laboratory experience. Additionally, this program positions UGA well to continue its leadership in this area.

9. Objectives of the program

List the program objectives and indicate how they are related to each respective degree program.

The objective of this program is to prepare students with strong training in the pharmaceutical sciences enhanced by specialization in either regulatory affairs or pharmaceutical and biomedical sciences. Our graduates will be able to integrate their knowledge with significant experience to enhance their career path development. The specific learning objectives for the program are listed in section 15 along with the method for assessing each objective.

The M.S. Area of Emphasis in Regulatory Affairs takes students with backgrounds in the pharmaceutical sciences and trains them in current drug regulations governing the development and manufacturing of pharmaceuticals, biologics, medical devices, animal health and combination products. Graduates with this combination degree would be ideal for Regulatory positions in CMC (chemistry, manufacturing and control) and/or research and development. The CMC area is a highly regulated portion of the drug development and approval process. Another area graduates may pursue would be positions in pharmacovigilance. This area of emphasis would provide students with considerable expertise in the global regulatory sciences and make them extremely competitive for positions in industry where most of this has to be learned on the job.

The M.S. Area of Emphasis in Pharmaceutical and Biomedical Sciences takes students with strong scientific backgrounds and provides them the ability to specialize in the areas of pharmacology, drug delivery, or medicinal chemistry. Graduates from this area of emphasis would gain considerable laboratory intensive training that would provide them with the practical experience to make them more competitive for research positions in industry or to prepare them for highly competitive graduate programs that value previous research experience.

10. Justification and need for the program

- a. Indicate the benefits for offering the dual degree program. Describe the process used to reach these conclusions, the basis for estimating this need, and those factors that were considered in documenting the program need.
- b. Indicate the student demand for the dual degree program. What evidence exists of this demand?
- c. Give any additional reasons that make offering the dual degree program desirable (i.e., to meet specific public or private sector needs).

The B.S. Program in Pharmaceutical Sciences already requires one year of research, the most of any undergraduate program at UGA. Therefore, the transition to a M.S. program is enhanced because the students already have exposure to research intensive laboratories and practices. In addition, projects that have been initiated during PMCY 4960 and PMCY 4970 provide students with a head start on their graduate thesis projects. This will also provide our program with a competitive advantage for recruiting these students because they know they can continue seamlessly into a graduate program.

Regulatory affairs is an area that we are particularly trying to grow since this is a field that has an effectively 0% unemployment rate (a 2013 Report from Price Waterhouse and Coopers & Lybrand discussed how Regulatory Affairs was a key area where Pharma/Biotech companies struggled to find qualified employees). We have graduated 45 M.S. students and 120 graduate certificate students and all of them are currently employed in this field. Students in the B.S. Program are exposed to regulatory affairs principles in our laboratories where we practice Good Laboratory Practice (GLP) and Good Manufacturing Practices (GMP) procedures and recordkeeping and in the Drug Development Courses. The Georgia Department of Economic Development frequently touts this program to companies considering locating in Georgia, therefore increasing the number of graduates from this program would be beneficial to industry (<http://lifesciences.georgia.org/files/brochures/finish.pdf>).

We have already seen a number of our B.S. Program students become very excited about laboratory research as a result of their undergraduate research experiences. Many of these students have expressed a desire to continue on to graduate school (see data below). Therefore, allowing these students to continue on in our Pharmaceutical and Biomedical Sciences area of emphasis would allow these students to expand their research experience and make them more competitive for either entering the workforce or continuing on to doctoral programs.

Data obtained from Purdue University on their Pharmaceutical Sciences program (established in 1972) shows that roughly half of their graduates continue on to graduate school. We expect similar numbers from our initial graduating class in spring 2015. During their most recent advising meetings, 6 of 11 stated their intent to pursue graduate studies. Additionally, 2 of 11 plan to pursue professional programs and the other 3 plan to enter the workforce. During the B.S. Program orientation in August 2014, we presented our plan for the 5-year B.S./M.S. degree program. There were approximately 40 students in attendance representing all 4 years of the program. Afterwards, 5 of the 11 fourth-year students asked whether they would be eligible to start this program right now. They cited the fact that they could obtain an M.S. degree with only one additional year of study as a major reason for their interest.

11. Describe the process by which the proposed program was developed.

The initial idea for combining the B.S. and M.S. program was discussed when we created the B.S. in Pharmaceutical Sciences in the fall of 2010. However, there was a consensus at that time that we should proceed stepwise and first establish the B.S. Program and once that was successfully completed continue on with the BS/MS program. With the creation of the B.S./M.S. option, we will still have stand-alone B.S. and M.S. programs as well.

A working group was established composed of the Director of the B.S. Program (Michael Bartlett), the Director of the Biopharma Regulatory Affairs Graduate Education Program (David Mullis) and the Graduate Coordinators for the two areas of emphasis (Michael Bartlett and Shelley Hooks). The routing for discussion and approval of the program is summarized in the table below.

| Level of Review | Vote |
|--|-------------|
| Department of Pharmaceutical and Biomedical Sciences | 13 Yes 1 No |
| Division of Nontraditional Education and Outreach | 5 Yes 0 No |
| College of Pharmacy Graduate Education Committee | 9 Yes 0 No |
| College of Pharmacy | 56 Yes 1 No |

12. Curriculum

List the entire course of study required and recommended to complete the dual degree program. Give a sample program of study that might be followed by a representative student. Provide a copy of the existing approved requirements for each major involved in the dual degree program proposal.

The curriculum for the B.S./M.S. Program was created to offer specialized advanced training in specific areas of the pharmaceutical sciences in a more time efficient manner than obtaining the two degrees separately. The courses recommended for the B.S./M.S. degree comply with all aspects of the University of Georgia and the University System Board of Regents policies for coursework requirements for undergraduate and graduate degrees. The credit hours for the B.S. portion of the degree are identical (120 hrs.) while the M.S. portion is reduced due to the ability to conduct research during the 3rd and 4th years of the B.S. Program (54 vs. 108). The first two years of coursework is distributed over the categories shown below. In terms of course content, there is no difference in the core courses of either

program; however, the major electives are more restricted when choosing the B.S./M.S. option in order to maximize the synergy between the programs.

| | |
|--|---|
| Area 1 – Foundation Courses (10 credit hours) | ENGL 1101 – 3 credits ENGL 1102 – 3 credits MATH 2250 – 4 credits |
| Area 2 – Science Courses (8 credit hours) | BIOL 1107/1107L – 4 credits CHEM 1211/1211L – 4 credits |
| Area 3 – Quantitative Reasoning (4 credit hours) | PHYS 1211/1211L – 4 credits |
| Area 4 – World Languages, Culture, Humanities and the Arts (12 credit hours) | COMM 1100 – 3 credits Remaining courses unspecified but must satisfy UGA requirements for inclusion in the area. |
| Area 5 – Social Sciences (9 credit hours) | Course unspecified but must satisfy UGA requirements for inclusion in the area. |
| Area 6 – Courses Related to Major (16 credit hours) | CHEM 1212/1212L – 4 credits CHEM 2211/2211L – 4 credits CHEM 2212/2212L – 4 credits STAT 2000 – 4 credits |
| Graduation Requirements (2 credit hours) | 1 credit hour of physical education 1 credit hour FYOS 1001 Students must satisfy the US/GA History, Federal and Georgia Constitution, Cultural Diversity, and the Environmental Literacy requirements. |
| Total Credit Hours for Areas 1-6 and Graduation Requirements | 61 |

The courses in years three and four of the program are shown in the table below. These courses contain additional foundation courses in statistics, calculus, biochemistry, and physical chemistry before moving into the more specialized courses in the degree program.

| | |
|--|--|
| Major Courses (46 credit hours including 42 upper division credit hours) | MATH 2260 – 4 credits BCMB(BIOL)(CHEM) 3100 – 4 credits BCMB 3600 – 3 credits ENGL 3590W – 3 credits PMCY 3000 – 4 credits PMCY 3200 – 3 credits PMCY 3300L – 1 credit PMCY 3500 – 3 credits PMCY 3800 – 3 credits PMCY 4200 – 3 credits PMCY 4300 – 3 credits PMCY 4500-4500L – 4 credits PMCY 4510-4510L – 4 credits PMCY 4960 – 2 credits PMCY 4970 – 2 credits |
| Fourth Year Area of Emphasis in Regulatory Affairs (10 credit hours) | PMCY 4010 – 4 credits – Introduction to Pharmaceutical, Biotechnology and Device Industries PMCY 5100 – 3 credits – Biostatistics PMCY 5200 – 3 credits – Ethics in Research |
| Fourth Year Area of Emphasis in Pharmaceutical and Biomedical Sciences | PMCY 5100 – 3 credits – Biostatistics PMCY 5200 – 3 credits – Ethics in Research One elective course from the approved list of major |

| | |
|--|-----------|
| (9-10 credit hours) | electives |
| General Electives (4 or 5 credit hours) | Undefined |
| Total Credit Hours for Years 3 and 4 | 59 |
| Total B.S. Program Hours including Graduation Requirements | 121 |

| | |
|---|--|
| Required Graduate Courses Area of Emphasis in Regulatory Affairs (16 credit hours graduate courses) (35 credit hours research) (3 credit hours thesis) PMCY 8200 – PBS Dept. Seminar – 1 credit per semester both years 4 and 5 PHAR 6020 – Food and Drug Law – 3 credits PHAR 6030 – Current Good Manufacturing Practices – 4 credits PHAR 6100 – Quality Control and Quality Assurance – 3 credits PHAR 6120 – Process Control and Validation – 3 credits PHAR 7000 – Master’s Research – 35 credits PHAR 7300 – Master’s Thesis – 3 credits | Required Graduate Courses Area of Emphasis in Pharmaceutical and Biomedical Sciences (14 credit hours graduate courses) (37 credit hours research) (3 credit hours thesis) PMCY 8200 – PBS Dept. Sem. – 1 credit per semester both years 4 and 5 PMCY 8020 – Fundamentals of PBS I – 3 credits PMCY 8030 – Fundamentals of PBS II – 3 credits PMCY 8040 – Methods in Pharmaceutical and Biomedical Sciences I – 2 credits PMCY 8050 – Methods in Pharmaceutical and Biomedical Sciences II – 2 credits PMCY 7000 – 37 credits PMCY 7300 – 3 credits |
| Total Credit Hours Year 3 | 12 (PHRM 7000 Summer) |
| Total Credit Hours Year 4 | 12 (PHRM 7000 Summer) |
| Total Credit Hours Year 5 | 30 |
| Total M.S. Program Hours | 54 |

- For a typical program of study for each area of emphasis, please see Appendix B.

13. Administration

Describe how the proposed program will be administered within the structure of the institution. Address how students will be admitted to the dual degree program. Explain how students will be advised once they are admitted to the program. Provide the name of a contact person for the program.

The program will be administered by a committee composed of the Director of the B.S. Program in Pharmaceutical Sciences, the Director of the BioPharma Regulatory Affairs Graduate Education Program, the Graduate Coordinators of the M.S. Program in Pharmaceutical and Biomedical Sciences and Regulatory Affairs, and two additional faculty members who will serve two-year terms. The Director of the B.S. Program in Pharmaceutical Sciences will act as chair of the committee.

This committee will evaluate applications to the program. Applicants to the program must be received by May 1 for admission beginning in summer semester. Students would have completed 90 credit hours of the B.S. program at the time of application. For admission to the B.S./M.S. program a student must have completed 14 credit hours of PMCY prefixed courses (PMCY 3000, PMCY 3200, PMCY 3300L, PMCY 3500, and PMCY 3800) with a grade of B- or higher; must have a cumulative GPA of at least 3.2; and must have a grade of C or higher in all Math, English, and Science courses. The applicant must submit a GRE score. The applicant must submit three letters of recommendation. In addition, the applicant student must provide an essay describing their interest in the B.S./M.S. degree program. The student must also designate either the Area of Emphasis in Regulatory Affairs or the Area of Emphasis in Pharmaceutical and Biomedical Sciences and identify potential thesis advisors.

Students admitted to the program will be advised by the Director of the B.S. Program in Pharmaceutical Sciences. The Director currently advises a significant portion of the B.S. Program students. The Graduate Coordinators will be responsible for determining progress on thesis projects using the current thesis committee evaluation forms and will alert the other members of the B.S./M.S. program committee should any student be found to be making insufficient progress. The B.S./M.S. program committee will work in conjunction with the student's thesis committee in order to form a remediation plan for the student. Students in the B.S./M.S. program will adhere to the UGA Graduate School Continuous Enrollment Policy.

The main administrative contact for the program will be Michael Bartlett.

14. Assessment

Indicate the measures that will be taken to assess the effectiveness of the program and the learning outcomes of students enrolled.

The assessment of the program will be conducted by the College of Pharmacy Assessment Committee under the direction of the College of Pharmacy Assessment Officer. The results of the assessments annual evaluation will be reported to the Faculty Council and the B.S./M.S. Program Committee for their use in program development.

The learning outcomes of the program can be broadly distributed into five categories. The categories and their outcomes measurements are provided below.

1. Develop a broad knowledge of the pharmaceutical and related sciences and be able to integrate and apply this knowledge to identify and solve problems.
 - a. Demonstrate a basic understanding of chemistry, biology, physics, statistics, and mathematics relevant to the pharmaceutical sciences
 - b. Demonstrate an understanding of physiology, pharmacology, pharmaceutics, pharmaceutical analysis, medicinal chemistry, and drug development.
 - c. Demonstrate the ability to solve problems by integrating multi-disciplinary scientific knowledge.
 - d. Develop a wide range of technical skills in various laboratory techniques.

Outcome Measurement: Students will complete CHEM, BIOL, PHYS, MATH, and PMCY courses with grades of "B-" (2.7) or better. Problem solving skills will be developed through the use of integrative problem sets and creative projects in the various pharmaceutical sciences courses. Technical skills are developed in PMCY 3300L, PMCY 4500-4500L, PMCY 4510-4510L, PMCY 4960 and PMCY 4970 and other science-based laboratory coursework. These courses will be completed with grades of B- (2.7) or greater. Advanced knowledge is obtained through the area of emphasis-specific graduate level courses which will all be completed with grades of B (3.0) or greater.

2. An understanding of drug discovery and development
 - a. Demonstrate a comprehensive understanding of the key stages in drug discovery and development.
 - b. Demonstrate an ability to relate applicable scientific disciplines to each stage of drug discovery and development.
 - c. Identify the legal and regulatory issues that affect: (1) development, (2) conduct of research studies used in each phase of drug product development, and (3) post marketing surveillance of drug products.
 - d. Identify questions addressed by research studies used in each phase of drug product development and the decision-makers who use this information.
 - e. Synthesize this information to create a preliminary drug development research plan for all phases of a new compound's life cycle.
 - f. Identify the potential roles of B.S. Pharmaceutical Sciences graduates in drug discovery and development.

Outcome Measurement: Students will pass PMCY 4500-4500L, PMCY 4510-4510L with a grade of B- or better. This objective will also be addressed through the area of emphasis-specific graduate level courses,

including PMCY 8200 (Departmental Seminar). The graduate-level courses will all be completed with grades of B (3.0) or greater.

3. Effective written and oral communication skills
 - a. Demonstrate proficiency in technical writing and presentations
 - b. Demonstrate knowledge and proficiency with current audio-visual presentation technologies.
 - c. Demonstrate an ability to communicate scientific knowledge in non-expert terms.
 - d. Develop examples of scientific communications (e.g., abstracts, manuscripts, reports, posters).
 - e. Demonstrate an ability to critically and constructively evaluate the presentations of others.

Outcome Measurement: Students will pass ENGL 3590W with a grade of B- (2.7) or better. Presentations of final project in poster and oral format will occur at a research day at the end of PMCY 4510-4510L. Successful completion of the final project in PMCY 4510-4510L will be a requirement to pass this course. Finally, successful completion of research hours will involve presentations, both oral and written, at group meetings. Involvement in technical writing and critical review of data is expected during the research courses (PMCY 4960 and PMCY 4970). Students will gain additional experience by participating in a departmental seminar. Writing and oral communications are a significant part of the completion of the thesis project. Additionally, presentations at scientific meetings are highly desirable.

4. An ability to contribute in various roles on effective teams to solve problems
 - a. Demonstrate an understanding of the interconnection between the scientific, clinical, and filing processes that constitute the backbone of pharmaceutical development.
 - b. Demonstrate a general understanding of how different areas of expertise must come together in order to discover and develop pharmaceutical products at the level of multi-participant collaboration.
 - c. Demonstrate an ability to engage in productive professional/technical interactions with others and be able to actively and skillfully participate in team-based projects related to pharmaceutical development.
 - d. Develop interpersonal skills such as negotiating and working with others, conflict management, and leadership skills.

Outcome Measurement: Student will pass ENGL 3590W, PMCY 4500-4500L and PMCY 4510-4510L with a grade of B- (2.7) or better. Laboratory portion of this course will have team projects which will simulate the scale of the typical drug development process. Throughout the year speakers from both industry and the government will deliver lectures and answer questions concerning specialized topics in drug development.

5. Demonstrate ethical, social and scientifically responsible conduct
 - a. Demonstrate awareness of cultural and social diversity through interactions with others.
 - b. Demonstrate a sense of self, community, and citizenship.
 - c. Demonstrate sensitivity to personal values and ethical principles in professional and social contexts.
 - d. Develop an understanding of social, economic, and professional responsibilities of the pharmaceutical industry.
 - e. Demonstrate the ability to conduct scientific research with the highest level of integrity.

Outcome Measurement: Students will satisfy some of these objectives by meeting the cultural diversity, environmental, and history/government requirements to complete undergraduate degrees from UGA. However, the program will expand and continue to improve these objectives by developing professional interactions with faculty, classmates, and working professionals in the field. In addition, all students in the program will be required to take a PMCY 5200, Ethics in Biomedical Research.

15. Fiscal and enrollment impact and estimated budget

Indicate any fiscal impacts on each supporting degree program. If a dual degree program is with another University System institution, are there any negative fiscal impacts on the University of Georgia?

In the case of each M.S. area of emphasis, the B.S. program in Pharmaceutical Sciences provides the ideal foundation for success. We anticipate an annual class size of 10 students. However, based on the number of sophomore declared majors (40) and freshman (140), this estimate is likely conservative.

With the recently completed facilities for the B.S. program there is adequate existing space to accommodate this program. However, there will be additional resources needed for administratively handling the increase in our graduate program numbers. These students will need more specialized advising and they also will increase general use of the research infrastructure of the department, and thus there will likely be an increase in maintenance costs for common equipment.

Our expectation is that these resources will be provided through the increased credit hour generation from this program. Using a conservative number of students (10 per year), the program would generate approximately \$192,000 from the credit hours.

In the third year this would represent an additional \$36,000 from the research hours taken during the summer semester. In the fourth year this would represent an additional \$66,000 since the students would move from undergraduate to graduate student status, and thus their credit hour reimbursement during the fall and spring increases from \$60,000 to \$90,000. Additionally, there would be another \$36,000 from the research hours generated during the summer. In the fifth year the students each take 30 credit hours and thus generate an additional \$90,000 in credit hour production.

| Year in Program | Credit Hours | Additional Funding |
|-----------------|--------------|--------------------|
| 3 rd | 120 | \$ 36,000 |
| 4 th | 420 | \$ 66,000 |
| 5 th | 300 | \$ 90,000 |
| Total | 840 | \$192,000 |

All three programs are prepared for increased enrollments. Initially, we do not anticipate more than 10 students entering per year. The enrollment for the B.S. in Pharmaceutical Sciences for fall 2015 is 20 majors beginning the junior year (up from 10 in fall 2014). Based on the enrollment numbers for the freshman and sophomore years, we expect that the number of majors will continue to climb and reach at least 50 per year. We anticipate half at most to have an interest in graduate school and less than that to meet the admission requirements or to have an interest in the B.S./M.S. program. Therefore, 20-25 students total per year is a very robust projection but would be easily accommodated by the current infrastructure of the programs.

Appendix A
Letters of Support

16 December 2010

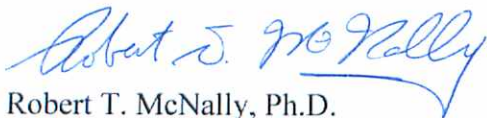
Re: Support for proposed degree B.S. in Pharmaceutical Sciences

As CEO of an HIV vaccine company, I find this to be a rather interesting concept for a nontraditional degree, but one with a particular focus which adds to its appeal. In my own career, my biomedical engineering degree, itself nontraditional, has served me well. When I led clinical research departments in the biotech industry, individuals with the B.S. degree in Biomedical Engineering were a perfect match for the job. Ideal candidates for this position required someone with the basic technical skills honed to a focus in medical products and systems who could understand the interaction of implantable products, run preclinical trials, converse with clinicians during regular trials, conduct research, and interpret the technical data. While early acceptance of this degree took time, the industry gradually recognized the field to where now, in some engineering degree programs, Biomedical Engineering is first or second in engineering discipline enrollment. I imagine a B.S. degree in Pharmaceutical Sciences would take much the same course as it matures into a recognized degree.

From an industry perspective, to offer such a degree program is both logical and attractive. With the complexity of drug development, whether in the oral or vaccine category, industry requires a multitude of disciplines, the full degree program for leadership and research expertise combined with bachelor level degrees fulfilling the work required to run the routine experiments. Until this degree becomes available, science majors had generic backgrounds, which required training to focus a small subset of the generic degree to developing drugs. Then, there are the facets of the job that the science bachelor degree does not address. Topics such as regulatory affairs and quality are integral to the job, but never included in traditional degree curriculums, for the very good reason that these programs are designed to be generic and not specific for a particular job function such as pharmaceutical drug development. The proposed curriculum goes further by including didactic training specific for the degree to include: membranes and organ systems, pharmaceutical science, technique and analysis.

My support for this degree grows as I explore its potential as a useful degree supporting the medical industry in Georgia. One of scientific objectives for the state is vaccine development. This coupled with the assorted medical products round out a vibrant industry for the state. Solvay (now Abbott), Merial, Ciba Vision (Novartis), Dendreon, Shionogi (formerly Sciele and recently moved), McKesson, Kimberly Clark, Bard, Porex, CryoLife, Immucor, and UCB Pharma form the major companies. These together with a list of much smaller companies, employ over 10,000 people in the state. Not included in this count are the numerous employees at area research universities and the CDC. Therefore, I believe UGA is proposing a very useful degree.

Sincerely,



Robert T. McNally, Ph.D.
President and CEO
GeoVax Labs, Inc.



January 11, 2011

Michael G. Bartlett, Ph.D.
Professor

Department of Pharmaceutical and Biomedical Sciences College of Pharmacy University of Georgia
Athens, GA 30602-2352
PH - (706) 542-5390
FAX - (706) 542-5358
bartlett@rx.uga.edu

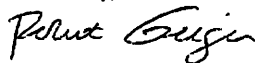
Dear Sir/Madam:

It is my pleasure to write a letter in support of BS in Pharmaceutical Sciences being submitted to the University of Georgia. For the last thirteen years of my career, I have worked in quality for Chemical and Pharmaceutical companies. We have always had a challenge hiring new graduates for our quality divisions. The challenge we face is the lack of knowledge or hands on experience with quality and regulatory guidelines. My companies have invested thousands of dollars training chemists/ biologists/ engineers in the area of quality. If the University of Georgia is able to implement this new BS program, this will save companies many hours and dollars in training. This program will also allow graduates advancement into higher level positions with Chemical, Pharmaceutical, and Biotech companies.

The biggest challenge my current company faces is adding new employees in the area of Quality/Regulatory. We recently filled an opening for Director of Quality/Regulatory after 8 months of extensive interviews. We hope that the University of Georgia is able to develop and implement this new program. We look forward to hiring future graduates from the University of Georgia.

In conclusion, I fully support the efforts of Dr. Bartlett to implement this program designed to train and educate students in all aspects of the Pharmaceutical Sciences. Any programs that can help our workforce make better decisions during the drug development process will benefit patients, doctors, and the community at large.

Sincerely,



Robert Geiger, Ph.D., MBA
Vice President of Quality
AmbioPharm, Inc.

GEORGIA BIO™
The Life Sciences Partnership

January 24, 2011

Michael G. Bartlett
Professor
Department of Pharmaceutical and Biomedical Sciences
College of Pharmacy
University of Georgia
Athens, GA 30602-2352

Dear Dr. Bartlett:

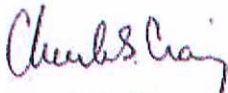
This letter is in support of the new Bachelors Degree program in the Pharmaceutical Sciences that is being proposed by the University Of Georgia's College Of Pharmacy.

We have reviewed the curriculum, and feel that the degree will provide students with a strong background in the basic biosciences, combined with a thorough understanding of the drug development process and regulatory environment. The inclusion of a one-year research experience, along with cGMP training in a working facility, will provide students with a unique background for entering the workforce or for continuing their post-graduate education. We have reviewed this curriculum with several of our pharmaceutical executives, and they enthusiastically endorse the curriculum.

Pharmaceutical sciences are important to Georgia's economy. According to "Shaping Infinity 2009", our annual industry survey, Georgia's pharmaceutical and medicine manufacturing companies provide 3,262 jobs and close to \$300 million in wages (21.5 percent and 30.4 percent of the life sciences industry total. Cancer, infections, and neurological conditions are the most commonly cited targets for pharmaceutical, biopharmaceutical, and diagnostic firms. Biologics companies identified therapeutics, blood, vaccines, cell cultures, and research materials as their main products. The product pipeline to the FDA is fairly well stocked, which is likely to result in more marketed products in the coming years.

We look forward to these graduates entering the workforce and helping to meet the needs of Georgia's bioscience firms in the future.

Sincerely,



Charles S. Craig
President
Georgia Bio
404-920-2043
charles.craig@gabio.org

R. EDWARD PERKINS
1250 COVENTRY ROAD
WATKINSVILLE, GEORGIA 30677

January 31, 2011

Dr. Michael G. Bartlett, Professor
Department of Pharmaceutical and Biomedical Sciences
College of Pharmacy
University of Georgia
Athens, GA 30602-2352

Re: University of Georgia Proposed BS in Pharmaceutical Science

Dr. Bartlett,

I am writing to endorse establishing a Bachelor of Science degree program in Pharmaceutical Science at the University of Georgia. As President of a pharmaceutical division of Johnson and Johnson, a member of the Board of Directors of the Georgia Medical Center Authority, and a participant in various economic development efforts at the local and state levels, I see the value of the program and the void it would help to fill.

The development of pharmaceutical products is a unique balance of science, medicine, interaction with regulatory agencies, and organizational dynamics. The average compound takes over ten years from discovery to market and a cumulative investment of \$700 million to \$1 billion dollars. Where we used to see 80% of compounds in Phase 3 ultimately reach the market that number has fallen to under 50%. Professionals are needed to work in and improve this process who not only understand the traditional sciences (chemistry, biology, etc) but understand the development procedures, clinical trial development, and regulatory issues unique to our industry.

Georgia has a key economic development strategy to attract life science companies and to aggressively support life science startup companies spun off from our research universities. The proposed Pharmaceutical Science major will enhance our efforts by providing trained employees for target companies and resources to support the home grown start ups.

I applaud the initiative to establish the Pharmaceutical Science curriculum and would be happy to assist in any way that I can.

A handwritten signature in black ink, appearing to read 'R. E. Perkins', with a long horizontal flourish extending to the right.

R. E Perkins
President, Noramco of Johnson & Johnson, retired
Board of Directors, Georgia Medical Center Authority
Board of Directors, Georgia Bio



1300 Gould Drive
Gainesville, GA 30504
T (770) 534 8239 F (770) 534 8247

February 9, 2011

Michael G. Bartlett, PhD, Professor
Department of Pharmaceutical and Biomedical Sciences
College of Pharmacy, University of Georgia

Dear Dr. Bartlett:

I appreciate the opportunity to review the proposed Bachelors Degree program in Pharmaceutical Science which is being considered by the College of Pharmacy.

The Pharmaceutical Industry, especially in the Southeast Region and most notably the State of Georgia would undoubtedly benefit from the program you have proposed. As you are well aware, the metro Atlanta and surrounding areas, has yet to achieve or sustain a significant representation of the Pharmaceutical Industry. This fact stands as a stark contrast to the availability of a world class transportation system, affordable and economical business atmosphere and ready access to Universities and Medical facilities of significant reputation.

It is worth noting that within the past seven years the number of Schools of Pharmacy in Georgia has increased from two to four. Although most of those graduates will find ready employment in the more traditional Pharmacy settings, it is reasonable to expect that as the region is exposed to a greater number of the specialized disciplines represented by professionals who teach programs of the type you have proposed these programs (Pharmacology, Pharmacokinetics, Pharmaceutics, etc.) along with the research grants and programs supported by these institutions can only increase the awareness, capability and availability of professionals to the Atlanta and surrounding areas whom would be available to support business interests moving to the area.

The Pharmaceutical Science program you have proposed can only serve to enhance the interest and availability of graduates who could also lend support to business plans for the area. It is not hard to envision that a program of this design when added to the other curriculums offered by UGA (Doctorate of Pharmacy, Masters in Regulatory Affairs and the Doctorate program in Pharmaceutical Science), could easily help bring a critical mass of students and activities to the University and add to the building blocks and support UGA's drive to become a multi dimensioned center of excellence for these fields of study. One only need to look toward programs such as at the University of Maryland and its recognized center of excellence in Pharmacokinetics (supporting FDA) to realize the possibility of relationships with the leading medical institutions in the area.

I commend your efforts to start this program and as I have supported the Masters in Regulatory Affairs program I offer my support to this program as you go forward.

Sincerely,



Roger Wayne Wiley, R.Ph.
Sr. Director, Regulatory Affairs
Elan Drug Delivery, Inc.

John E. Nine
11134 Estancia Way
Carmel, IN 46032
317-705-0641 Phone
317-705-0642 FAX

Michael G Bartlett
Professor
Department of Pharmaceutical and Biomedical Sciences
College of Pharmacy
The University of Georgia
Athens, GA 30602-2352

Dear Dr Bartlett,

The process of developing a BSPS Course of study in the Pharmaceutical Sciences Program at The University of Georgia College of Pharmacy will fill an unmet need the State of Georgia.

The latest year of 2010 Graduates in the BSPS Program at the College of Pharmacy at Purdue University is similar to last year to the past 3 years. The program have about 10 to 20 students each year.

The graduates this past year were offered Employment Offers as follows:

| | |
|----------------------|----|
| Graduates | 11 |
| Continuing Education | 6 |
| Employment | 3 |
| Interviewing | 2 |

Industry Salary: \$56,000 to \$61,000

The BSPS Program is significant in developing students who plan to continue for their PhD in Research.

The BSPS Program provides to develop a critical unmet need in the State of Georgia.

Sincerely,



John E Nine
Pharmacy 1963
Purdue University
Schering Plough Retired

February 19, 2011

Dr. Michael G. Bartlett
Department of Pharmaceutical and Biomedical Sciences
College of Pharmacy
University of Georgia
Athens, GA 30602-2342

Dear Dr. Bartlett,

I have reviewed the proposed B.S. Program in Pharmaceutical Sciences at the University. I sincerely believe this kind of program is very much needed to train students in the science of drug development and registration.

Currently, about the only way to get this knowledge is hands-on experience, and this program will certainly provide an excellent foundation for the students. I am certain that this will be embraced by the Pharmaceutical Industry as well.

As former Head of Animal Health and Pharmaceutical Research and Development, first at Merck, then at Merial, and now Chief Scientific Officer and Executive VP of Animal and Human Health at TyraTech, I can assure you I will be following this program with big expectations.

Please let know if I can be of assistance in your program.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Kevin T. Schultz', with a stylized flourish at the end.

Kevin T. Schultz, DVM, PhD

Jason Zastre, Ph.D.
Assistant Professor
College of Pharmacy
Department of Pharmaceutical & Biomedical Sciences
University of Georgia
Room 222 / Lab 202

February 24, 2011

Dear Jason,

I have reviewed the proposed educational program in Pharmaceutical Sciences and hereby confirm that Novartis supports this initiative. Indeed, the proposed training program is deemed very relevant for students who would aspire to have a career in health care industry and in particular at Novartis. I believe the program covers all key areas that are required and meets our expectations.

Regards,



Franck Leveiller, Ph.D.
Global VP & Head
Research & Development



February 18, 2011

Dr. Michael G. Bartlett
Professor
Department of Pharmaceutical and Biomedical Sciences
250 West Green Street
College of Pharmacy
University of Georgia
Athens, GA 30602-2352

Dear Dr. Bartlett,

Thank you for contacting me in regards to the initiation of a curriculum at the University of Georgia for an undergraduate degree in Pharmaceutical Sciences. As we discussed, I was closely involved in the development of a similar program initiated approximately 12 years ago at Purdue University College of Pharmacy to confer a B.S. in Pharmaceutical Sciences (BSPS degree).

As a senior executive within the pharmaceutical industry, I recognized that there was an unmet need for technical employees, who were educated in the pharmaceutical sciences, to fill production and quality assurance support positions within our operations. Candidates with similar backgrounds were primarily PhD's and usually over-qualified for positions we were typically offering. The PharmD graduates had a strong background in pharmacology and very little education related to pharmaceuticals. Once the BSPS program was underway and producing graduates, we filled several of our technical and production management positions with these candidates. They immediately contributed to the operations and all have advanced rapidly through various career paths. In some cases, individuals went on to pursue advanced degrees in pharmaceuticals and were extremely successful, having had the solid undergraduate training in the subject.

A key aspect of the program was the mandatory inclusion of a summer internship in a pharmaceutical company or laboratory environment. Many of our permanent employees had been our interns prior to graduation. I believe there continues to be a need for this type of graduate within the pharmaceutical industry and I would support your internship program at the University of Georgia when you are successful at initiating this program.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mark W. Fitch".

Mark W. Fitch
Sr. V.P., Operations
Nycomed US Inc.
60 Baylis Rd.
Melville, NY 11747-0103
631-393-2306
mark.fitch@nycomedus.com



Georgia Institute of Technology
311 Ferst Drive, NW, Mail_Code: 0100
Ford Environmental Safety & Technology Building, Room L 1326
Atlanta, GA 30332-0100
O: 404-385-7372; C: 404-569-0670
Email: Shlevin@gatech.edu

February 25, 2011

Dr. Michael G. Bartlett, Professor
University of Georgia
Department of Pharmaceutical and Biomedical Sciences
College of Pharmacy
Athens, GA 30602-2352

Dear Professor Bartlett,

RE: Proposed Bachelor Degree Program in Pharmaceutical Sciences

I have reviewed the proposed program curriculum for your program in Pharmaceutical Sciences and offered suggestions to further enhance the course offerings. I strongly support the need for this new program as it helps assure a workforce educated in the industry required skills and aligns very nicely with a strategic priority of the State to build a vibrant life science industry in Georgia. A well trained scientific workforce is a critical element of the ecosystem needed to build a sustainable life science industry in Georgia.

I am currently engaged at ATDC as a manager and startup catalyst in helping GT faculty and other entrepreneurs across the State in forming and growing new bioscience companies. My past twenty-five years of experience in the global pharmaceutical, medical device and allied industries is perhaps more relevant to the importance of the course curriculum you are proposing. Therefore, I would like to share with you my experiences and the difficulties in Georgia of finding graduates with appropriate training relevant to the pharmaceutical industry.

I moved to Atlanta in 1991 as a founder and senior manager of CIBA Vision Ophthalmics, a start-up specialty ophthalmic pharmaceutical company. At that time, it was virtually impossible to find scientists in the local area that had a background of experiences and skills relevant to the pharmaceutical industry. While we could find excellent undergraduate and graduate educated students in the major science disciplines, we could not find job candidates that had industry-relevant practical experience. By relevant pharmaceutical industry experience, I mean knowing how to operate a laboratory under cGMPs, how to develop, characterize and develop a new drug formulation, how to scale bench formulations into a pilot or manufacturing facility, how to problem solve stability and other issues in pharmaceuticals, etc. Also, while excellent scientists, students from Georgia universities had minimal to no exposure to the drug discovery and development process. As a result, we found ourselves having to import experienced talent into the area to staff our science positions in pharmaceutical chemistry, formulations, characterization, quality assurance, pharmaceutical manufacturing, etc. This was extremely expensive and time consuming.

In 1996, I joined Solvay Pharmaceuticals as Sr. VP of R&D and Business Development and subsequently served as their CEO. At Solvay, we found ourselves having to deal with a nasty FDA compliance situation. The root cause of this problem was a long-standing lack of appropriate industry skills and

Enterprise Innovation Institute


A Unit of the University System of Georgia An Equal Employment Opportunity Institute

experience of our scientific staff. To address this situation, we had to upgrade the quality of our scientific staff particularly in the areas of pharmaceutical sciences, quality assurance and regulatory affairs. Thanks largely to efforts to improve work-force development in life sciences, such as those at UGAs extension division of the School of Pharmacy and some educational efforts that Solvay and UCB undertook with Kennesaw State, the pool of available talent and their industry knowledge base was better than when I moved to Georgia in 1991. However, there was still a need for further improvement in the practical and industry-specific skills available in recent undergraduate students looking for entry level jobs.

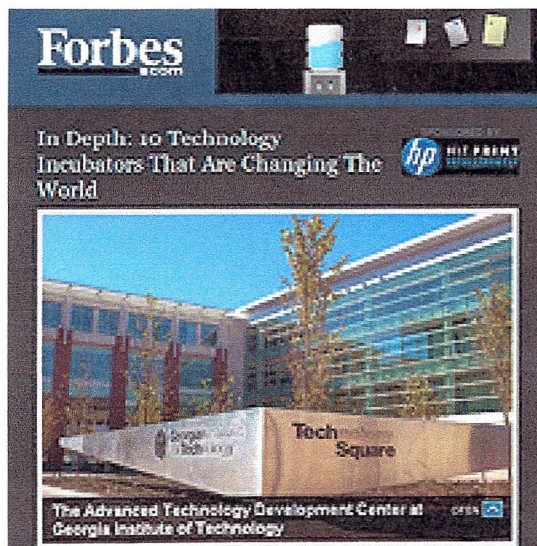
I believe your new program will fill an unmet need in providing a pool of talent which will be of value to the life science industry here and across the nation. In many respects, the program is somewhat similar to and builds upon the program at Purdue. The Purdue program has proven highly successful in supplying students well positioned with practical experience and knowledge for careers in the industry and many graduates of Purdue's program have become senior leaders in the industry. I would expect successful graduates of your new program to be offered similar career opportunities.

I applaud your efforts to build this new program into your curriculum and would be glad to help in any ways that would be helpful.

Sincerely yours,



Harold H. Shlevin, PhD
Manager & StartUp Catalyst
Advanced Technology Development Center – Biosciences
Georgia Institute of Technology



Appendix B
Programs of Study

Appendix B

Typical Program of Study for an Area of Emphasis in Regulatory Affairs

| | |
|--|--|
| <p>First Year Fall</p> <p>ENGL 1101 – English Composition I CHEM 1211 – Freshman Chemistry I CHEM 1211L – Freshman Chemistry Lab I MATH 2250 – Calculus I for Science and Eng. FYOS 1001 – First-Year Odyssey Seminar Area IV or V Elective</p> | <p>First Year Spring</p> <p>ENGL 1102 – English Composition II CHEM 1212 – Freshman Chemistry II CHEM1212L – Freshman Chemistry Lab II PHYS1211/L – Principles of Physics Sci. and Eng. COMM 1100 – Introduction to Public Speaking</p> |
| <p>Second Year Fall</p> <p>CHEM 2211 – Modern Organic Chemistry I CHEM 2211L – Modern Organic Chemistry Lab I BIOL 1107 – Principles of Biology I BIOL 1107L – Principles of Biology Lab I Area IV or V Elective Area IV or V Elective</p> | <p>Second Year Spring</p> <p>CHEM 2212 – Modern Organic Chemistry II CHEM 2212L – Modern Organic Chemistry Lab II STAT 2000 – Introductory Statistics Area IV or V Elective Area IV or V Elective Area IV or V Elective</p> |
| <p>Third Year Fall</p> <p>BCMB 3100 – Intro. Biochem. and Mol. Biology PMCY 3000 – Human Physiology MATH 2260 – Calculus II for Science and Eng. ENGL 3590W – Technical and Professional Comm.</p> | <p>Third Year Spring</p> <p>PMCY 3200 – Intro. to the Pharmaceutical Sci. PMCY 3300L – Pharmaceutical Techniques PMCY 3500 – Pharmaceutical Analysis PMCY 3800 – Introduction to Pharmacology BCMB 3600 – Bioinformatics and Genomics</p> |
| <p>Summer Third Year</p> <p>PHRM 7000 – Master’s Research</p> | |
| <p>Fourth Year Fall</p> <p>PHRM 8200 – PBS Seminar PMCY 4500/L – Drug Development I PMCY 4200 – Pharmaceutical Sciences II PMCY 4960 – Pharmaceutical Sci. Research I PHAR 5100 - Biostatistics PMCY 4010 – Intro. to Pharmaceutical, Biotechnology and Devices Industries</p> | <p>Fourth Year Spring</p> <p>PHRM 8200 – PBS Seminar PMCY 4510/L – Drug Development II PMCY 4300 – Medicinal Chemistry PMCY 4970 – Pharmaceutical Sci. Research II PMCY 5200 – Ethics in Research General Elective</p> |
| <p>Summer Fourth Year</p> <p>PHRM 7000 – Master’s Research</p> | |
| <p>Fifth Year Fall</p> <p>PHRM 8200 – PBS Seminar PHAR 6030 – Cur. Good Manufacturing Practices PHAR 6100 – Quality Control and Assurance PHAR 7000 – Master’s Research</p> | <p>Fifth Year Spring</p> <p>PHRM 8200 – PBS Seminar PHAR 6020 – Food and Drug Law PHAR 6120 – Process Control and Validation PHAR 7000 – Master’s Research PHAR 7300 – Master’s Thesis</p> |

Typical Program of Study for an Area of Emphasis in Pharmaceutical and Biomedical Sciences

| | |
|--|--|
| <p>First Year Fall</p> <p>ENGL 1101 – English Composition I CHEM 1211 – Freshman Chemistry I CHEM 1211L – Freshman Chemistry Lab I MATH 2250 – Calculus I for Science and Eng. FYOS 1001 – First Year Odyssey Seminar Area IV or V Elective</p> | <p>First Year Spring</p> <p>ENGL 1102 – English Composition II CHEM 1212 – Freshman Chemistry II CHEM1212L – Freshman Chemistry Lab II PHYS1211/L – Principles of Physics Sci. and Eng. COMM 1100 – Introduction to Public Speaking</p> |
| <p>Second Year Fall</p> <p>CHEM 2211 – Modern Organic Chemistry I CHEM 2211L – Modern Organic Chemistry Lab I BIOL 1107 – Principles of Biology I BIOL 1107L – Principles of Biology Lab I Area IV or V Elective Area IV or V Elective Area IV or V Elective</p> | <p>Second Year Spring</p> <p>CHEM 2212 – Modern Organic Chemistry II CHEM 2212L – Modern Organic Chemistry Lab II STAT 2000 – Introductory Statistics Area IV or V Elective Area IV or V Elective Area IV or V Elective</p> |
| <p>Third Year Fall</p> <p>BCMB 3100 – Intro. Biochem. and Mol. Biology PMCY 3000 – Human Physiology MATH 2260 – Calculus II for Science and Eng. ENGL 3590W – Technical and Professional Comm.</p> | <p>Third Year Spring</p> <p>PMCY 3200 – Intro. to the Pharmaceutical Sci. PMCY 3300L – Pharmaceutical Techniques PMCY 3500 – Pharmaceutical Analysis PMCY 3800 – Introduction to Pharmacology BCMB 3600 – Bioinformatics and Genomics</p> |
| <p>Summer Third Year</p> <p>PHRM 7000 – Master’s Research</p> | |
| <p>Fourth Year Fall</p> <p>PHRM 8200 – PBS Seminar PMCY 4500/L – Drug Development I PMCY 4200 – Pharmaceutical Sciences II PMCY 4960 – Pharmaceutical Sci. Research I PMCY 5100 – Biostatistics Major Elective</p> | <p>Fourth Year Spring</p> <p>PHRM 8200 – PBS Seminar PMCY 4510/L – Drug Development II PMCY 4300 – Medicinal Chemistry PMCY 4970 – Pharmaceutical Sci. Research II PMCY 5200 – Ethics in Research General Elective</p> |
| <p>Summer Fourth Year</p> <p>PHRM 7000 – Master’s Research</p> | |
| <p>Fifth Year Fall</p> <p>PHRM 8200 – PBS Seminar PHRM 8020 – Fund. of Pharm. Biomed. Sci. I PHRM 8040 – Techniques Pharm. Biomed. Sci. I PHRM 7000 – Master’s Research</p> | <p>Fifth Year Spring</p> <p>PHRM 8200 – PBS Seminar PHRM 8030 – Fund. Of Pharm. Biomed. Sci. II PHRM 8050 – Techniques Pharm. Biomed. Sci. II PHRM 7000 – Master’s Research PHRM 7300 – Master’s Thesis</p> |