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INDUSTRY ORGANIZATION

November 6, 2008

Secretary JudyAnn Bigby, MD
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Secretary Daniel O'Connell
Executive Office of Housing and Workforce Development
One Ashburton Place, Room 2101
Boston, MA 02108

RE: Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care.

Dear Secretaries Bigby and O'Connell:

On behalf of the more than 1,200 members of the Biotechnology Industry Organization (BIO), we are writing with regard to the promulgation of rules for the implementation of Chapter 305 of the Acts of 2008 (SB 2863) "An Act to Control Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care." We appreciate the opportunity to submit comments to ensure that the implementation of Chapter 305 does not have unintended consequences on bioscience research and development within the Commonwealth.

As one of the world's leading medical centers and biotechnology industry hubs, we acknowledge the need for Massachusetts to be at the forefront of implementing policies to improve health care. We are committed to working with the Department of Health to ensure that the regulations for Chapter 305 balance the original intent of the law - disclosure of sales and marketing expenditures - and do not impede or hinder bioscience research and development in the Commonwealth.

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Please accept the following recommendations:

Ensure that Section 14 does not require the disclosure of confidential proprietary information, impede medical research, or compromise the training or education of health care providers

The life science community would like to ensure that Section 14, Subsection 2 accommodates the need for legitimate research and development practices. We respectfully request that the following practices should be clearly exempted from disclosure requirements:

(1) the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;
(2) the purchase of advertising in peer reviewed academic, scientific or clinical journals;
(3) prescription drugs provided to a health care practitioner solely and exclusively for use by the health care practitioner's patients;
(4) compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or a clinical trial;
(5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

These activities are allowable per the bill, but it should be made clear that they are not required to be disclosed.

- Additionally, we would like to ensure the mandated data disclosure will not require companies to release confidential business information thus giving competing companies insight into clinical research programs. Disclosing this type of information puts Massachusetts-based companies, or any companies conducting research in the Commonwealth, at a competitive disadvantage. In Governor Patrick's letter signing Bill 2863 into law, he acknowledged the potential breadth of interpretation of sections of the bill but stated his confidence that the DPH will develop regulations that will not require the disclosure of trade secrets or proprietary information. We recommend that the DPH allow companies to designate information they submit per the disclosure requirements as proprietary trade secret information, defined as information "which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it." If companies are not permitted to appropriately designate certain of their information as proprietary trade secret information, it is difficult to see how the DPH would be able to determine what that company would consider proprietary or trade secret. The Department is simply not in a position to do so.

Consider a grace period for companies to comply with the law

We understand the effective date of this law is January 1, 2009. However, we ask the Department to consider the fact that not every company currently marketing products in the Commonwealth is

a member of PhRMA or AdvaMed and therefore may not have adopted the marketing codes put forth by those organizations. Many member companies of BIO, which are not members of PhRMA or AdvaMed, are committed to complying with the intent of Chapter 305, but may not endorse either of the above-mentioned marketing codes. Small bioscience companies may not even have the infrastructure or staff to compile and report marketing expenditures. Companies with only one product in the marketplace, or who license their products to other companies, may not be aware that they are bound by the "approved" marketing codes.

We respectfully request a grace period for companies that are not PhRMA or AdvaMed members to put in place the requisite infrastructure/staffing to compile the data necessary to comply with the law. We ask that the department consider deferring implementation of the disclosure elements of Chapter 305 until 2010. This will allow companies to staff a compliance department, create adequate procedures for disclosure, and to educate and inform their respective sales forces.

The infrastructure costs and proposed Fee Schedule will further add to the financial burden of small companies

Bioscience research and development is the one of the most complex and capital intensive endeavors that can be undertaken. Many biotechnology companies with products on the market have yet to become profitable companies. The recent financial crisis has further exacerbated the already tenuous nature of bioscience research and development. Of the publicly traded biotech companies, over 90% have experienced a significant reduction in valuation, many incurring losses of more than 50% of their market capitalization. Many companies are trading below their cash value and almost 40% have less than one year cash remaining. (Source: BioCentury 10/13/08)

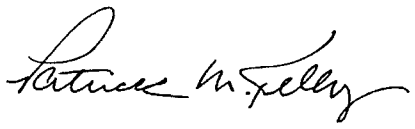
We are very concerned about increasing the cost burden on bioscience companies. Companies will already have to expend resources to put in place additional infrastructure and staffing necessary to comply with Chapter 305. We urge the department to carefully consider the details of the reporting requirements which may significantly increase the burden of reporting. Some of these issues were discussed at the industry meeting that was held on August 27, 2008. For example, with respect to the $50 threshold for reporting in the bill, it is yet to be determined whether that would be tracked as a cumulative amount over time or per interaction, which could require significantly more resources to track. There was also a discussion of reporting ranges rather than exact amounts, which again requires more infrastructure and staffing. Couple those costs with a yet-to-be-determined fee schedule to underwrite the cost of implementing the law, and companies are going to face additional challenges in leveraging already greatly diminished capital resources. We strongly urge the department to take these challenges into consideration when promulgating regulations. We feel that the aims of the bill can be accomplished – the disclosure of sales and marketing expenses – in a way that minimizes the financial impact to already struggling companies.

With the passage of innovative programs like the Life Science Initiative and the Commonwealth Care Program, the Commonwealth has sent a clear signal to the rest of the country that it is serious about promoting life science innovation and improving access to quality health care. We

ask the Department carefully implement this new law so as not to discourage future innovation and unintentionally impede the delivery of the newest and most effective treatments to physicians and their patients.

We appreciate this opportunity to share our members' concerns. We stand ready to work with the Department to provide additional information or further comment as necessary.

Sincerely,



Patrick M. Kelly
Vice President,
State Government Relations
BIO

cc: Kristen Golden
Office of Health and Human Services

Governor Deval Patrick