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INDUSTRY ORGANIZATION

July 24, 2008

Department of Health
Office of the General Counsel
825 North Capital Street, N.E.
Fourth Floor
Washington, DC 20002

Subject: **Department of Health, Chapter 83, Pharmaceutical Detailers, of Title 17, Business Occupations and Professions, of the District of Columbia Municipal Regulations (DCMR).**

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks you for the opportunity to comment on the District of Columbia (the District) Department of Health's proposed rules on the reporting requirements for "Pharmaceutical Detailers." These proposed rules address the content and reporting requirements for the licensure and regulation of the practice of pharmaceutical detailing in the District as defined in Title I of the SafeRx Amendment Act of 2008 (D.C. Law 17-0131; 55 DCR 4462, published on April 25, 2008) (the Act).

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

BIO and our member companies remain dedicated to the advancement of medical science and the improvement of patient care. In pursuing this mission, we recognize that adherence to strict ethical standards and compliance with applicable District laws is critical to our industry's ability to continue our collaboration with healthcare professionals and maintain the trust of patients, and it is with this commitment in mind that BIO respectfully submits the following comments regarding the proposed licensure requirements, and the associated reporting requirements for the practice of pharmaceutical detailing in the District.

Clarification Requested Regarding Section 8399 Definitions – Definitions of the Practice of Pharmaceutical Detailing and Medication Advisory Committee

Clarification of the definitions of "practice of pharmaceutical detailing" and "medication advisory committee" would greatly enhance the regulated community's ability to comply with the licensing requirements. While the proposed regulations correctly define the practice of pharmaceutical detailing as set forth in the Act, the proposed regulations offer no clear guidance to the regulated community regarding the class of individuals who are potentially subject to the licensing requirement. As currently drafted, the proposed regulations potentially require the licensure of individuals who do not participate in sales-related activities, but do communicate with licensed healthcare professionals located within the District.[1] Given the

[1] For example, as currently defined, the regulated activity could potentially include individuals such as medical science liaisons (MSLs), medical affairs professionals, clinical research professionals, attendees at

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ambiguity of the definition, we ask that the Board provide clarification that only the individuals employed as pharmaceutical detailers engaged solely in sales-related activity are the class of employees required to be licensed under the Act. We request that the Board provide examples of activities that do not fall within the scope of the defined practice of pharmaceutical detailing.

In light of the fact that Section 8305.7 does not permit a pharmaceutical detailer to offer gifts or remuneration of any kind to a member of a medication advisory committee, BIO requests confirmation as to whether or not "medication advisory committee" as defined in the Act and proposed regulations is limited to those individuals who are currently serving on the District of Columbia's Medical Assistance Administration Pharmacy and Therapeutics (P&T) Committee. BIO also requests that the Board provide licensed detailers and the public at-large with an accurate and updated list of current Committee members in order to ensure regulatory compliance. Under Mayoral Order 2007-46 (dated January 23, 2007), a list of Committee members shall be maintained by the Medical Assistance Administration and shall be made available to the public upon written request.

Clarification Requested Regarding Section 8305 Code of Ethics

Section 8305 sets forth a number of provisions regarding marketing activities and communications of pharmaceutical detailers. BIO is concerned that several of these provisions are duplicative of, and/or inconsistent with, Food and Drug Administration (FDA) federal regulation of communications by biopharmaceutical manufacturers regarding their products.

Specifically, section 8305.1 states that a detailer may not engage in any "*deceptive* or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact" (emphasis added). FDA has broad authority over labeling and advertising of prescription pharmaceutical products, with the primary directive from Congress being the prohibition on disseminating labeling that is "false or misleading." Section 502(a) of the Federal Food Drug & Cosmetic Act (FFDCA). Use of the term "deceptive" in the proposed regulations is not reflected in the FFDCA or FDA's implementing regulations. Further, the term is not defined in the proposed regulations. Accordingly, it would be vague and confusing to use the phrase "deceptive", rather than "misleading", applying two different standards to pharmaceutical communications. BIO believes that it would be appropriate to eliminate this section in the final rule, given that the area is already adequately regulated by FDA. In the alternative, it is necessary to revise the language in section 8305.1 to be consistent with the FFDCA.

Section 8305.9 also raises concerns regarding consistency with FDA policies. This section states that a pharmaceutical detailer shall provide information that is "accurate, fairly balanced, and *consistent with FDA approved labeling*" (emphasis added). However, there are instances in which FDA has recognized that dissemination of information that is different from FDA-approved labeling is permissible, including published, peer-reviewed medical journal articles and other non-promotional exchange of scientific information[2]. Again, BIO believes that it would be appropriate to eliminate this section in the final rule, given that FDA fully regulates this area, and our members are required to fully comply with all aspects of FDA regulations. In the alternative, it is necessary to revise the language to assure that detailers and their employers will not be subject to two different and inconsistent standards regarding what information may properly be distributed. Accordingly, language in the final rule should state: "A pharmaceutical detailer shall provide information to healthcare professionals that is approved for use by the manufacturer's review committee and meets manufacturer's company standards,

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conferences and national medical meetings occurring within the District, and attendees of company-sponsored meetings occurring within the District.

[2] See, FDA, Draft Guidance for Industry, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (April 2008).

and is consistent with and permissible under the laws, regulations, and policies enforced by the FDA."

Clarification Requested Regarding Section 8309 Authority to Collect Information and Record Retention

The proposed regulations state that the Board is "authorized to collect information" from pharmaceutical detailers related to their communications with health professionals, or with employees or representatives of health professionals. The language in the proposed regulations is vague as to what information will be requested of pharmaceutical detailers, and leaves the door open for requests of information that are not related to the Board's authority to carry out its functions under the Act. We recommend that the Board clearly define what types of information would be responsive to a request, as most communications with health professionals are not formally documented by pharmaceutical detailers.

Pharmaceutical detailers, as employees of manufacturers and not independent agents, have obligations to their employers regarding the disclosure of communications and the disclosure of information. Therefore, we recommend that all requests for information subject to Sections 8309.1 and 8309.2 should be submitted solely to the manufacturer in writing. Furthermore, the document retention requirements of Section 8309.4 should solely be the responsibility of the manufacturer as owners of the requested information.

Lastly, we request that a provision be added to this section of the proposed regulations to provide for protection of information that is designated as confidential or trade secret by the manufacturer.

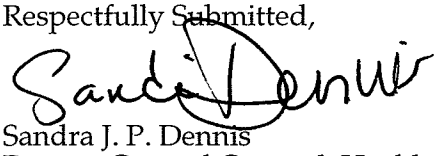
Clarification Requested Regarding Section 8301 Term of License and 8304 Application for Licensure

We recommend that licenses be subject to renewal every two (2) years based on the date of issuance instead of simultaneously expiring on the date specified in Section 8301.1. As currently proposed, a pharmaceutical detailer would have insufficient time to complete the required minimum fifteen (15) contact hours of approved continuing education credit (See Section 8306.3) prior to the renewal deadline. Staggering the terms of licensure renewal ensures that a pharmaceutical detailer seeking license renewal can comply with the continuing education requirements.

Finally, BIO requests clarification that social security numbers provided under Section 8304.1 will not be used for individual licensee identification. BIO recommends that the Board issue independent unique numbers to each individual license holder for identification purposes.

Thank you for your consideration of these comments. We would welcome the opportunity to further discuss these issues. Please contact me at (202) 962-6673 or at sdennis@bio.org if you have any questions regarding these comments.

Respectfully Submitted,



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