

January 17, 2008

Dear Esteemed Members of the California Board of Pharmacy:

As the California Board of Pharmacy prepares for its January 23-24 meeting in San Diego, the National Coalition of Pharmaceutical Distributors (NCPD) appreciates the opportunity to provide the following commentary concerning the prospect of extending the deadline for the implementation of California's electronic pedigree requirements. Representing the interests of more than 4,000 secondary/independent pharmaceutical distributors nationwide, the NCPD believes that patient safety and consumer protection must be the Board's highest priority when considering the possibility of extending the implementation date to January 1, 2011.

At the same, the NCPD recognizes the practical realities confronting the various elements of the pharmaceutical industry as they seek to become compliant with California's law. The following issues have presented the pharmaceutical industry with legitimate challenges to meeting the January 1, 2009 deadline: 1) the availability and effectiveness of industry-compatible tracking equipment and software; 2) costs associated with purchasing tracking equipment and software; 3) costs associated with hiring and training employees to administer the tracking process; and 4) the seamless interoperability between the various segments of the pharmaceutical industry required to provide pedigree.

With this in mind, the NCPD firmly believes that the measures necessary to become compliant with California's pedigree law are far from insurmountable. Indeed, the secondary/independent sector of the pharmaceutical distribution industry is presently required to provide pedigree verification for every transaction involving prescription pharmaceuticals. As such, the NCPD is confident that some degree of pedigree implementation is currently possible.

In the absence of the ability to fully implement this statute by January 1, 2009, the NCPD maintains that the consumers and patients of California should enjoy at least a partial degree of protection associated with tracking the chain of custody of pharmaceutical products being distributed throughout the state. More precisely, the NCPD supports the concept of a "phased-in" implementation of California's pedigree law. As part of this approach, pharmaceutical products that are the most susceptible to counterfeiting and adulteration could initially be subject to some basic form of pedigree verification (e.g., paper pedigree; or, electronic tracking of lot numbers and expiration dates), with the remaining products following suit as soon as feasibly possible.

In this manner, the citizens of California would enjoy some of the same fundamental protections as their counterparts in the 18 other states that are currently administering pedigree laws and requirements. It is acknowledged, however, that the Board does not have the authority to extend the pharmaceutical industry the ability to gradually implement the requirements of California's pedigree law. Recognizing the Board's lack of statutory flexibility to impose such a "phased-in" program, it is suggested that every effort to engage the state legislature and seek this authority should be exhausted. Even a paper pedigree back to the original AD is better than no pedigree at all for another two years in California. Considering the Board's oft-repeated statements that its mission is first and foremost to protect the California consumer, NCPD cautions against letting the Perfect become the enemy of the Good. California's consumers will continue to be at risk so long as California lacks at least *some* sort of track-and-trace mandate.

Thank you for your consideration of the concerns outlined in this letter. As always, the NCPD welcomes the opportunity to provide the Board of Pharmacy with any assistance and/or information that may be helpful as it considers the issue of pedigree verification.

Sincerely,

Karen Moody  
President