Graduate Program Review Committee Report

University of Washington School of Pharmacy

8-9 February 2010

Review Committee:

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This Report approved and submitted by the Review Committee 24 February 2010.

1. Executive Summary: This review covers six Ph.D. and M.S. training programs within the University of Washington School of Pharmacy: Ph.D. programs in Medicinal Chemistry (MEDCH), in Pharmaceutics (PCEUT) and in Pharmaceutical Outcomes Research and Policy (PORPP); and M.S. programs in Pharmaceutics, in Pharmaceutical Outcomes and in Policy and Biomedical Regulatory Affairs (MSBRA). This is an opportune time to review these programs for several reasons: the last full program review was in 2001; the School has a new Dean, Dr. Thomas Baillie, who was appointed in Fall, 2008; a School-wide strategic planning effort will be completed this Quarter (Winter, 2010); there has been sufficient time to assess the performance and prospects of the PORPP and newer MSBRA programs; and a combination of new faculty hires and new research initiatives provide a sense of positive direction and momentum to the School's graduate training and research efforts. We summarize the most important strengths, weaknesses and opportunities from the review below, and provide more specific detail and recommendations in subsequent sections that focus on individual training Programs.

Strengths:

- Enthusiastic new leadership in the form of Dean Thomas Baillie.
- Imminent delivery of a broadly developed, School-wide strategic plan.
- Internationally recognized and accomplished senior faculty.
- Good new junior faculty hires (including women and minorities) across many programs.
- Several solid, well-established Ph.D. training programs, and a strong, still-developing PORPP program offering both Ph.D. and Masters training.
- Enthusiastic and accomplished students.
- Strong and exciting new research directions and initiatives.
- A well-recognized Corporate Advisory Board.
- Strong potential for new research funding from federal and industry sources.

Weaknesses:

- Inadequate space to support even current School research and training missions.
- Modest institutional support for School research and training missions.
- Inconsistent trainee support, teaching and internship opportunities.
- No consistent curricular development plan or student/peer evaluation of teaching.
- Poor and inconsistent communication of program expectations and requirements.
- Deficient training in biomedical research integrity/responsible conduct of research.
- Unacceptably long time to degree for MedChem and Pharmaceutics Ph.D. students.
- Few Program or School-wide activities to foster communication, recruitment and training.
- Substantial concerns about the MSBRA curriculum, especially the practicum experience; about faculty oversight and appropriateness; and the Program's long term fiscal viability.

Opportunities:

- Readily achievable 'economies of scale' in graduate recruiting, program development, teaching effectiveness evaluation and cross-School and Program communication.
- Excellent prospects for coupling curricular reform and training with exciting new research directions.
- A unique opportunity to develop a discipline-specific, UW Pharmacy-branded research integrity/IP/tech transfer curriculum with federal, UW and industrial partners.
- Excellent local environment in which to develop new programs, training opportunities and broader funding base.

2. Review Process

The Charge Meeting for the UW School of Pharmacy Program Review was held 26 May 2009 (please see the Appendix for a copy of the Charge Letter, together with documents and communications reviewed as part of the Review process). All of the Review Committee with the exception of Victoria Holt participated in the Charge Meeting in person or by phone, together with representatives of the School of Pharmacy, UW Graduate School, Graduate School Council, Office of the Provost and UW Graduate and Professional Student Senate (GPSS). The Review Committee compiled a list of requested information at the completion of this meeting to be added to the list of Program Review & Self-Study questions provided by the School.

The Review Committee was provided with the UW Pharmacy Graduate Program Review and Self-Study document in mid-November 2009. This document included additional information requested by the Review Committee on 26 May 2009 in a series of Tables and Appendices in the Self-Study document. The Review Committee also received in early February 2010, as a separate e-mail, the results of a questionnaire of Department of Pharmacy Graduate Students developed and administered by the GPSS.

The schedule for the Site Visit was developed by the Graduate School, School of Pharmacy and Review Committee in late Fall, 2009 and January 2010. Victoria Holt joined the Review Committee prior to the February Site Visit to replace Emily White of the UW School of Public Health. The Review Committee conducted the Site Visit and Program Review on 8-9 February 2010, and prepared this report based on documentation and discussion prior to the Site Visit, together with findings from the Site Visit. This Report was completed and approved by all members of the Review Committee, and was communicated to the UW Graduate School on 24 February 2010.

3. School of Pharmacy

We have divided the remainder of this report into sections addressing the School of Pharmacy as a whole and issues that affect all training Programs, followed by sections focused on individual training programs. The Appendix, as noted above, collects documents used for the Review and Site Visit.

Leadership: The new Dean of the School of Pharmacy is Dr. Tom Baillie, who returned to the University of Washington in 2008 after having served for many years as a senior executive at Merck. The School is fortunate to have recruited such an accomplished pharmaceutical scientist as their new Dean. Dean Baillie requested a Strategic Plan from the faculty that looks out 5 years and included the research and training missions of the School. This plan is near-complete and will be delivered this quarter, Winter 2010. Three Department Chairs are responsible for oversight of the individual graduate programs in the School of Pharmacy and run these Programs with their respective graduate faculty colleagues. The Department Chairs are highly regarded scientists, and have done a superb job in maintaining the quality of the programs as senior faculty have retired and/or assumed administrative roles. The Department Chairs are undoubtedly stretched very thin with administrative responsibilities for faculty and graduate students in their Departments, by teaching responsibilities at both the professional (PharmD) and graduate programs, by their very active research programs and associated NIH-funded training grants and/or program project grants. Specific recommendations regarding decision-making, program review, and program planning are provided below to help better deal with this demanding menu of responsibilities.

Faculty: This is by virtually all measures a distinguished faculty. Many are internationally recognized for their scientific expertise, and have been extremely successful in maintaining grant and contract support for their research programs while continuing to publish in the highest quality journals. The faculty have been very resourceful in getting support from the private sector, and in developing revenue-generating services to support their research and graduate training programs. A number of junior faculty have been hired over the past few years, and there is a healthy distribution of faculty by rank across the School. Of note has been the recruitment of both female and minority faculty members, which is notable as both groups are very heavily recruited and the available pool of accomplished candidates nationwide is small. One continuing area of concern, mentioned repeatedly in the Program Review and Self-Study and at the Site Visit, was planning for senior faculty retirement.

Students: The graduate programs have consistently attracted high-caliber students to both the Ph.D. and Masters training programs. There are a large number of applicants to the doctoral programs in the School, many of whom have competitive statistics (high GREs and GPAs) and are training grant-eligible. The programs have maintained high admission standards. It is interesting to note that almost no applicants with PharmD degrees have applied to the Pharmaceutics or Medicinal Chemistry programs. Further development of the joint PharmD/PhD program might encourage a few more professional students to consider graduate training in the pharmaceutical sciences. While the numbers may be small, these individuals are of great importance for the future of the field as a whole.

Graduate students in the School of Pharmacy publish the results of their research in highly regarded scientific journals, win competitive research and travel awards, and are highly sought after by employers for industrial, academic and regulatory positions. Student satisfaction regarding training program quality appears to be high. Based on exit surveys and discussions during the site visit, students gave high marks to academic standards of the Departments and the quality of the faculty. Students were confident that they are well-trained as independent scholars/researchers in contemporary areas of the discipline, particularly in Medicinal Chemistry and Pharmaceutics.

The current size of the individual graduate programs seems reasonable considering the funding base and number of graduate faculty in each Department. However, the time to degree is unacceptably long for students in MedChem and probably Pharmaceutics, and careful attention must be given to addressing this issue. It is critical for each graduate program to maintain “critical mass” to ensure the health and vitality of their–and the School’s–training and research missions. Assuming that the number of new students accepted into the program each year is roughly dependent on the number of yearly graduates, students that spend longer than 6 years in training are consuming resources that could be better allocated to support new students.

Staff: Current budget constraints are clearly stretching the administrative staff that support the graduate programs. Some staff seemed highly capable and engaged, and undoubtedly serve as a great resource for individual graduate programs.

Space and Facilities: New space is a critical aspect of institutional support for this highly visible and accomplished School and its training Programs. The University must address the space shortage with a commitment that details specifics (square footage, location and timeline). A failure to do so in the immediate future will severely limit the vitality, growth–and ultimately the quality–of the highly rated graduate programs and internationally recognized research leadership of the School. Faculty and graduate students have access to a wide array of state-of-the-art instrumentation, technology and core

facilities. Continued institutional support of this critical research infrastructure is essential. While the necessary equipment and core facilities appear to be adequate to meet current research needs, research space is clearly inadequate to support even current research and training efforts. Moreover, faculty reported a limited ability to seek additional external funding due to lack of available space to conduct their research.

An effort to ameliorate this problem has included expansion to additional off-campus space, at three different locations, that now totals slightly over 20% (10,235 ft2, or 20.5%, of School-wide space). This expansion has helped, though clearly compromises certain aspects of School-wide research and training. This issue was a major concern noted repeatedly by students, faculty and administrators. Space constraints are particularly problematic for new initiatives such as viral and vaccine development, and a fully functional biophysical core facility. New research and training programs in molecular structure and systems biology cannot proceed without new space. The current space allocations for the graduate programs in the School of Pharmacy further contribute to the “silo” mentality that is apparent among the programs.

Training Program Support: Support provided by the Graduate School/University appears to be extremely limited. A highly regarded university of the size and caliber of the University of Washington should provide, at a minimum, competitive, named Graduate School Fellowships and recruitment incentives to help attract highly competitive graduate applicants, and adequate support for graduate student travel to attend national/international meetings. Considering the quality of students that the graduate programs in the School are attracting, at least some students should receive competitive Graduate School Merit Fellowships.

In addition, teaching assistantships for graduate students in the School of Pharmacy are extremely limited (Medicinal Chemistry: 2.7 student lines of 0.5 FTE each; Pharmacy: 2 student lines of 0.5 FTE each) and inadequate to meet demand. Many graduate students expressed interest in gaining teaching experience, but did not have the opportunity to serve as teaching assistants. Students expressed concern in exit surveys that they did not feel adequately prepared to teach. This reflects in large part a lack of opportunities for TAships, and is a major problem at the national level: as a majority of Pharmacy faculty across the country are nearing retirement, we do not have an adequate cadre of young pharmaceutical scientist/educators fully prepared to teach the next generation of pharmacists and pharmaceutical scientists. Further emphasis on developing the PharmD/M.S.─and especially the PharmD/Ph.D.─tracks represent a real opportunity for the UW, as UW Pharmacy has strengths in both areas and the protential to offer both exemplary professional or research training together with teaching experience.

Heavy reliance of a graduate program on funding from individual and program project grants is risky in the current fiscal climate, and is becoming increasingly difficult to justify from a grants management perspective. It remains unclear whether the pharmaceutical industry will be able to continue to fund graduate training at the level that this School of Pharmacy has enjoyed previously.

Industrial relations: The School and individual Programs have enjoyed an excellent relationship with industrial partners who provide advice, support and Fellowships to bolster the research and training missions of the School. There is a funded, highly sought-after Allergan Fellowship in place. The School has a well-established Corporate Advisory Board representing virtually the whole of Big Pharma, in addition to members drawn from many smaller biotech and pharmaceutical partners. The Board meets yearly in the Fall, in Seattle, and this meeting includes substantial contact with School faculty and students.

School-wide Recommendations:

- *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.* UW Pharmacy is well behind the times in this area, and could achieve several economies of scale while improving communication, program administration and recruiting success by moving in this direction. Rotating responsibility among faculty would bring junior or mid-level faculty into program administration, would provide valuable leadership training opportunities and would provide a clear mechanism to ensure succession. This coordinated effort would provide as well an immediate mechanism to review, coordinate and improve curricula across all programs.

- *Develop better communication of critical information across all Program students, faculty and staff.* The School Graduate Student Handbook can be used to detail more general School or institutional policies (*e.g.,* vacation and leave policies, including parental leave) and procedures (*e.g.,* grievance procedures). Specific programs should provide an annually reviewed, date-stamped and web-accessible 'Fact Sheet' that details required courses by year and entering year in program; requirements for advancement and graduation; and an 'FAQ' section with contacts and/or links that covered other issues of high interest and important to trainees (course websites, advising, support, *etc*). Make the School website a common portal and resource, and dedicate the support needed to develop and maintain a high quality, up-to-date and easily navigated 'public face' and common informational resource for the School and training Programs.

- *Integrate curricula across Programs and continuously assess student progress.* Program expectations and requirement need to be clearly—and repeatedly—communicated each year by the Program faculty head. Curricula should be reviewed to eliminate unnecessary and less than useful overlap with the PharmD curriculum, and the current General Exam must—repeat ***must***—be changed and required no later than Yr 3 for the Ph.D. Programs. The best format for a revised General Exam would be to require students to use their Yr 2-3 research experience to develop and present evidence of readiness to perform graduate level work at an acceptably high level, together with a review of potentially viable thesis projects. Yr 3 Generals will be a confidence booster for students, and allow the needed 800-level credits to be acquired by Yr 5 to ensure timely completion of degree research. The current time-to-degree will be a show-stopper in any future attempts to maintain—or seek new—T32 support.

- *Institute an acceptable biomedical research integrity/ethics training program for all students in the School*. Another key issue for training and training grant support is to plug this hole as soon as possible. Imaginative and economical use could be made of the current UW BRI training taken by training grant-supported students, together with training that is Program-specific and appropriate for all students. Done correctly, this could be both an excellent training addition and could provide a strong example of discipline-specific training to peers nationwide. The progressive and careful addition of material on IP, human subjects/clinical research and tech transfer that is School- and program-specific would provide a way to expand this offering once the initial deficit was rectified.

- *Use standard mechanisms to evaluate teaching effectiveness*. The UW course evaluation forms for graduate level courses include both quantitative and free-form feedback, and are more than flexible enough to accommodate Program-specific courses. Some Programs are already doing a good job in the area (PORPP), but there needs to be a School-wide standard.

Posting of student reviews on the UW website, as is routinely done for other Programs, would allow students to do a better job of course selection and would increase the likelihood that non-Pharmacy students might enroll in Pharmacy courses where appropriate. Peer evaluation of faculty teaching effectiveness is critical for faculty promotion, so this should be started immediately with a focus on Assistant and Associate Professors. Acceptable methods to do peer evaluation are in place across the neighboring School of Medicine, so see what model works best from the several available then get started.

- *Develop common Program- and School-wide activities focused on recruiting.* Recruiting, as a School and Program-wide activity, on one or two dates each year, should be instituted immediately. This approach will aide recruiting success, and provide a common annual focus for students, staff and faculty to interact and work together. This approach can be progressively broadened to include additional School-wide activities to aid research and training integration across the School.

- *Leverage existing space and opportunities:* ***New space is a critical aspect of institutional support for this highly visible and accomplished School and its training Programs. The University must address the space shortage with a commitment that details specifics (square footage, location and timeline). A failure to do so in the immediate future will severely limit the vitality, growth—and ultimately the quality—of graduate programs and research within the School.***

  This problem will not be solved at the Departmental or Program level, but will clearly benefit from a little advance thinking on the best utilization of new space *as it becomes available*. In the meantime and as part of the strategic planning process, see if a few key moves within existing space (e.g., between MEDCH and PCEUT faculty, between floors and/or among locations) would facilitate research programs and integration or better utilize or locate instrumentation. In similar fashion, there are excellent, already established collaborations and joint ventures, e.g. with UW Bioengineering, Pharmacology and other Departments and Programs, that bring considerable additional strength in the form of related coursework, training and clinical/translational or research opportunities. Seattle is an excellent environment to develop these types of growth opportunities, so grow these where you can though remain cognizant of the requirement to keep courses critical to individual Programs under School or Program control to ensure quality, appropriateness and student access.

4. Ph.D. Graduate Program in Medicinal Chemistry (MEDCH)

The goal of the Medicinal Chemistry Ph.D. program is to train independent research scientists. The Department and Program have consistently been among —or *the*—top ranked national medicinal chemistry program by several important metrics: research productivity; visibility; total and FTE-based funding; and training of the next generation of medicinal chemists. The Department consists of 11 faculty, of whom 9 tenure-track core faculty play a role in graduate training. New faculty hires number 3, including one woman and one Hispanic faculty member. There are 27 Ph.D. trainees in the Department and Program.

Traditional Departmental and program strengths have been in the areas of drug metabolism and toxicology. More recent efforts have focused on two important growth areas. First, the growing importance of a systems biology of drugs and therapeutics, as revealed by a deeper mechanistic understanding of targets and modes of action. Second, the recognition that future therapies will include a substantial—and growing—number of biologics and macromolecules, and that newer generation vaccines will require a sophisticated understanding of viral and other immunization/ delivery approaches. These newer classes of therapeutics and vaccines present substantially

different production and delivery challenges than do more traditional small molecule therapeutics, and require a different range of approaches to develop, deliver, and assess targets and mechanisms of action.

These new directions are being incorporated into the research efforts of the faculty, and in training in the form of new coursework and training opportunities focused specifically on newer types of therapeutics and vaccines. The Department and Program hopes to further integrate and develop these new efforts, while maintaining traditional research and training strengths in order to prepare the best students for academic, industrial or government/regulatory careers.

Program Strengths:

- Faculty excellence, as assessed by visibility, productivity, funding, research direction and enthusiasm.
- Growing emphasis on several of the most important disciplinary growth areas.
- Strong collaborative instincts that extend beyond the School and institution.
- Faculty accessibility and collegiality, especially in areas related to trainee access to labs and instrumentation, and in the mentoring and support of junior faculty.
- Enthusiastic graduate students, and a sufficiently large student body (27) to ensure critical training mass.
- Adequate student/trainee support in the form of institutional RA-ships and a long-running T32 shared with Pharmaceutics.
- Strong student publication records and success in competing for national awards.
- Newly developed research resources and instrumentation, e.g., the new Biophysics facility
- Adequate career preparation.

Program Weaknesses:

- Lack of clearly identified program contacts. It needs to be clear to students and faculty alike who among the staff and faculty run the program on a day-to-day basis and are recognized as Program ‘go-tos’ by trainees.
- Absence of a coordinated graduate recruiting effort at the Program or School level.
- Slow curricular reform and streamlining to incorporate new areas of research and practice, and to improve time to degree.
- Failure to clearly and accurately communicate program expectations and requirements.
- Unacceptably long time to degree (6.2 yrs), a rosy average that does not reflect the large number of post-6th year trainees interviewed at the time of the Site Visit.
- Unacceptable biomedical research integrity/ethics training.
- Lack of teaching assistantships and opportunities to gain mentored teaching experience.
- Uncertainty regarding availability and desirability of industry or other internships.
- Absence of a uniform mechanism for student and peer evaluation of teaching effectiveness.
- Lack of programmatic activities that consistently engage faculty and trainees within Department and Program and across the School.
- Clearly inadequate space to support even *current* research and training efforts.

Opportunities:

- Current strategic planning provides an opportunity to reassess School-wide organization and training (however, this process was charged with looking out only 5 years, a surprising choice given the resources crafting this Plan will require).
- Clear and easily achieved ‘economies of scale’ , with improved communication and recruiting success, could be had by moving to 1 or 2 School-wide ‘Recruitment Days’ each year.

- Strategic planning will provide an opportunity to change organizational structure and responsibilities within the School and among training Programs.
- The shift towards translational research provides opportunities for new collaborations within the School, and with other training programs across the institution and in Seattle.

Recommendations: *All* of the School-wide Recommendations apply to the MEDCH Program. Special note should be taken of the recommendation for improving time to degree and the format of the General Exam.

Overall MEDCH Program Recommendation*:* Continuing status with review in 10 years.

5. Ph.D. Graduate Program in Pharmaceutics (PCEUT)

Based on all metrics (productivity, graduation rates, research funding, publication record, general impact in the field), the University of Washington School of Pharmacy graduate program in Pharmaceutics is an *outstanding*, top-ranked program.

Program Strengths:

- The Pharmaceutics program seeks to provide students with a fundamental understanding of drug disposition, delivery and action; with competence in pharmacokinetic theory and modeling, drug absorption and delivery; and with knowledge of drug metabolism and transporters as well as mechanisms of drug-drug interactions. The program is most well-recognized for expertise in the latter areas, due in part to the web-based Metabolism and Transport Drug Interaction Database which is an extremely useful and widely utilized resource.
- The faculty are excellent teachers and scientists and serve as very accessible role models for graduate students.
- Senior faculty appear to be very collegial and supportive of junior faculty, provide strong mentorship of young faculty in developing grant funding, and in encouraging new graduate students to join the laboratories of junior faculty.
- The research emphases in the Department are contemporary and aligned with collaborative strengths in other programs (e.g., Medicinal Chemistry, Bioengineering, translational research)
- The number and quality of graduate student applicants appears to be high.
- Morale among faculty and students appears to be high.
- Pharmaceutics graduate students seem to be very satisfied with their program of study, including stipend and tuition support.
- Graduate students in Pharmaceutics publish, on average, 3-4 manuscripts during their program of study in high quality journals. This accomplishment is particularly noteworthy.
- Interaction between Pharmaceutics and Medicinal Chemistry students appears to be good, in part due to a joint seminar series.
- Career preparation and job placement for graduates appears to be excellent.

Program Weaknesses:

- It is not clear who runs the graduate program on a day-to-day basis, particularly graduate student recruitment, admissions and progression assessment.
- The average time-to-graduation (5.6 yrs) may be too long.
- Communication at all levels needs to be improved. For example, students indicated that they were not fully informed about policies, procedures and benefits.
- It is unclear who is responsible for curricular review and curricular change Or whether there is student input into these processes.

- Students are unfamiliar with course requirements, and often rely on advice from senior students or faculty advisors that may not always be correct.
- Only one faculty member appears to have a research program in small molecule drug delivery. The Department will need to provide significant additional resources to continue to support this research area and recruit a junior faculty member.
- There is little mention of nanotechnology in the curriculum. This is an important aspect of drug delivery that could interface with the MEDCH and Bioengineering.
- The Pharmaceutics Department provides students with sophisticated training in fundamental pharmacokinetic principles. However, additional pharmacodynamic and pharmacometric or related training does not appear to be available currently, but can be found elsewhere at UW.

Opportunities:

- The current strategic planning process provides an opportunity to consider changes in the organizational structure and administrative responsibilities of the graduate program.
- The shift towards translational research provides opportunities for new collaborations.
- The availability of NIH funding to support qualified students enrolled in PharmD/PhD programs could increase the number of pharmacy-trained graduate students.

Recommendations:

- 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. This would enable more focus on key aspects of the graduate program by faculty who are not distracted by extensive administrative responsibilities. This would also provide excellent leadership training for mid-career faculty and ensure succession planning.
- A graduate student handbook detailing policies (*e.g.,* vacation and leave policies, including parental leave) and procedures (*e.g.,* grievance procedures) should be provided to each student when they enter the program; this information also should be available on the website. Updates to the handbook should be dated so that it is clear which requirements apply to which cohort of students. This handbook should detail the requirements for the Ph.D. degree, guidelines for review and progression and the sequence of classes that students are expected to take to meet program requirements. General information regarding the content of each course, including prerequisites, also should be readily accessible.
- 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.
- 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 the MedChem exists. It would be logical to partner with the Department of Bioengineering rather than independently investing significant resources to strengthen the areas of drug delivery including nanotechnology, and pharmacometrics. Expanding the scope of research and training must be balanced with concerns about diluting current research strengths. Finally, it would be difficult to envision how highly-regarded research and training programs in new areas could be developed without new resources to support the hiring of new faculty and the development of new research programs.

Overall PCEUT Program Recommendation: Continuing status with review in 10 years.

6. Ph.D. Program in Pharmaceutical Outcomes Research and Policy (PORPP)
As with other graduate programs at the University of Washington School of Pharmacy, the Pharmaceutical Outcomes Research and Policy Ph.D. Program (PORPP) is one of the nation's best. This relatively new program has quickly established itself as a leader in the field of pharmaceutical outcomes research.

Program Strengths:

- Since its inception a little over 10 years ago, PORPP has grown into a nationally recognized leader in providing doctoral level training in cost-effectiveness, health technology assessment, and pharmaceutical policy. The program is attracting highly qualified faculty and talented graduate students, and has an excellent reputation for preparing graduates for the highly-competitive world of extramural research.
- The program is led by a senior faculty member who has an extensive outcomes research publication record, including articles in the *New England Journal of Medicine* and *JAMA*.
- Program Faculty, though small in number, are national and international leaders in the field of outcomes research, and they have served in several leadership positions in the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).
- Faculty have been remarkably successful in obtaining NIH and AHRQ grants to support their research programs, with notable recent successes in Recovery Act awards, despite the limited funding available for outcomes research.
- There appears to be a high-degree of collegiality among the faculty both within the University of Washington and also with external researchers in the local community. Global health research collaborations with PATH, WHO, the Gates Foundation, and the IHME program in the UW Department of Global Health are particularly strong.
- The quality of graduate students is impressive. Students from the program have been successful at obtaining a number of awards at ISPOR meetings. Two students have obtained prestigious American Foundation for Pharmaceutical Education (AFPE) pre-doctoral awards, and two have also been awarded pre-doctoral awards from the PhRMA Foundation.
- Also impressive is the productivity of the graduate students. The number of published papers ranges from 2 to 9, with most students having more than 3 articles. More importantly, these papers have appeared in prestigious journals.
- Graduates of the Ph.D. program have been successful in obtaining tenure-track faculty positions and competitive positions within the pharmaceutical industry. Employers of graduates include: Group Health Cooperative; GlaxoSmithKline; Amgen; GE Healthcare; The University of Texas at Austin, University of Colorado; and Genentech.
- In general, PORPP graduate students speak highly of the program and their ability to receive mentoring from faculty, with particular mention of the openness and accessibility of faculty members for informal discussion and advice.
- A strength of the program is that advisors are assigned early in student training, and mentoring appears to occur consistently throughout the program.
- PORPP has clearly articulated academic achievement milestones for students, with benchmark exams early in the curriculum. This helps to ensure timely completion of doctoral studies (mean time to degree: 5 years).
- The handbook and graduate student orientation are very helpful, and staff support for the program appears to be excellent.
- Because the graduate students share a common office space, there are excellent opportunities for interaction between junior and senior students

Program Weaknesses:

- The basis for assigning financial support has not been clearly communicated to all students, and appears inequitable in some circumstances. Students at early stages in their training are concerned about funding for later years in the program.
- Teaching assistantship opportunities are quite limited, and what could be a valuable part of the educational process is not required of students. Preparation for teaching received the lowest rating in exit surveys of recent PORPP Ph.D. graduates.
- The program relies heavily on courses taught outside of the School of Pharmacy, for both core content and popular electives. Access to these courses appears to be difficult at times, with students reporting various tactics employed to convince instructors to allow them to take non-SOP elective classes. However, no student indicated that they were unable to get into a required course in a reasonable period of time.
- More guidance on early elective options is needed.
- Perhaps as a consequence of reliance on non-Pharmacy courses, what students are expected to be getting from coursework is not well-defined. Students also indicated the need for more insight into the content of the preliminary exam.

Opportunities:

- The recent training grant application, if funded, should ease student funding concerns and broaden student research opportunities.
- Recent awards for comparative effectiveness research will continue to raise the stature of the program in this important new area of study; the challenge will be the sustainability of this funding stream. The emerging focus on new research areas of health informatics and genomics shows similar promise.
- The emphasis on global health by several faculty is a growth area that will attract high-quality students from around the world. Seattle is an excellent environment to further develop this opportunity.

Recommendations:

- Develop a more formal structure for administering the graduate program, such as appointing a Director of Graduate Admissions and a Director of Graduate Studies. This would enable more focus on key aspects of the graduate program by faculty who are not distracted by extensive administrative responsibilities. This also would provide excellent leadership training for mid-career faculty and succession planning, as well as enhance communication of programmatic expectations to students.
- Ensure equitable funding opportunities for all graduate students enrolled in the program, and communicate how funding decisions are reached.
- 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.
- To the extent possible within the curricular structure, provide more teaching assistant opportunities to students or provide access to a course on teaching methods.
- 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.

Overall PORPP Ph.D. Program Recommendation*:* Continuing status with review in 10 years.

7. Master of Science in Pharmaceutical Outcomes Research and Policy (PORPP MS)
Like its doctoral counterpart in the University of Washington School of Pharmacy, the Masters Program in Pharmaceutical Outcomes Research and Policy Program (PORPP) is a relatively new program that is enrolling highly competent, enthusiastic students. Many of the general issues described in relation to the PORPP doctoral program apply to the masters program as well. In what follows, we focus primarily on issues central to the Masters Program.

Program strengths:
- As discussed in relation to the doctoral program, associated faculty have excellent reputations and active research programs, many with external funding.
- The Masters degree seems to be attractive to students who are pursuing other advanced degrees, primarily the PharmD degree, but not exclusively.
- The program provides students who are pursuing a concurrent degree with a secondary speciality that is likely to strengthen their credentials at graduation.
- Current students seem collegial and quite positive about the program.
- Students seem to see the value in the conceptual emphases on epidemiology and biostatistics courses, and they value flexibility in requirements when students come with relevant backgrounds in related fields.
- Staff support seems to be strong, and is very much appreciated by students.

Program challenges/weaknesses:
- Students in the Masters program, like their counterparts in the doctoral program, report difficulty in gaining access to courses outside the School of Pharmacy. This was specificially highlighted for required courses in Public Affairs. Of the 66 required credits, only 13 come from courses taught by the School of Pharmacy, not counting the quarterly one-credit Pharmacy seminar and the 9 credits of thesis.
- The extent to which the Masters program is intended as a stand-alone degree (in contrast to the combined PharmD/MS program) is unclear, especially on the current web site. If the PORPP MS is envisioned as a viable stand-alone degree, it should be publicized to the level of the School's other Masters programs. Currently, the PORPP doctoral program and combined PharmD/PORPP MS seem to overshadow the Masters program.

Program opportunities:
- 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. The clinical focus in the PharmD program may limit PharmD students' awareness of and potential interest in the PORPP masters degree. Better communication and broader awareness of the sample course schedule for the PharmD/PORPP MS concurrent degree could improve enrollment from the PharmD program and enhance the professional prospects of the dual-credentialed graduates. Increased enrollments in the PORPP masters program would, however, intensify the need to improve access for Pharmacy students to required courses outside the School of Pharmacy and the need for additional resources to provide adequate Program support.

Overall PORPP MS Program Recommendation*:* Continuing status with review in 10 years.

8. Master of Science in Biomedical Regulatory Affairs (MSBRA)
The Masters of Science program in Biomedical Regulatory Affairs (MSBRA) is a relatively new program that was approved in 2006, and begun with a first entering class in 2008 that will graduate this year (Spring 2010). The Self-Study states the demand for the program came from

industry and students. There are 43 students enrolled in MSBRA from a variety of backgrounds including law, medicine and industry and with a range of degrees (MS, PhD). Successful completion of the program is based on coursework, including a practicum. The combination of evening coursework and practica make the MSBRA more akin to executive MBA programs than to other graduate programs including other M.S. Programs in the School of Pharmacy.

The MSBRA program is directed by Dr. Tom Hazlet. Prior to joining the University of Washington, Dr. Hazlet was employed at the California Department of Health Services' Food and Drug Branch. His qualifications to direct the program are unquestionable. Dr. Feagin is a senior lecturer and provides 50% effort to the program and has a background in medical parasitology. The other instructors in the program are lecturers or affiliate faculty. There was a discrepancy between Table A and Appendix C: Table A lists 6 core faculty for the MSBRA program, whereas Appendix C lists only Drs. Hazlet and Feagin.

The curriculum is modeled on a certificate program in biomedical regulatory affairs, but certification is not a required component of the program. The course descriptions provide a sense that the fundamental basis of the regulation of medical technologies is adequately addressed. Because the program is relatively new (established within the past 2 years) exit surveys have not been conducted, making it difficult to evaluate student's perceptions of the program's curricula.

Program Strengths:

- Strong demand for the program during its first two years.
- Substantial participation by affiliate faculty. This suggests that Dr. Hazlet has been successful in building strong community ties that are essential for the program to operate.
- A well-qualified program director. As stated above, the qualifications of Dr. Hazlet to direct this program are excellent. His past regulatory experience is an invaluable asset and uncommon among academicians.
- High quality students. The group of students selected to appear before the Review Committee were well qualified for the program and highly motivated.

Program Weaknesses:

- 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. 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.
- The requirement for 17 students per year to enroll in the program in order for it to be financially viable may lead to the acceptance of marginal candidates if future demand diminishes. During the first two years the program accepted almost all students who applied.
- 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. While there are a substantial number of affiliate faculty who provide instruction, the lack of more program faculty is problematic. Moreover, 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.
- 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.

- 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, M.S.-level programs can be an incredible time-sink.
- 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.
- 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.
- Students expressed concern about the certification exam. Expectations for this exam were unclear, and need to be clearly stated in program materials.
- 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.

Opportunities:

- This degree program is unique and fills a needed gap in the biomedical regulatory workforce. Because of its uniqueness it appears the program will continue to attract interest from North America and around the world. Consequently, there is the potential to expand the program to an on-line offering in the future once there is sufficient experience with the traditional didactic program. However, regulation of medical products is likely to vary substantially by country, so it will be important to recruit qualified faculty for jurisdictions outside the United States and crucial to provide adequate SOP-based faculty oversight of all students' studies and practica.

Recommendations:

- 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. 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.
- 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.
- 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.

Overall MSBRA Program Recommendation:

- *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.

9. Appendix: UW School of Pharmacy Review and Site Visit Materials

Note: Due to the size of the Appendix, we have provided a listing of all material contained in the Appendix below and have provided these materials in a separate document.

A. Charge Letter to the Review Committee, UW Graduate School (dated 28 May 2009).

B. Report of the UW School of Pharmacy 10-Year Review (April 2001).

C. UW School of Pharmacy Graduate Program Review and Self-Study (19 November 2009).

D. Final Site Visit Agenda, 8-9 February 2010 Site Visit (13 January 2010).

E. Materials provided as part of the Site Visit by School of Pharmacy faculty members and students:

i. School of Pharmacy On- and Off-Campus Space location and square footage (1 page).
ii. UW School of Pharmacy Corporate Board Members and Meeting Attendee Roster (2009, 4 pp.).
iii. MEDCH/PCEUT 527 Advanced Drug Metabolism course outline and student evaluations (Winter 2009, 3 pp.).
iv. MEDCH 528 Biophysical Enzymology and Biopharmaceuticals course outline (Winter 2010, 2 pp.)
v. PHARMA 528 Medical Risk Analysis and Management course outline (Winter 2010, 3 pp.).
vi. PHARM 532 Introduction & Regulation of the Medical Products Industry outline and student evaluation (Spring 2009, 7 pp.).
vii. GPSS Catalyst Survey Report from Yr 1-5+ Students, UW Department of Pharmacy (undated – received 2 February 2010 from Liz Williams, GPSS Chief-of-Staff).
viii. Draft Student Progress timeline slide (2010, Allan Rettie and Ken Thummel, 1 Powerpoint slide).
ix. Additional comments provided by students in the PORPP and MEDCH Ph.D. Programs (2 e-mails, of 1 and 4 pp., received 11 and 18 Feb 2010 and used Included with the written permission of each student).