BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

November 20, 2008

Department of Health
Board of Pharmacy
717 14th Street, NW
Suite 600
Washington, DC 20005

Dear Sir or Madam,

Thank you for the opportunity to provide comments on the Draft "Frequently Asked Questions: Licensure and Regulation of Pharmaceutical Detailers in the District of Columbia." The Biotechnology Industry Organization (BIO) appreciates the Board of Pharmacy's efforts in seeking to clarify the provisions of the regulations enacted pursuant to the SafeRx Amendment Act of 2008. However, BIO continues to have concerns regarding the interpretation and lack of clarity with regard to certain provisions of the law and regulations. As addressed below, certain issues related to the applicability of the law and the definition of "pharmaceutical detailer" remain ambiguous and some of these concerns previously communicated by BIO and other stakeholders have not been addressed by the Board.

Conventions and Medical Conferences

We remain concerned with the ambiguity regarding whether individuals that are employees of biopharmaceutical companies attending or speaking at conventions or conferences in the District would be subject to licensure requirements under the SafeRx Amendment Act of 2008 if District health professionals attend the convention or conference. If such licensure is required, this could have a direct and immediate impact on our organization as well as sponsors of other medical conventions in the District. BIO produces the annual BIO International Convention, the world's largest gathering of the biotechnology industry. In 2011, the BIO International Convention will be held in the Washington Convention Center and is expected to draw approximately 20,000 biopharmaceutical industry representatives. The question BIO submitted to the Board on October 21, 2008 regarding this issue has not been addressed. We continue to seek guidance from the Board on our original question:

"By way of example: A physician, licensed to practice medicine in the District, attends a convention in the District (e.g. at the Washington Convention Center) and attends a session where a pharmaceutical company employee, likely an MD or PhD, speaks about a company product, e.g., presenting new scientific or medical information. Would that pharmaceutical company employee, even though clearly not a pharmaceutical detailer, be required to register as a pharmaceutical detailer in the District?"

Interpreting the law to encompass speakers at conventions and medical conferences held in the disctict would be misguided and would not serve to further the purpose of regulating the practice of pharmaceutical detailing. We recommend that the Board address this issue in the Frequently Asked Questions document, to clarify that such speakers would not be required to obtain a license. In considering this issue, we request that the Board take into account the potential impact on DC if sponsors of conventions and conferences choose to locate elsewhere.

1201 Maryland Avenue, SW • Suite 900 • Washington, DC 20024-2149 • 202.962.9200 • Fax 202.488.6301 • www.bio.org

Medical Liaisons

BIO is concerned about the Draft FAQ #26, which states that Medical Liaisons are required to be licensed under the DC SafeRx Act. In clarifying which employees should be licensed under the Act, BIO recommends that the Board focus on job function, rather than focusing on titles, such as Medical Liaison. Titles of personnel vary from company to company, and accordingly, the role and function of a Medical Liaison varies by company. BIO recommends that the Board distinguish between biopharmaceutical company employees that have a sales or marketing function —and properly can be considered as conducting a pharmaceutical detailing function—from those that do not. A company employee who provides information without the purpose of selling or marketing a product should not be required to obtain a license.

In addition, we recommend that a company representative should not be required to obtain a license if providing information in response to unsolicited requests for information from a health professional in the District. If this situation is not addressed, physicians and other health professionals could have to wait up to sixty days, while a license application is being processed, before the information can be provided. This is problematic for the physician needing information important to their clinical practice and would not serve the best interest of patients in the District.

Further, for particular drugs that are subject to Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS), certain company representatives serve the function of communicating with practicing physicians to educate, gather and provide information to achieve full implementation of and compliance with the specific REMS requirements imposed by FDA. Such employees are not focused at all on sales or marketing. They generally have advanced medical or scientific expertise. They are charged with assuring that a particular drug is prescribed in accordance with stringent safety and monitoring requirements so that it may be provided to and used by patients under safe conditions of use. Such activities should not trigger licensure requirements.

Pharmacy and Therapeutic Committees

BIO has similar concerns regarding Draft FAQ #27, which states that a company employee communicating with a Pharmacy and Therapeutics Committee would be required to be licensed. Generally, when companies are communicating with these committees, they are responding to requests for information from the committee. There is a wide variety of types of communication that a company might have with a pharmacy and therapeutics or medication advisory committee. Again, BIO recommends that the licensure requirements be based not on who meets with the committee but rather the function of the individual presenting at the meeting. If a company representative meeting with a pharmacy and therapeutics or medication advisory committee provides information without the intent of selling or marketing a product, and selling or marketing a product is not part of that individual's job function, that person should not be required to obtain a license.

Again, we thank the Board for the opportunity to comment on the proposed Frequently Asked Questions document. We hope that the issues we raised can be clearly addressed by the Board. If the Board requires additional information or would like to discuss the above-mentioned comments, please contact Sandra Dennis at (202) 962-6673.

Sincerely,

Sandra Dennis

Sandra Dennis
Deputy General Counsel, Healthcare Regulatory Affairs
Biotechnology Industry Organization

cc: Members of the Council of the District of Columbia