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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

DECISION OF THE CALIFORNIA STATE BOARD OF PHARMACY PURSUANT TO BUSINESS & PROFESSIONS CODE SECTION 4163.5

March 25, 2008

The California State Board of Pharmacy is very aware that California, the United States, and the world face a persistent and increasing threat to our prescription drug supply, from counterfeit as well as misbranded, adulterated, or diverted drugs. Recent incidents involving contamination or counterfeiting by overseas suppliers of the blood-thinner Heparin underscore the importance of a safe and secure supply chain. Yet federal and state efforts to date have not brought an end to the efforts of counterfeiters or others to impact the U.S. supply chain. For instance, recent statistics from the Food and Drug Administration show that in the four fiscal years from 2004 to 2007, its Office of Criminal Investigations opened over twice as many counterfeit drug investigations as it had in the four prior fiscal years, whereas the number of investigations opened in 2003 was itself a five-fold increase over the number opened in 2000. This is undoubtedly one of the reasons that in July 2003 the FDA established its Counterfeit Drug Task Force. The full scope of the problem is unknown, but the Center for Medicines in the Public Interest projects that global revenues due to counterfeit drug sales will reach $75 billion by 2010, a 92 per cent increase from 2005, and the World Health Organization has estimated that counterfeit drugs may comprise anywhere from up to 1% of sales in developed countries to up to 10-70% of sales in many developing countries.

Against this backdrop, California has taken a leading-edge approach to addressing vulnerabilities in the supply chain, by enacting legislation which, among other things, requires a comprehensive electronic pedigree system, to track and trace the passage of prescription drugs through the entire supply chain. The comprehensive California model for electronic pedigree has received acclaim and support from all segments of the industry, from the FDA, and from other states, as the most effective means to add security to the pharmaceutical supply chain. In the innumerable meetings with industry convened by the Board to facilitate understanding of and compliance with the law since its initial passage in 2004, the Board has been roundly assured of the value of this model.

Yet this Board also recognizes that this sort of comprehensive model is not easily implemented, and that it has required and will require significant efforts by industry participants. These efforts have and will include an unprecedented level of communication and cooperation by supply chain partners. The response to the California law from industry has been impressive. While not all of the participants in the supply chain have engaged willingly in the process, and while an earlier or more uniform focus on full implementation by the industry would have been desirable, the Board is nonetheless cognizant of and grateful for the good faith efforts shown by many companies.

The Board has heard from a not-insignificant number of supply chain partners that they could be ready for implementation of the electronic pedigree requirements by January 1, 2009, the present deadline in the law. The Board is particularly grateful for the efforts of these companies. Their examples demonstrate the feasibility and utility of compliance with the pedigree requirements.

However, the Board has also heard from a wide majority of the industry, most recently in written submissions made prior to the January 23-24, 2008 meeting and prior to today's meeting, and in oral presentations given at both meetings, about obstacles to compliance by January 1, 2009. In addition, even those companies that could themselves be ready by January 1, 2009 acknowledge that their own readiness will to some degree depend on or be hampered by others' unreadiness.

In nearly every case, the companies asserting an inability to be ready for compliance by January 1, 2009 have offered concrete assurances to the Board, backed by statements of their plans that are in many cases illustrated by specific timelines and milestones, that they can and will be ready for full implementation by January 1, 2011. Many members of the industry have asserted that an additional two years would be crucial to development of the necessary technical infrastructure.

After consideration of all of the evidence presented to the Board, both by supply chain partners and by the numerous technology vendors that have made written or oral presentations before the Board, the Board concurs that the additional two years to January 1, 2011 is, in the language of Business and Professions Code section 4163.5 "require[d]" in order to effectively "implement electronic technologies to track the distribution of dangerous drugs within the state." Though it appears that many of the technical solutions have already been developed, and that there are an impressive number of very significant technology vendors involved in this endeavor, the pace of development and implementation has accelerated mightily in the last six to eighteen months, and many of these innovations and applications would benefit greatly from additional time to mature. This is perhaps particularly true with regard to Radio Frequency ID (RFID) technologies.

The industry has repeatedly assured the Board that delay will not diminish its recent momentum, and that the additional time will simply allow for greater development and refinement of existing technical standards, and greater maturity of technologies. Also, given the scale of the pedigree project, a delay will allow a more measured scale-up of implementation. It will also allow some time for the Board to continue its partnership work with the FDA on the development of federal unique identifier standards, to ensure that California and federal standards remain consistent.

Lastly, the Board has concluded that in the absence of such delay, the California drug supply and potentially the entire U.S. drug supply may very well be negatively impacted, both or either with regard to availability of life-saving medicines and/or with regard to access to and affordability of those medicines, by an imperfect or non-uniform implementation of pedigree requirements. For the moment, the Board concludes that its primary duty to protect the public is better served by a delay permitting a less disruptive implementation, than by a rush to secure industry compliance.

Accordingly, based on the effort exhibited thus far by industry, the expectations of the Board that this effort will continue unabated in the intervening period, the express assurances by industry of full implementation by January 1, 2011, and the Board's conclusions that more time is necessary for technology development and adoption and that in the absence of such additional time there is a significant risk of disruption of the drug supply, by vote of the members of the Board held this March 25, 2008, the Board exercises the authority delegated to it by the Legislature in Business and Professions Code section 4163.5 to delay the date for implementation to January 1, 2011.

Dated: March 25, 2008

William Powers

WILLIAM POWERS
President, California State Board of Pharmacy