NEBA
NEW ENGLAND BIOTECH ASSOCIATION

January 19, 2009

Ms. LouAnn Stanton
Office of the General Counsel
Department of Public Health
250 Washington Street
Boston, MA 02108

Re: Written Comments - Proposed 105 CMR 970.000, *Pharmaceutical and Medical Device Manufacturer Conduct*.

Dear Ms. Stanton:

I am submitting these comments on the above-referenced proposed regulations (the "Proposed Rules") on behalf of the New England Biotech Association ("NEBA"). As the regional policy and public affairs voice for the biotechnology and biopharmaceutical community, NEBA represents state biotech associations, companies, academic institutions, and other organizations consisting of more than 600 entities.

As an initial matter, we support the comments of our partners the Massachusetts Biotechnology Council and the Biotechnology Industry Organization, which share our concerns over the breadth and reach of the governing statute at M.G.L. c. 111N (the "Act"), as well as the many ambiguities it introduces. We are also mindful of the resulting challenges faced by the Department in officially interpreting this law. Nonetheless, once the Department promulgates the Proposed Rules in accordance with this difficult legislative mandate, the Massachusetts biopharmaceutical industry will face the most comprehensive and onerous regulatory environment in the nation. While we remain concerned about the impact of such sweeping and radical rules here in Massachusetts, there will undoubtedly be a ripple effect across New England. Therefore, we urge you to adopt the following amendments to the Proposed Rules that, that in our view, will help mitigate the negative impact of this law on the New England biotechnology sector.

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First, we support the Department's election to interpret the disclosure requirements of Section 6 of the Act as limited to "sales and marketing activities." 105 CMR 970.009.1. In our view, such a clarification is consistent with the intent and scope of the Act. We recommend, however, that the Department further clarify that the definition of "sales and marketing activities" excludes certain expenditures that are in fact not related to sales and marketing. These include, for example, prescription drug rebates and discounts, free samples of prescription drugs intended to be used by patients, patient assistance programs, and contractual business transactions for patient services. Such an amendment would align Massachusetts disclosure requirements with those adopted in several other states.

Second, we remain concerned about the Department's apparent intent to apply the Proposed Rules to physician interactions occurring outside of Massachusetts. In our view, such an interpretation is unduly burdensome on companies participating in activities outside of this state, and also inconsistent with the intent of the Act. Applying the Department's interpretation, covered companies participating in events outside of this state will be responsible for identifying Massachusetts physicians for the purpose of complying with the uniquely stringent and comprehensive Massachusetts rules. Needless to say, this process would raise numerous and difficult challenges despite our members' best efforts and intentions for compliance. Moreover, in our view the language of the Act signals the Legislature's intent to limit its scope to activity within the Commonwealth. *See* M.G.L. c. 111N, § 1 (defining pharmaceutical or medical device marketers as those operating "in the Commonwealth."). Consistent with this language, the Proposed Rules should similarly apply only to covered activities taking place in Massachusetts. We urge the Department to adopt and clarify this limitation consistent with the intent of the Act.

Third and finally, the Proposed Rules do not provide sufficient guidance with respect to the calculation of the $50 threshold for reporting. 105 CMR 970.009.1. There is, for example, no indication as to whether this limitation is based on a single expenditure, or instead is to be calculated cumulatively per annum. In our view, the plain language of the Act requires that the limitation be applied per single expenditure. Given the complications that will undoubtedly

be associated with an already burdensome reporting requirement, we urge the Department to so clarify the Proposed Rules.

We appreciate the opportunity to share NEBA's concerns with the Proposed Rules. We look forward to working with the Department and the Administration on policies that will continue to ensure New England remains a global leader in the life sciences.

Sincerely,

Paula C. Newton

Paula Newton
Chair, New England Biotech Association

cc: Secretary Judy Ann Bigby, Executive Office of Health & Human Services, Commonwealth of Massachusetts
Commissioner John Auerbach, Department of Public Health, Commonwealth of Massachusetts
David Morales, Deputy Chief of Staff, Office of the Governor, Commonwealth of Massachusetts