



NEW ENGLAND BIOTECH ASSOCIATION

Testimony of Paula Newton, Chairman,
New England Biotechnology Association

Re: Attorney General's Hearing on Advisability of Requiring
Disclosure of Free Samples of Prescribed
Products Given to Vermont Healthcare Providers
October 27, 2009 – Montpelier, VT

The New England Biotechnology Association (NEBA) respectfully submits the following comments regarding the Attorney General's hearing on the advisability of requiring disclosure of free samples of prescribed products given to Vermont healthcare providers.

NEBA is a 501(C)(6) non-profit, member driven organization comprised of state biotech associations, academic institutions, biotechnology and biopharmaceutical companies, and other organizations with a collective mission to support and grow the biotechnology industry in New England. Representing over 600 members from all six New England states, NEBA is committed to educating policy makers and the public about the biotech industry; promoting public policies that foster innovation; encouraging economic development in the biotech sector; and advocating continued patient access to life-saving and life-improving biotechnology medicines. The Vermont Biosciences Alliance (VBA) is partner of NEBA and shares its mission.

Under the provisions of Act 59 of 2009, passed as SB 48 (the "Act"), samples are exempt from disclosure. The Act directed the Attorney General, in consultation with the Vermont Commission on Health Reform, to conduct a study on the advisability of modifying the Act to require such reporting in the future. In our view, biopharmaceutical samples provide a major benefit to patients and physicians in Vermont by allowing a product to be tried and found effective prior to a significant patient or insurer expense. This is particularly critical for patients on biopharmaceutical products which can have a significant out of pocket cost to the patient and may be the only product available to treat a patient's disease.

Guidance Requirements Regarding Disclosure of Biologic Samples

In late September 2009 the attorney general distributed a revised guidance document and a revised Q&A that for the first time contained references suggesting that samples of biologics and medical devices are currently subject to disclosure. The Act does not include any reference to this type of disclosure. In fact, the "Legislative Findings" portion of SB 48, along with the Act's definition of a "prescribed product," clearly equate biologics with traditional, chemical-based pharmaceuticals.

To date, pharmaceutical samples are exempt from disclosure. Thus, we question under what statutory basis the Office of the Attorney General interprets the Act as requiring current disclosure of biological medicine samples. Because the guidance from your office appears inconsistent with the statute, we seek timely clarification on this matter.

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Federal Regulation of Samples

All aspects of pharmaceutical and biologic sample distribution and management are highly regulated by the FDA¹. While the Act fails to define samples, they are defined under federal law in the Prescription Drug Marketing Act (PDMA) of 1987 (P.L. 100-293, 102 Stat. 95). Under PDMA a sample is defined as follows: “Drug sample means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.” However, there are units of drugs and biologics that are provided to patients free of charge but which do not fall within the PDMA because they are not intended for promotional purposes. An example would include products provided under a compassionate use programs. For this reason, we urge the Attorney General to specifically define the term “Sample” under the Act and adopt the federal definition.

Additionally, because of the significant level of regulation already governing samples, we ask the Attorney General to be mindful that any further inconsistent state regulation will create a complicated and administratively burdensome additional layer of regulation. For this reason, NEBA believes it is critical that any potential requirement related to sample disclosure be consistent with federal regulations and, to the extent required, make use of that information manufacturers are already required to report to the federal government.

Proprietary Nature of Sample-Related Data

Finally, the distribution of samples is proprietary information that is highly valued by manufacturers, like those represented by NEBA. 18 V.S.A. Section 4632(4)(A) was modified by the Act to state “Information on allowable expenditures and gifts required to be disclosed under this section, which shall be presented in both aggregate form and by selected types of health care providers or individual health care providers, as prioritized each year by the office.” In the event the legislature amends the Act to include sample disclosure, NEBA urges the Attorney General recommend that samples be disclosed to the state only in the aggregate form and by type of provider but not by specific provider, subscriber or manufacturer.

Thank you for considering NEBA’s concerns on this issue and we look forward to hearing from you on the specific issue of biologics disclosure. Please feel free to contact us if you would like any additional information.

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¹ The following link provides an outline of federal regulations (Title 21 CFR § 203) governing prescription drug samples. (<http://ecfr.gpoaccess.gov/cgi/t/text/txt-idx?c=ecfr&rgn=div5&view=text&neode=21:4.0.1.1.4&idno=21#21:4.0.1.1.4.4.1.2>)