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VIA EMAIL @: acadprop@mhec.state.md.us

James D. Fielder, Jr., PhD
Secretary
Maryland Higher Education Commission
6 N. Liberty Street
Baltimore, MD 21201

Dear Dr. Fielder:

I have reviewed the Mount St. Mary's University (MSMU) proposal to the Maryland Higher Education Commission to start a Post-Baccalaureate Certificate (PBC) in Quality Assurance and Regulatory Science. Their proposed PBC represents an unreasonable duplication of a program currently offered at the University of Maryland Baltimore (UMB) and poses a significant demonstrable harm to our program due to competition for students.

This letter outlines several issues that we ask the Commission to consider as it evaluates the merits of the MSMU proposal:

Proposed Program

The PBC proposal indicates: "The graduate certificate in Quality Assurance and Regulatory Science is designed for biotechnology and biopharmaceutical professionals who are seeking advanced knowledge and training in the area of quality assurance, quality control, regulatory affairs, and risk assessment. Completion of the program will provide students with:

- An understanding of applicable FDA standards and processes, international regulations, Good Manufacturing Practices and supporting GxP standards
- A working knowledge of quality systems and quality management
- An understanding of international and U.S. product-specific industry and regulatory standards
- Improved writing and oral communication skills
- A foundation for ethical decision-making"

The proposal lists the following six courses (of which five are required):

MSQ 5xx Quality Systems and Regulation
MSB 5xx Biostatistics
MSQ 6xx International Regulation
MSQ 6xx Quality Management

MSQ XXX Regulatory Compliance for Biologics and Drugs
MSQ XXX Regulatory Compliance for Medical Devices and Combination Products

The proposal indicates: "Our proposed program is an innovative program in several respects, not the least of which is the novelty of the program itself which will be unique in the state and the region. Currently, anyone interested in becoming credentialed in QA/RS would have to sign up for a two-year Master's degree in Regulatory Science at JHU or UMBC, enroll at Temple University in Philadelphia or enroll in a fully-online certificate program. ... In Maryland, there are no Bachelor's or Master's degree programs nor any post-baccalaureate certificate programs in Quality Assurance and Regulatory Science and, consequently, none that focus on the biotechnology industry. ... In summary, our proposed program is unique in that it is a post-baccalaureate certificate with a mix of on-site and online courses and an emphasis on ethics."

Unreasonable Duplication and Significant Demonstrable Harm

Respectfully, I disagree with MSMU's due diligence in demonstrated need for an additional program. MSMU failed to recognize or mischaracterized the MS in Regulatory Science offered at the University of Maryland, Baltimore (UMB). UMB offers an exclusively online MS in regulatory science degree in conjunction with the School of Pharmacy (see the program's website at www.pharmacy.umaryland.edu/regulatoryscience). The Master of Science (MS) in Regulatory Science provides graduates with the knowledge and skills necessary to contribute to drug and biologics regulation and pharmaceutical product lifecycles. According to the Food and Drug Administration (FDA), "regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products." UMB's online program is primarily designed for working professionals with Bachelor of Science (BS) degrees who now work in (or would like to work in) regulatory science in industry or government. Graduates of this program become confident in the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.

The UMB program is composed of five courses:

- REGS 603 Drug, Biologic, and Device Regulation
- REGS 614 Drug and Biologics Discovery
- REGS 631 Drug and Biologics Development
- REGS 621 Clinical Research
- REGS 641 Regulated Products in the Marketplace

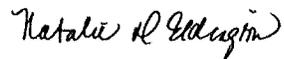
Since MHEC approval in January 2014, the program has graduated 52 students, with another 33 professionals poised to graduate May 2017.

We disagree that with the statement that "In Maryland, there are no Bachelor's or Master's degree programs nor any post-baccalaureate certificate programs in Quality Assurance and Regulatory Science and, consequently, none that focus on the biotechnology industry." The proposal makes no reference to the UMB MS in regulatory science program.

We have placed significant resources in the UMB MS in Regulatory Science program. Likewise, the proposed new program targets a significant portion of our target audience (i.e. working professionals in biotechnology). Although the proposed new program is a PBC while the UMB program is a MS, there is substantial duplication in scope (i.e. quality/development and regulatory science of biologics).

In summary, we believe that the approval of MSMU's PBC proposal would result in demonstrable harm and needless program duplication to the already approved MS in regulatory science program at UMB. Please feel free to contact me at 410-706-7651 if I can provide additional clarification or further information.

Sincerely,



Natalie D. Eddington, PhD, FAAPS, FCP
Dean and Professor