

January 9, 2008

California State Board of Pharmacy
1625 N. Market Boulevard
Suite N 219
Sacramento, California 95834

Re: Submission Regarding Implementation Date of California ePedigree Laws (Bus. & Prof. Code, §4163.5)

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 January 1, 2009 implementation/compliance date for the ePedigree laws. 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.

Counterfeit Pharmaceuticals Pose a Threat to the Public Health

BIO commends the Board for its commitment to securing California's drug supply against counterfeit drugs and biologics. Protection of the public is a priority for BIO and all of the pharmaceutical and biologic manufacturers we represent. The American drug distribution system is the most secure in the world. Indeed, several of our member companies that experienced counterfeit attacks in 2001 and 2002, have reported that they have not detected any counterfeits of their products in the U.S. pharmaceutical supply chain since then. However, it is noteworthy that there has been an increase in counterfeiting activity outside of the U.S. Due to the efforts of the U.S. Food and Drug Administration (FDA), drug manufacturers, distributors, and patients have high confidence that the drugs they are prescribed are safe and effective.

Nevertheless, the presence of any amount of fake, adulterated, sub-potent, or super-potent drugs in the U.S. pharmaceutical distribution system poses a threat to the public health. These dangers can be even greater with counterfeit or adulterated biologic drugs, which must be injected or infused directly into a patient's bloodstream. Our industry has been proactive in combating counterfeiters, and the industry has taken productive 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.

However, there is an opportunity for industry to do more to address the problems and secure the drug supply to ensure continued patient safety.

Implementation of ePedigree Technologies

BIO recognizes that there are vulnerabilities within certain parts of the supply chain that could be remedied through the use of ePedigree technology. Implementation of electronic track-and-trace technology would help create transparency, disclosing the origin and distribution history of drug and biologic products. BIO supports its use within the drug distribution system in a responsible manner. BIO believes that fully implemented electronic tracking from the manufacturer to the pharmacist will reduce any gaps in the supply chain which could lead to opportunities for counterfeit medicines entering the distribution system. If products carry serialized machine-readable tags, their authenticity can be verified through the electronic pedigree at every level of distribution. Indeed, such serialized machine-readable tags could also be used effectively to authenticate the drugs being dispensed at the pharmacy or clinic, thereby protecting patients with a single-system, negating the need to create a complex interoperability matrix.

Current Industry Efforts to Comply with the 2009 Implementation Date

In November 2007, BIO and the California Healthcare Institute (CHI), conducted a joint survey of our collective members to ascertain timelines and milestones toward compliance with the ePedigree laws¹. Overall the results revealed that the manufacturers we represent are working diligently toward implementing the changes in business practice that will be required to bring them into compliance with the ePedigree mandate. It should 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. With so many business components directly

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

affected by the adoption of an electronic track-and-trace system, great care and deliberation must be employed to ensure that a safe, appropriate, and cohesive structure is put in place.

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 California 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. Most of our surveyed companies have indicated that they are currently in the planning phase, testing various technology applications internally. Only a small percentage of our responding companies indicated that they are currently implementing track-and-trace technology for all or a limited number of product lines. There are many technological and production hurdles for manufacturers to overcome before any system can be implemented. Companies continue to develop, deploy, and adopt standards that will serve as the basis for a new supply chain that will ensure safe, secure, and reliable pharmaceutical distribution.

Barriers to 2009 Implementation of ePedigree Requirements

As manufacturers work toward the January 1, 2009 compliance date, 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/re-labeled to comply with the ePedigree laws. Biologic manufacturers face major cold chain issues and impediments. BIO is also concerned that biological stability will be impacted. Most biotechnology products 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 California consumers of prescription drugs.

Industry Members are Unable to Meet the January 1, 2009 Compliance Date

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. The vast majority of our member companies are working to implement the necessary technologies to meet the compliance date. However, it has become clear that it will not be possible to create an interoperable system that can ensure effective delivery of medicine to patients by January 1, 2009. In order to accomplish this goal and not deprive California patients of needed medicines, additional time is needed. **BIO, on behalf of our membership, requests that the Board exercise its authority to extend the date for compliance to a new date of January 1, 2011.** The biotechnology industry will continue to work with all segments of the supply chain to implement the law, ensuring that the standards, distribution processes and technologies employed will further protect the California 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,



Patrick M. Kelly
Vice President
State Government Relations
Biotechnology Industry Organization (BIO)