SCHOOL OF PHARMACY
UNIVERSITY of WASHINGTON
Office of the Dean

April 1, 2010

David Canfield-Budde, PhD
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University of Washington
G-1 Communications, Box 353770
Seattle, WA 98195

RE: Response to the School of Pharmacy Graduate Program Review Committee Report of February 24, 2010

Dear Dr. Canfield-Budde,

First, the School would like to thank the members of the Graduate Program Review Committee and the staff from the Graduate School for their time and effort in arranging and carrying out the review of our programs. Our faculty, staff, and students recognize that the review process provides useful information and important recommendations to improve our graduate programs.

The report was circulated and widely discussed among our faculty. Comments to the Committee's recommendations are in the attached document. We agree with the general assessment that the programs are of high-quality and well-positioned to use their strengths to enhance the School's stature, despite meager state resources. The faculty, staff and students were encouraged by the positive tone of the review, and look forward to working with the University administration to make the improvements suggested to ensure continued success in our graduate training and research missions.

Again, we thank all involved with the process.

Sincerely,

Thomas A. Baillie, PhD, DSc
Dean

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SCHOOL OF PHARMACY

UNIVERSITY *of* WASHINGTON

Thomas A. Baillie, Dean

Graduate Program Review Committee Report Response

April 1, 2010

The School of Pharmacy would like to thank the members of the Graduate Program Review Committee for their candid and thoughtful comments for improving the School's Graduate Degree programs. In general, we concur with most of the Committee's comments and this response to the Committee's report is provided to clarify a few areas and to briefly demonstrate the progress the School has made in incorporating many of their recommendations. The comments in italics are from the Review document.

School-wide Recommendations Response

Institute a School-wide — and more formal — structure to develop, administer and review graduate training programs and to recruit the best students to all Programs.

We have built on the existing departmental graduate training structures to appoint a new standing committee of the School — the Graduate Programs Steering Committee. Members will be the four Directors of Graduate Studies; one from each degree program. The title "Director" is a change from the previous "Coordinator" title and is designed to recognize the increased responsibility of these faculty members and of the Committee. Within each degree program, the Directors of Graduate Studies will continue to guide the graduate students' initial work at the School. In addition to maintaining familiarity with policies and procedures of the Graduate School and providing overall coordination of graduate activities within the unit, the Directors, as members of the Graduate Programs Steering Committee, will serve an oversight and coordinating function for the School's graduate programs.

The charge of the Committee is to meet at least quarterly to 1) identify areas of commonality and best practices from both within and external to the programs, 2) provide suggestions to the Departments and the Dean for improving graduate degree programs, especially in identifying and coordinating shared solutions and opportunities, 3) identify problematic issues within the programs and an agenda to explore their resolution, and 4) make recommendations to the Dean and Faculty as appropriate. The Committee will provide a very brief written report to the Dean and Faculty yearly, outlining the progress made over the previous year in improving graduate education within the School.

Develop better communication of critical information across all Program students, faculty and staff.

We believe our new web site, scheduled to go live this Autumn, will provide a clearer and more accessible "public face" for our stake-holders — in particular existing and prospective students. Over the coming months, our Graduate Programs Steering Committee will consolidate the Student Handbooks where possible and will ensure that program specific and timely "Fact Sheets" or "FAQs" are developed and easily accessed from the web site. Each program will develop or refine and focus its annual orientation of students to ensure appropriate policies and procedures are revisited.

The introduction of School-wide graduate student seminars and social gatherings will be explored. We have discussed the possibility of organizing a quarterly seminar, jointly attended by all graduate students, on a topic co-presented by faculty from each program (e.g., warfarin therapy, pharmacogenetics and cost-effectiveness issues).

Integrate curricula across programs and continuously assess student progress.

Individual Directors of Graduate Studies, along with their Chairs, will lead each department in discussions to ensure that their curricula remain streamlined and modern. Medicinal Chemistry is already actively undergoing a major review of their curriculum. The issue of the timing of General Exams and co-existing "pre-proposal," "MS bypass," and "pre-general" assessments to assure efficient progression will be considered by the Directors, and recommendations will be shared with the Chairs and Faculty for

action. There is broad agreement that a reasonable target for completion of the General Exam is before the end of the first quarter of the 4th year in each doctoral degree program.

Institute an acceptable biomedical research integrity/ethics training program for all students in the School.

Again, we are in general agreement with this suggestion. We are exploring a relevant mix of training formats and are considering adding the five areas of the NIH core biomedical research integrity/ethics presentations, perhaps along with supporting discussion sessions tailored to our students.

Use standard mechanisms to evaluate teaching effectiveness.

The Graduate Programs Steering Committee will recommend a consistent process for gathering quantitative and free-form course level feedback using standard University processes.

Develop common Program- and School-wide activities focused on recruiting.

Our initial evaluation of this recommendation is that our four programs are sufficiently different that a major opportunity for a single recruiting day does not exist; it would not provide the best venue for highlighting the uniqueness of each of our programs. Nevertheless, the Graduate Programs Steering Committee will continue to explore opportunities to develop and share resources. For example, all programs plan to join efforts to facilitate the recruitment of minority candidates, and will consider developing a recruiting brochure highlighting our graduate programs to be distributed at meetings and conferences.

Leverage existing space and opportunities.

We strongly agree with this suggestion. It is clear that program growth is hampered because of space limitations. We are exploring options for generating synergies with programs and departments who share research interests. With the support of the University Administration, we have secured additional space in the South Campus Center close to the School's H-Wing offices and laboratories, that will bring some School faculty closer to their colleagues and save the School funds that were going to rent. However, this will be a temporary solution and we look forward to working with the University Administration on longer-term plans.

Department of Medicinal Chemistry Response

Institute a school-wide structure to develop, administer and review graduate training programs and to recruit the best students.

As indicated above, we have instituted a School-wide Graduate Programs Steering Committee consisting of the Directors of Graduate Studies from each department to explore ways to enhance cross-School consistency in graduate program administration. William Atkins has been appointed the Director of Graduate Studies for the Department of Medicinal Chemistry.

Develop better communication of critical information.

In Medicinal Chemistry, a meeting has already been scheduled in which the Chair and Director of Graduate Studies will meet with all students in the program to solicit suggestions, and to clarify administrative and curricular issues, and degree requirements as they currently stand. The Student Handbook will be updated with additional information concerning institutional policies about leave, vacation, etc., and the handbook will be made accessible on the departmental web page. The annual written evaluations/reappointment procedure will continue and we will consider ways to emphasize

specific milestones to be achieved for each student in the written reports. Each advisor will be expected to discuss the report with his or her students.

Integrate Curricula.

The Department of Medicinal Chemistry will undergo further review of its curriculum with the explicit goal of streamlining the didactic courses so that core courses and electives will be completed earlier. Possible changes include a reduction in the number of quarters of MEDCH 501–503 required, as well as reduction of the pharmacology requirement. The Department will also explore the best way to ensure that the General Exam is completed before the end of the first quarter of the 4th year.

Teaching Evaluations.

The Department of Medicinal Chemistry, which has historically used in-house customized course evaluations for its graduate courses, will begin to use either the existing university evaluation forms adapted to best serve our program, or a School designed evaluation that is standardized across programs as much as possible. We aim to make the change effective Autumn 2010.

Department of Pharmaceutics Response

A more formal structure for administering the graduate program, such as appointing a Director of Graduate Admissions and a Director of Graduate Studies, might be advantageous.

The current Graduate Program Coordinator and the Graduate Program Assistant oversee the program on a day-to-day basis. Though these positions were transitioned to new individuals in the last two years, they have been able to substantially improve graduate student recruitment and admissions. They are in the process of setting up a new system to assess academic progress. The Pharmaceutics Graduate Admissions Committee consists of the Chair, the Director of Graduate Studies, and another mid-career faculty member who rotates among other Department faculty. Yvonne Lin has been appointed the Director of Graduate Studies for the Department of Pharmaceutics.

A graduate student handbook detailing policies and procedures should be provided to each student when they enter the program; this information also should be available on the website.

The website is currently being updated and has a link for the Student Handbook. Our current Handbook details the requirements for the MS and PhD degrees, core classes and guidelines for progression. The Handbook is provided to students when they interview and also when they enter the program. Information regarding the content of each course is listed on the website.

We agree with the reviewers that we can improve communication. We intend to remind students about the policies, procedures and benefits at a yearly departmental meeting. Using our new system of assessing academic progress, students will receive regular feedback about their progress.

Current program requirements, including core coursework, required progression exams, and research requirements should be reviewed and pruned where appropriate to shorten time to degree. Students should be encouraged to take their general exam in their 3rd year to avoid delays in progression. Tracks within the program could be considered.

The average time-to-graduation (5.6 yrs) reported in the review includes all students in the program. By excluding one outlying student who took substantially longer to finish due to personal and family reasons, the average time-to-graduation is reduced 5.3 years. Moreover, the average time-to-graduation for the last five years was 5.0 years.

It is unclear who is responsible for curricular review and curricular change or whether there is student input into these processes.

As discussed on page 12 of the self-study document, a major departmental review of the Pharmaceutics doctoral program was conducted in 2006–07. The exercise included an internal review of the curriculum and the pace of doctoral research. It also included written input from graduates who had received their degree in the last 15 years, asking for a critical assessment of how relevant the existing coursework and thesis research was to the performance of their job since leaving graduate school. In addition, two graduate students served on the committee and made critical contributions to all aspects of the review; most importantly, they helped craft an alumni survey, analyzed the response data and formulated recommendations for change. We have subsequently streamlined the coursework and departmental requirements to allow students to progress at a more rapid pace to the PhD. As we have made these modifications in the last two years, it will be several more years until we can assess if these improvements decrease the time to graduation. A hallmark of our graduates is that they are cross-trained in several key areas: pharmacokinetics, drug metabolism and transporters. We disagree that curricular tracks would be beneficial to the program. This would narrow our students' training and reduce their career opportunities in academia and industry.

Due to the breadth of pharmaceutics, the research strengths of Departmental faculty, the shift towards translational research and projected future needs of the discipline, it may be logical for the Department to stay focused primarily on areas of current strength (drug metabolism and transporters, and mechanisms of drug-drug interactions), where significant synergy with Medicinal Chemistry exists.

We agree that the department should focus its instructional and research programs along areas of traditional strength, and we will continue to do so. However, we see also value in pursuing opportunities where new resources can be used to leverage support external to the School and broaden the scope of our instructional and research activities in ways that are fully compatible with our core mission. For example, we are working closely with the Department of Bioengineering to strengthen the areas of drug delivery and pharmacometrics as evidenced by research collaborations and a joint pharmacometrics faculty candidate search currently underway. This new direction for the department and School should integrate well with existing programs in drug metabolism and transport and drug-drug interactions in pharmaceutics, as well as disease based therapeutics programs in the Department of Pharmacy, providing an expanded foundation for translational pharmaceutical research within the School.

Department of Pharmacy Program in Pharmaceutical Outcomes Research and Policy Response

PhD in the Program in Pharmaceutical Outcomes Research and Policy

Develop a more formal structure for administering the graduate program, such as appointing a Director of Graduate Admissions and a Director of Graduate Studies.

David Veenstra has been appointed the Director of Graduate Studies for the Department of Pharmacy Program in Pharmaceutical Outcomes Research and Policy (PORPP).

Ensure equitable funding opportunities for all graduate students enrolled in the program, and communicate how funding decisions are reached.

We will reiterate our funding policy, which is stated in offer letters, to students during our in-person orientation session. Our standard policy is to guarantee funding for the first two years (RA support plus tuition for 3 quarters), although we have had to qualify these offers this year because of uncertainties in the state budget and availability of RA and TA slots. After the 2nd year, students are expected to identify and pursue funding in collaboration with faculty. We will also clarify that several industry-sponsored

research fellowships are available on a competitive basis that provide a greater level of support than a typical RA position.

Develop more internal courses and/or obtain formal agreements with the School of Public Health and other UW Schools for access to key courses; integrate content of non-Pharmacy courses with discussion of the applicability of that content to the School of Pharmacy and to outcomes research.

We have recently formed a Curriculum Revision Committee (Beth Devine, Chair). This committee will seek to identify key areas for development of additional PORPP courses such as health economics, advanced methods, and comparative effectiveness research. These courses will be developed in consultation with Health Services, and formal agreements with the School of Public Health for access to core courses will be sought.

To the extent possible within the curricular structure, provide more teaching assistant opportunities to students or provide access to a course on teaching methods.

We will propose at our next PORPP faculty meeting to require at least one quarter of TA-ship for all of our PhD students.

Continue to expand the program faculty, especially those with full-time appointments in the Department of Pharmacy. The program has several senior faculty nearing retirement, and it will be important to attract and retain highly-qualified individuals to contribute to the continued success of this graduate program.

We are moving forward to fill our current faculty vacancies, and have created a search committee (D. Veenstra, Chair) for our soon to be available Assistant Professor position, drafted a position announcement, and are in the process of receiving University approval for the advertisement. We are seeking individuals with expertise in comparative effectiveness research, including quantitative analysis of clinical trial or observational data, cost-effectiveness and value of information analysis, or quality of life research.

MS in the Program in Pharmaceutical Outcomes Research and Policy

The PORPP Masters program seems to have considerable potential for attracting more students from the UW PharmD program, since students can add a PORPP Masters with 4 additional quarters of study.

We recruit students for the PharmD/MS track-in program via three mechanisms: 1) an "Introduction to Pharmacoeconomics" course, 2) an "Introduction to Managed Care" course, and 3) support of an Academy of Managed Care Pharmacy (AMCP) student chapter. We have admitted one student to the PharmD/MS program this fall, and a physician oncology fellow from the Fred Hutchinson Cancer Research Center to the MS program.

Department of Pharmacy Master of Science in Biomedical Regulatory Affairs Response

There was a discrepancy between Table A and Appendix C: Table A lists 6 core faculty for the Master of Science in Biomedical Regulatory Affairs (MSBRA) program, whereas Appendix C lists only Drs. Hazlet and Feagin.

Dr. Feagin's time will increase to 75% Spring 2010. The discrepancy for core faculty is noted; all of the Appendix C Table A faculty are indeed "core."

The curriculum is modeled on a certificate program in biomedical regulatory affairs, but certification is not a required component of the program.

The MSBRA curriculum was developed locally with significant input from an expert panel from industry. The Regulatory Affairs Professional Society Certification (RAC) examination may be pursued by students, but certification is neither a requirement of the program, nor is the program designed to "teach" to the RAC. The content of the RAC examination does represent a convenient map for evaluating the completeness of our curriculum. Some confusion may have arisen from the "certificate" terminology referring to the Biomedical Regulatory Affairs and Clinical Trials certificate programs that also are core to the MSBRA program; these differ from the RAPS "certification".

The dependency on a fee-base operating budget requires at least 17 students per year to be enrolled in the program. It is unclear whether there will be sufficient demand for the program in subsequent years to ensure sustainability.

A central tenet of the fee-based programs offered through UW Education Outreach (UWEO) is that programs respond to demand — if demand is exhausted the program is terminated. All of the UWEO budgets make provision for orderly termination of programs as sufficient funds are identified to allow enrolled students to complete their programs. The BRA certificate program is in its eleventh year with no evident depletion of local interest. Query and application patterns for the Autumn 2010 cohort have shown significant interest from both domestic and international students.

Enrolled students noted that with the current economic downturn and the overall downsizing of the pharmaceutical industry, a number of experienced individuals are competing for jobs with forthcoming program graduates.

It is important to note that most of the Pacific Northwest jobs in regulatory affairs are with medical device rather than pharmaceutical manufacturers. Additionally, there is a deep pool of regulatory affairs professionals in the Seattle area, many of whom already teach in our courses.

During the first two years the program accepted almost all students who applied.

This pattern is typical of UWEO programs, but the report fails to acknowledge the Graduate School's and program's minimum requirements. With the experience of admitting two classes, and in the process of admitting the third, we are becoming more selective. For instance, we have increased our TOEFL requirement for international students to a minimum of 100 overall and 25 for "listening" while the Graduate School has an overall minimum of 92 (TOEFLiBT).

The burden of the program is being shouldered by one tenure track faculty member who reports spending 25% effort, and a senior lecturer with 50% effort.

Dr. Feagin's effort will increase to 75% in Spring Quarter 2010. The program budget makes provision for another 50% position, presently unfilled because the last recruiting effort yielded no adequate candidates. A suggestion has been made that the program develop a fellowship program in regulatory affairs as a means of "growing our own" and this and further recruitment options will be explored in 2010–2011.

Dr. Feagin stated that she has little experience in regulatory affairs, and relies on affiliate faculty to evaluate practicum proposals. It is unclear what mentoring is provided to students, especially for the practicum component of the program.

This comment from the Graduate Program Review Committee appears to reflect a misunderstanding. Dr. Feagin has substantial prior experience with biohazard and animal care regulations and holds Certificates from the UW Biomedical Regulatory Affairs and Clinical Trials programs.

The Biomedical Regulatory Affairs practicum provides a practical experience for students, allowing them to develop or expand skills in shepherding new medical products (drug, device and biologic) through regulatory, clinical, and quality assurance aspects. Students identify a site and preceptor, define a project, create a detailed work plan, and seek approval from Dr. Feagin before its implementation. The project must generate a written final report of high quality, to be submitted to program faculty, and students must present the project orally. Some practicums occur at the student's workplace, some at other sites. Students are encouraged to network to identify sites and projects which meet their needs; in addition, Dr. Feagin, who coordinates the practicum, contacts potential sites to solicit practicum projects, then forwards these opportunities to the students.

Dr. Feagin's role includes coordination of sites, following student progress, and ensuring academic integrity within the context of UW's intellectual property/public records constraints. She helps identify and develop practicum sites and projects, communicates regularly with students and preceptors; evaluates the brief proposal, work plan, progress reports, final report, and presentation; and facilitates problem resolution.

Mentoring for the practicum portion of the program is provided principally by the preceptor at the practicum site, plus his or her colleagues with whom the student may interface. Dr. Feagin's role in this aspect of practicum is oversight to assure that projects are of appropriate focus and scope, the site and preceptor are appropriate for the proposed project, and reasonable progress is maintained. Several independent "content experts" — highly experienced regulatory affairs professionals — are available for Dr. Feagin to consult when any questions arise.

Faculty selection, oversight and evaluation need to be better defined and continuous to ensure that the teaching faculty and topics are high quality and relevant.

Faculty selection, oversight and evaluation procedures are specified in the Department of Pharmacy's "Guidelines for Documents in Support of Merit Salary and/or Annual Review."

The Department Chair, UWEO Academic Programs Director and Program Director meet annually with each course master (whether school based academic faculty or affiliate faculty) to review the course and student comments, and to seek input for program improvements. Thomas Hazlet has been appointed the Director of Graduate Studies for the MSBRA program.

There is a concern that the needs of the MSBRA program may draw resources away from the PORPP graduate program. While there is a logical relationship between the programs in terms of faculty interests and issues, MS-level programs can be an incredible time-sink.

The budget for the MSBRA program provides for both administrative and faculty support, either through direct hires or offset, as well as rental office space. We were mindful of the "time-sink" issue for the faculty when the program was created, and have sufficient flexibility to make adjustments as necessary.

Practica are highly dependent on availability and access to pharmaceutical and medical technology companies in the Seattle area. Based on information provided during the Site Visit, there were not enough practicum sites for second year students.

Practicum sites are not pre-selected, for three reasons:

1. We want to match each student with a project that meets his or her goals and interests rather than defining projects to which they are limited.
2. Most of our students work full-time so we need to match the student with a site, preceptor, and project that can accommodate his or her availability, which cannot be predicted ahead of time.
3. The timing of projects in the medical products industry is subject to change, based on a number of factors. Availability of an appropriate project cannot be predicted well in advance.

The current second year cohort is the first class, hence the first to do practicums. All students from the cohort now have practicum sites. We expect that finding sites in future will be easier, as companies become familiar with the concept of practicum and the quality of our students. Consistent with this, we already have 13 sites interested in hosting a practicum for the second cohort and Dr. Feagin is contacting other potential sites.

Current students noted that regulation of devices is substantially different from pharmaceuticals, and some expressed frustration that the program and coursework were not highly relevant to their interests or needs. Two tracks could be created to allow the program to be better-tailored to student interests.

The program description and all introductory courses stress that the program focuses on both drugs and devices; we identify this as a unique program strength. We have no intention of creating separate drug and device tracks. With combination products becoming increasingly common, regulatory affairs professionals who are familiar with both drug and device regulation will be more effective and more valued than those with focused attention to just one aspect of the medical products industry.

Students expressed concern about the certification exam. Expectations for this exam were unclear, and need to be clearly stated in program materials.

Please see response above.

Dr. Feagin's office is in a separate building from Dr. Hazlet. These two faculty should be located in close proximity to facilitate effective communication and ensure consistent interaction between the two individuals administering this program.

The suggestion is appreciated. The physical separation is unfortunate but Dr. Hazlet's responsibilities require that he be located near other PORPP faculty and there is no appropriate office space available in the vicinity for Dr. Feagin.

In addition to maintaining frequent contact via phone and email, Drs. Feagin and Hazlet have recently begun holding regular meetings with Carol Hayes, the program coordinator; Eric Irvin, the MSBRA program administrator for UWEO, often attends as well. Although the situation is not optimal, it has not adversely impacted the program and we are focused on optimizing communication.

Develop more practicum sites to ensure that students have sufficient training opportunities. While western Washington is home to a number of practicum partners, many of these are start-up entities and may be sold, acquired, moved, or go out of business during a practicum. This may adversely affect students' ability to complete the program in a timely manner.

Companies that anticipate major changes in their organizations are unlikely to have accepted a student for practicum. However, we recognize this possibility and have a contingency plan in place to deal with it if necessary.

Only a handful of firms are listed on the program's website, and it is not clear how many students can be placed at these organizations. The number of practicum locations should be monitored closely, and enrollment should be adjusted accordingly to ensure the continued availability of practica for all students.

A list of companies that have hosted practicums will be added to the website this summer. Fifteen sites hosted students in the first cohort and we expect that finding sites in future will be easier, as companies become familiar with the concept of practicum and the quality of our students. Consistent with this, we already have 13 sites interested in hosting a practicum for the second cohort, and are following up additional possibilities.

Consider recruiting other faculty with experience in biomedical regulatory affairs. The program is thin on internal faculty with sufficient expertise in this area, and thus highly dependent on external faculty to provide a high quality learning experience. Moreover, changes in the industry such as mergers, lay-offs and relocation can affect the participation of affiliate faculty.

Few academic faculty have significant experience with regulatory affairs. Our reliance on affiliate faculty is a strength rather than a weakness for the program. These faculty are active regulatory affairs professionals and bring a wealth of experience and a keen understanding of the current regulations to their teaching. In a rapidly changing field like regulatory affairs, this offers the students a major advantage.

As noted elsewhere in this response, we will pursue several options for filling the vacant half-time position either through recruitment or the fellowship option.

Create more opportunities for 1st and 2nd year students in the program to meet and interact. Due to the structured curriculum it appears that students in the second year of the program have little interaction with students in their first year. Annual or semi–annual social events and/or seminars would be beneficial to all students. Second year students could pass down lessons learned, and help identify potential practicum sites and projects for 1st year students.

Several options within the MSBRA program and more broadly, for all School of Pharmacy graduate students are under consideration.

School of Pharmacy review of the MSBRA program in 3 years. Because this program is new it should be reviewed again by the School of Pharmacy in 3 years. This near-term review would provide a timely opportunity to identify and ameliorate persistent structural or operational problems that often accompany new degree programs.

External review of the MSBRA program in 5 years. A full external program review should be conducted within 5 years to measure progress towards addressing the above mentioned weaknesses; to determine if the program continues to be viable; and whether the program could be further expanded. This external review should critically evaluate all aspects of the program, while giving particular attention to program faculty, curricular development and availability of practica appropriate to the student body.

The MSBRA program was provisionally approved in 2007, with a scheduled UW Graduate School Council (not national) review in the 2012–2013 academic year. The MSBRA program requested inclusion in the School-wide graduate program review, and have already initiated several curricular changes coincident with, and resulting from, the school-wide review.

We propose to conduct a thorough internal (School of Pharmacy) review of the MSBRA program during the summer following graduation of the third cohort (2012). We believe that an external review of the program in 5 years would be both financially and operationally burdensome and does not appear justified. Rather, we respectfully propose that the next external review of the MSBRA program be during the 2019–2020 academic year, consistent with the 10-year cycle for full Graduate School program reviews.