

January 09, 2008

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

RE: CHI Request for Extension of Implementation Date of California ePedigree Laws  
(Business & Professions Code Section 4163.5)

Dear Sir or Madam:

The California Healthcare Institute (CHI) welcomes this opportunity to submit comments to the California Board of Pharmacy (Board) regarding the implementation of the state's electronic pedigree requirements scheduled to go into effect on January 1, 2009. Business and Professions Code section 4163.5 vest the Board with the authority to extend the date for compliance with these requirements to a new date of January 1, 2011, if the Board "determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state." Based on a survey of our member organizations, it is clear that while some entities may be able to meet the individual requirements needed for implementation, the supply chain as a whole will not be prepared to implement an interoperable system sufficient to safely and efficiently provide patients in California access to the medicines they need by January 1, 2009. Accordingly, CHI respectfully requests that the Board exercise its authority under the law to delay implementation.

California is the worldwide headquarters for biomedical research and development. As the leading biomedical public policy association in California, CHI represents over 260 of the state's premier biotechnology, pharmaceutical, medical device and diagnostics companies, as well as the leading academic and non-profit research institutions. Our membership represents the broad spectrum of the industry through all stages of the product development pipeline. Forty-two percent of CHI's member companies currently have products on the market, ranging from inhaled and infused biologics, injectables, vaccines, implantable medical devices, diagnostic testing equipment, and traditional prescription drugs.

CHI's mission is to advocate policies that promote medical innovation, access to the best medicines and therapies, and promote the health and well being of patients. CHI strongly supports the Board's goal of protecting the citizens of California from the threat of counterfeit drugs. Our members are committed to providing patients access to safe and effective therapies and have implemented and continue to update policies and procedures to achieve that goal. We are, however, concerned that premature implementation of an electronic pedigree system may disrupt the supply chain, jeopardizing patients' access to the medicines they need. This risk far outweighs any risks that exist in the current system. We remain committed to working with the

Board and other stakeholders to address current challenges to meet the goal of a safe and efficient supply chain.

The changes that manufacturers must put into practice to comply with the requirements of the law are extensive. Creating and implementing a system to track all individual units of products moving through the supply chain is an enormous undertaking for companies of all sizes. Changes to current business practices will affect manufacturing facilities, packaging lines, and distribution centers, as well as operations of third-party partners and logistic providers. With so many business components directly affected by electronic pedigree requirements, great care and deliberation must be taken in order to ensure that a secure and effective system is put in place – a system that functions smoothly, with minimum disruption.

In preparation for the most recent Board Enforcement Committee meeting on December 5, 2007, CHI in conjunction with the Biotechnology Industry Organization (BIO) conducted a survey of our memberships to address the Board's request for more information from industry on current activities and the challenges to meeting the requirements of the law. The results of this survey were presented to the Enforcement Committee on December 5 and have been submitted into the public record. From the results of the survey it is clear that CHI's members are working diligently towards implementation. A small percentage of respondents have or are currently running track-and-trace pilots with outside parties on all or a limited number of product lines, but the majority today remain in the planning phases. They are working internally and with service providers, testing various technology applications on their product lines to gain a better understanding of what suits their particular businesses and products. Two-thirds of those surveyed expect to begin outside pilots with other members of the supply chain within the next year. Survey respondents voiced specific reasons for delaying pilot tracking systems.

### **Technology Concerns**

The major issue to be resolved prior to widespread adoption is industry consensus on an appropriate interoperable technology platform. At present, there are no agreed upon standards for electronic pedigree. Companies are testing a variety of technologies, including RFID (high and ultra-high frequency), 2-D barcodes and others. Absent agreement on standards that will provide interoperability, there is no way to ensure a safe and effective drug supply chain. By placing tags or barcodes on products, an individual company may be technically compliant under the law. But this serves little purpose if downstream partners are unable to read them.

Lack of a uniform technology standard has the potential to cause significant disruption to the supply chain. If required to meet the January 1, 2009 implementation deadline, a company has limited options. In order to sell their product in the state a company will have to choose and then implement a specific technology. With no agreed upon standard there will be a variety of platforms put forth in the beginning. Over time one technology standard is sure to rise above the others. This puts companies in a very difficult situation. Some companies will be fortunate enough to be able to overcome the lost investment of millions of dollars, however, there is the very real possibility that companies working on slimmer margins will be forced out of business. As a last resort, companies may have to make a business decision to pull their products from the California market until they have a clearer idea of which technology to invest in. Either way, pushing forward without an agreed upon standard is sure to hurt California's patients by limiting their access to the medicines they require.

### **Reliance on Third Parties**

Solution Providers – With the January 1, 2009 deadline looming there is no feasible way for technology suppliers, even if a technology standard is developed, to provide all members of the supply chain with the hardware, software, and support necessary to implement an effective system. Smaller companies are concerned that, under time pressure, suppliers would overlook them in favor of larger customers.

Business Partners – In addition to activities and processes performed in-house, the majority of our members rely on third party manufacturers, packagers, labelers and carton suppliers to move products into distribution. In our survey results there was significant concern regarding these third parties' ability to comply and move product into the marketplace. Even if these business partners can become compliant, there was significant concern on the part of smaller companies about their needs being met.

### **Production Issues**

The manufacturing and production of medicines is a complex and carefully monitored process. Implementation of the law will effectively require all manufacturers to redesign and reconfigure current manufacturing and packaging lines. These processes are regulated by the Food and Drug Administration (FDA) and will require validation under the agency's Good Manufacturing Practices (GMP) requirements. Any change in manufacturing processes may invalidate a company's GMP certification. The result of this would be a disruption of manufacturing that would reduce or eliminate the supplies of medicines for patients. In addition, there is a lack of surplus packaging capacity required to ensure a continuous supply of product while the packaging lines are being reconfigured. This will be even more prevalent as all entities in the state attempt to meet a single deadline.

The biomedical industry in California is committed to improving lives and protecting patients by providing access to safe and effective therapies. The passage of the state's electronic pedigree law will build upon current safeguards established by the FDA and upheld by manufacturers and distributors that provide patients with the confidence that their supply chain is the safest in the world. While we fully support the Board's goal of protecting the integrity of the supply chain, we strongly believe that moving forward with the January 1, 2009 implementation date will jeopardize access to medicines for millions of Californians. In consequence, CHI respectfully requests that the Board exercise its authority to extend the date for compliance.

Thank you for the consideration of this request and we look forward to continuing our work with you to protect the citizens of California. Please do not hesitate to contact us if we may be of any assistance to you.

Sincerely,



David L. Gollaher, Ph.D.  
President & CEO  
California Healthcare Institute