Ms. Anna D. Jeffers, Esq.
Legislative and Regulations Manager
Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215

Re: Wholesale Distribution Senate Bill 759 Workgroup: Target Date for Implementation of Electronic Track and Trace Pedigree Technology for Maryland

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment in response to the Board of Pharmacy's (Board's) request for information from stakeholders regarding industry readiness for the implementation date for the electronic track and trace pedigree technology for Maryland. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. In particular, many of our members are involved in the research and development of life-saving therapies and play a critical role in delivering treatments that both prolong life and reduce the burden of disease for patients worldwide.

Biotech Industry Securing the Safety of Maryland's Drug Supply

BIO commends the Board for its commitment to securing Maryland's drug supply against counterfeit drugs and biologics. The biotechnology industry has been proactive in combating counterfeiters, and has taken steps to secure drug and biologic products with holograms, color shifting dyes, and numerous other anti-counterfeiting technologies. In addition to these product-based security features, many companies have put in place integrated programs to protect their medicines. These processes often include:

- Full-time, dedicated staff to ensure company-wide vigilance in the fight against counterfeiting.
- Contractual requirements for distributors to buy directly and only from the manufacturer, and to report any evidence of product diversion or counterfeiting.
- The use of secure distribution practices to prevent a drug shipment from being stolen, tampered with, or otherwise interfered with in transit.
- Investigation of all complaints received from patients, health care providers, and others in the chain of distribution and use.

Current Industry Efforts to Create Electronic Track and Trace Pedigree Technology

In November 2007, BIO conducted a survey of our members to ascertain timelines and milestones toward creation of electronic track and trace pedigree technology[1]. It should

[1] The results of this survey were presented to the California Board of Pharmacy Enforcement Committee on December 5, 2007.

be noted that the creation and implementation of new electronic technologies to track the distribution of drug and biologic products is a tremendous undertaking for large pharmaceutical companies and small biotech companies alike. These changes in business practice will have profound consequences for the highly complex operations of manufacturing facilities, packaging lines, distribution centers, and the operations of third-party partners and logistics providers.

Our survey results show that the manufacturers we represent are actively engaged in the process of working toward the development of an interoperable track and trace system that will benefit the industry, the supply chain, and all consumers of drug and biologic products. There is no quick or simple solution to addressing this problem. Companies responding to our survey indicated diverse levels of readiness.

Barriers to Implementation of Electronic Track and Trace Requirements

As manufacturers work toward electronic track and trace, numerous implementation barriers have come to light. Specifically, companies continue to struggle with technological obstacles, a lack of clear standards, and business process limitations. At the forefront of concern for most manufacturers, and other members of the supply chain, is the fact that to date there is no uniform, agreed upon standard for track-and-trace technology. Additionally, companies are working to overcome the substantial business process system changes, validation issues, interoperability issues, and hardware issues.

There are also outstanding challenges related to packaging and labeling. Modifications will be needed for packaging lines and these projects require validation per FDA Good Manufacturing Practice (GMP) requirements. Packaging line modifications pose a significant concern due to the inherent risk that the validation will not prove successful and may result in lost manufacturing capacity that could lead to supply disruption.

There are also specific concerns related to biologic products. A particularly difficult issue facing manufacturers of biologic products relates to the extent that biologics will have to be reworked/relabeled to comply with the electronic track and trace laws.

Biologic manufacturers face major cold chain issues and impediments to ensure that track and trace technologies do not affect the biological stability of our products. Most biotechnology drugs are complex, protein-based biologics that are produced by living systems and are particularly vulnerable to changes in their environment. Biologic manufacturers must ensure their products are safe from chemical impurities following the application of the apparatus to be used to track-and-trace the product. With this goal in mind, manufacturers are deliberately and methodically working toward implementing the safest and most appropriate system possible. BIO member companies do not want to make premature decisions or adopt incomplete or inadequate track-and-trace technologies that may be detrimental to the pharmaceutical supply chain and consumers of prescription drugs.

Target Date for Industry Implementation

The biotechnology industry has developed more than 200 drugs and vaccines that have helped millions of people worldwide. Improving the lives and well-being of patients is

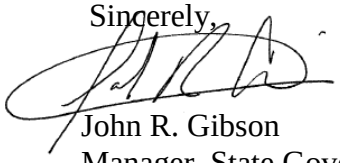
our first priority. The adoption of electronic track and trace technology should support patient safety and public health. However, it remains unclear what effect currently available track and trace technologies will have on biologic medicines. In order to ensure that Maryland residents get the safest, most effective medicines available, additional time is needed to study what impact track and trace technologies will have on our industries products.

On behalf of the biotechnology industry, including the hundreds of biotechnology companies located in Maryland, we respectfully request that the Board exercise its authority to delay the establishment of a target date for implementation of electronic track and trace pedigree technology. The biotechnology industry will continue to work with all segments of the supply chain, ensuring that the standards, distribution processes and technologies employed will further protect the public.

Conclusion

We thank the Board for the opportunity to provide our comments and look forward to continuing to work with the Board and all members of the supply chain to fight counterfeit drugs. If we may be of further assistance on any of the topics addressed above, please do not hesitate to contact us.

Sincerely,



John R. Gibson
Manager, State Government Relations
Biotechnology Industry Organization (BIO)