Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

November 5, 2009

Wendy Morgan
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, Vermont 05609

Re: Potential Disclosure of Biologic Samples given to Vermont Health Care Providers

Dear Ms. Morgan:

The Biotechnology Industry Organization ("BIO") requests clarification from the Attorney General's Office ("the Office") regarding the statement in the "Guide to Vermont's Prescribed Products Law for FY10 Disclosures" ("the Guide"), "free samples of prescription drugs need not be reported, but free samples of biologics and devices must be reported." Act 59 requires a study of the disclosure of information regarding samples of prescribed products. However, it is our understanding that the Act does not require disclosure of samples, therefore making the Office's policy under the guidance document inconsistent with the statutory mandates.

BIO is a national trade organization, based in Washington, D.C., representing more than 1,200 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. In Vermont we work closely with the Vermont BioSciences Alliance, whose membership is comprised of research centers, academic institutions and members of the business community.

As stated above, Act 59 mandates a study by the Office, in consultation with Commission on Health Reform, to provide a recommendation to the Legislature on whether the disclosure of samples of prescribed products should be incorporated into the current law. Specifically, the law directs the Office to conduct a review of the advisability of modifying the Act to require the disclosure of, "samples to health care providers by manufacturers of prescribed products." "Prescribed products" is defined in the Act to include drugs, devices, and biological products. The Office is required to provide its findings to the House Committee on Health Care and the Senate Committees on Finance and Health and Welfare no later than December 15, 2009. Pursuant to this mandate, the Office held a public hearing on October 27, 2009 related to the "Advisability of Requiring Disclosure of Free Samples of Prescribed Products given to Vermont Health Care Providers." During the hearing there was no discussion of, or reference to, the disclosure of biologic samples as incorporated into the Guide and accompanying Disclosure Form for Manufacturers of Prescribed Products. The hearing correctly focused on the mandate to determine whether "prescribed products," which include biologics, should be subject to disclosure. However,

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despite the appropriate focus on the advisability of the disclosure of samples of prescribed products, BIO is concerned about the lack of attention to what appears to be a misinterpretation or misapplication of the statute that, prior to any discussion, has already been reflected in the Guide and Disclosure Form. We are concerned that these statements regarding the disclosure of biologic samples directly conflict with the underlying statute and legislative intent. We have addressed our concerns in detail below.

Act 59 of 2009 (enacted as Senate Bill 48)

Act 59, in part, provides for a prohibition on gifts to health care providers, as well as increased transparency for consumers by requiring certain disclosures of allowable expenditures and gifts to health care providers.

- First, section 4631a provides that it is unlawful for a manufacturer of a prescribed product to give a gift to a health care provider.
- Then, Section 4632 provides for the "Disclosure of Allowable Expenditures and Gifts by Manufacturers of Prescribed Products." Certain allowable expenditures and gifts are explicitly listed as being exempt from the required disclosures. Section 4632 (a)(1)(A)(4) exempts, "samples of a prescription drug provided to a health care professional for free distribution to patients" from disclosure.
- Although "prescription drug" is an undefined term under the Act, the definition of "prescribed product" is provided in Section 4631a. The Act defines a prescribed product as, "a drug or device as defined in section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321, or a *biological product* (emphasis added) as defined in section 351 of the Public Health Services Act, 42 U.S.C. § 262."
- Further, the Act defines a manufacturer as, "a pharmaceutical, *biological product* (emphasis added), or medical device manufacturer or any other person who is engaged in the production, preparation, propagation, compounding, processing, packaging, repackaging, distributing, or labeling of prescribed products."

Section 4632 should be interpreted to only require the disclosure of allowable expenditures and gifts that are not listed as exceptions. Samples properly should include samples of products manufactured by pharmaceutical and biological companies. The Act does not distinguish between drugs and biological products for the purpose of disclosure. In fact, the Act states in the Legislative Findings section that prescription drugs and biological products should be treated in the same manner under the Act. Accordingly, there is no basis for the Guidance to make a distinction between a prescription drug and a biologic.

Further, the Office's change in the Guidance is premature—in advance of the conclusion of the study and report to the legislature. Under Section 5a of the Act, relating to the Study of Disclosure of Drug Samples, the language plainly and specifically states that the mandated review by the Office pertain to, "the disclosure of information about the provision of samples to health care providers by *manufacturers of prescribed products* (emphasis added)." The Act gives the Office narrowly proscribed authority to conduct a study related to whether the underlying statute should be revised to include the disclosure of information about samples by manufacturers of pharmaceutical and biological products. There is nothing in the statutory language that would provide the Office with the ability to require disclosure of biologic product samples prior to the conclusion of the review and recommendation by the Office, and any subsequent legislative changes based upon those recommendations.

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Guide to Vermont's Prescribed Products Law for FY10 Disclosures

On October 1, 2009 the Office published the Guide. Additionally, the Office posted on their website a document titled, "Answers to Submitted Questions – FY10 – Updated 9/28/09." This Q and A document contains a section dedicated to submitted questions related to, "Gifts and Allowable Expenditures – Free Samples/Donations/Loans." In this section the Office provides answers to questions which make a distinction between prescription drug samples and free samples of biologics. Specifically, answers are provided which indicate that, "No disclosure of prescription drug samples is required at this time," and then in a subsequent question, "free samples of biologics and medical devices must be reported. See II(c)(1) of the FY 10 Guide." These statements are inconsistent with the mandates of the Act. Further inconsistencies exist in the language of Section II(c)(1) of the Guide which provides new language stating, "NEW: Free samples of prescription drugs need not be reported, but free samples of biologics and medical devices must be reported," and Section IV(b) detailing exemptions from disclosure stating, in part, "NEW: Free samples of prescription drugs (not all prescribed products) provided to a health care professional for free distribution to patients. . ." Through the Guide and Q and A document the Office is making clear and unsupported distinctions which are counter to the statutory definitions, intent, and clear statements in the Act.

For the reasons described in detail above, we believe the Office's interpretation of the Act and any subsequent implementation of the Guidance exceeds the authority granted by the Legislature under the Act regarding the disclosure of biologic samples. BIO requests that the guidance and the Q&A be revised accordingly.

Thank you for your consideration of these comments. We would welcome the opportunity to discuss these issues in-depth. Please contact Sandra Dennis at (202) 962-6673 or India Valentine at (202) 962-9514 if you have any questions regarding our comments.

Respectfully submitted by:

Sandra J.P Dennis
Deputy General Counsel

India Valentine
Director, State Government Relations

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