

**Written Testimony of David Wilcox on behalf of the  
National Community Pharmacists Association before the  
Enforcement Committee of the California Board of Pharmacy  
Hearing on E-pedigree  
December 5, 2007  
Sacramento, California**

**I. Introduction**

Members of the Enforcement Committee (the Committee), on behalf of the National Community Pharmacists Association, I thank you for this opportunity to testify on E-pedigree issues.

NCPA represents the nation's independent pharmacists, including the owners of more than 23,000 pharmacies, with 75,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care. In California we represent 2,215 independent pharmacies and their over 30,000 employees.

Many NCPA members are California pharmacists like me. I live in Fresno and am currently the president of PharmKee, Inc., a group of 10 pharmacies serving rural areas including Colinga, Caruthers, Easton, Lodi, Madera, San Joaquin, Mendota, Kerman and Fresno. I have been a practicing pharmacist since 1979 and am active in my community with the Chamber of Commerce, Planning Commission and the California Pharmacists Association, of which I am a former president. Serving rural patients is the primary focus of our pharmacies. We further specialize in serving the health care needs of low-income families.

**II. The January 1, 2009 Implementation Deadline Should be Extended to January 1, 2011**

We support the need for a safe drug chain of custody. NCPA wants to work with the Committee and the California Board of Pharmacy (Board) to facilitate a smooth transition to the new system. However, in order for independent pharmacists to obtain and maintain the E-pedigree technology, there must be a mechanism of financial support for community pharmacy to offset the monetary costs associated with implementation of an interoperable electronic system.

As you know, we are the end of the line in the drug chain of custody and are concerned that the lack of interoperability will force pharmacists to purchase multiple track and trace technologies – readers, scanners, etc. – with associated upgrades and to spend time training staff to understand and use the equipment and systems. It will also be necessary to spend considerable administrative time in our pharmacies managing any track and trace functions. None of these activities are being financed by the state. The state has, in effect, handed community pharmacy an “unfunded mandate!” At the end of the day, NCPA believes the public good is best served by implementing E-pedigree only when there is a complete, interoperable electronic system that can truly prevent, in an economical fashion, counterfeit drugs from entering the system.

**B. The E-pedigree technology is not ready -- and the public good is best served by delaying implementation**

NCPA is unaware of any vendor that has the technology ready to be purchased and operated at an affordable price. More importantly, there is no evidence that the existing technology is universally interoperable. Since the California law requires that E-pedigree shall be “created and maintained in an interoperable electronic system, ensuring compatibility throughout all states of distribution” *Section 4034(a)* and certain companies are not prepared to implement E-pedigree, then by definition, there is no single, interoperable system. Therefore, anyone who tries to move or sell prescription drugs would then be in violation of the law. *Sections 4034(c), 4263(c), 4263(d), 4034(i)*.

NCPA has advocated for a single, federal, standardized and interoperable system of pedigree, serialization and electronic track and trace technology at the retail level that requires only one set of equipment to facilitate. We believe that the California law largely mandates interoperability, but it can be argued that it does not explicitly mandate a single interoperable technology. The pharmaceutical industry appears to be proceeding with the understanding that multiple technologies and devices are in compliance with the law. We are concerned that enforcing the current deadline would cause too many implementation problems as a result of this situation.

The statutory matter before the Board is whether, and if so, in what manner, to extend the implementation date. Ideally, NCPA believes that the pharmacy would be the end recipient of the chain of E-pedigree custody and that E-pedigree requirements are best designed to be implemented up to the wholesaler level. We recognize, however, the state of California law and advocate two approaches that will help to successfully implement E-pedigree issues:

- 1) NCPA advocates a phased-in approach to meet an extended implementation date, which places priority on high-risk drugs that are most susceptible to counterfeiting and diversion. While NCPA acknowledges that phased-in implementation may not be an ideal solution, it appears that a phased-in approach is necessary. The Board must decide whether phased-in implementation would begin before or after January 1, 2011.
- 2) Whenever implementation begins, the requirements should become binding at the retail pharmacy level after it is mandated upstream. Additional implementation time of one year or more will help address the magnitude of the logistical, administrative, financial and quality of care issues of requiring implementation of the new technology at the retail pharmacy level.

**C. The Cost to Pharmacy should be recognized and addressed in the implementation process.**

As E-pedigree is implemented, independent pharmacists should be compensated for the costs associated with the purchase of multiple technologies. The costs to a retail pharmacy to comply with E-pedigree requirements are estimated to be anywhere between \$10,000 to \$40,000. These costs include obtaining the hardware, software and staff training necessary to administer, monitor and maintain the system as required by law. *Section 4169(5)*.

The above-stated estimate is consistent with implementation estimates that were presented by retail pharmacies to the California Board of Pharmacy at its September meeting: Chain pharmacies have estimated initial per store implementation costs at \$25,000 - \$35,000 with an additional \$5,000 - \$6,000/year. One chain pharmacy stated that even once the plans of upstream trading partners are known, an additional 15 - 18 months would be necessary to implement E-pedigree. Another chain pharmacy projected that it would take \$54 million for one distribution center covering 591 pharmacies to achieve end-to-end serialization. They, too, are hindered by the lack of preparation by upstream manufacturers. Another chain pharmacy concluded that its pharmacies cannot support multiple technologies and systems considering the scope of trading partners involved, nor can they deploy multiple technologies at each location to ensure connectivity with each trading partner. For those of us in the independent pharmacy sector the consequences are even worse because we are small businesses and do not have the resources of a national chain pharmacy.

I understand that the Committee and Board would like to receive detailed projections and analyses. We know that the Board would like to have active industry involvement in evaluating costs, such as through participation in pilot studies. To the degree that independents are able to participate in such studies, NCPA would be glad to facilitate such participation.

What concerns me, however, is the apparent acceptance of Walgreen's September statement that it is preparing a "very big catcher's mitt" to catch the variety of serialization approaches that it expects to receive. Walgreens stated their intent to adapt to the variety of serialization technologies that various manufacturers may choose to use. Independents simply cannot adapt to the variety of pedigree, serialization and track and trace technology that will be used under the current status of preparedness for implementation.

NCPA believes that it will not be in the best interest of public safety to proceed with implementation when it has been demonstrated that the undeveloped nature of the technologies falls far short of the interoperability as required by California law to be achieved in time to ensure compliance with the January 1, 2009 date. The Board has the authority to mandate an extension of the deadline, but the Board cannot by fiat say there is compliance with the law if E-pedigree is implemented without true interoperability. Not only is it good public policy to extend the implementation date, but requiring universal E-pedigree to begin without ensuring interoperability runs counter to the California law.

In 2006, the first year of implementation of the Medicare prescription drug program, 1,152 independent pharmacies in the United States were closed or sold to other companies. After five years of stability in the independent sector, we witnessed this five percent decrease in community pharmacies in just one year. The costs associated with implementing E-pedigree will be too high for some California pharmacists to absorb. This means even more small business pharmacies will be put in jeopardy. This will harm patient access to prescription drugs and consultation care.

**D. Recent Federal Law is Another Reason to For the Board to Proceed Prudently to Ensure Government Mandates do not Run Ahead of Universal Standards and Technological Developments**

To review, the pedigree language passed by Congress this past fall included provisions that require the FDA Secretary to develop a standardized numerical identifier "(which, to the extent

practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging . . . at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.” *P.L. 110-085, Sec. 913*. The Secretary must do so by late March, 2010 (30 months after enactment).

In order to avoid the very real possibility of implementing a California standard only to face a different federal standard, it would be helpful for the Board to extend the implementation deadline to the date authorized by Section 4163.5 -- January 1, 2011. Choosing the extension does not mean that pedigree preparation should or will come to a halt. Instead, the interagency collaboration and industry consultation as mandated by the federal law will give affected parties an opportunity to work together to create a uniform system of pedigree within the confines of both the federal and California laws. NCPA would appreciate strong support by the Board for the interest of independent pharmacies and their patients in the state and federal process.

The need for careful work to harmonize the federal and California law is highlighted by the federal law highlighting RFID as a promising technology<sup>1</sup>, even though the FDA has historically not been receptive to RFID technology. It is unknown how the Secretary will react to the most recent discussions about track and trace technology in California. E-pedigree and track and trace technologies are not a well-developed field either in terms of technological or commercial acceptance. NCPA believes there is a definite benefit to extend the deadline to allow the pharmaceutical community better opportunity to plan likely federal developments before California E-pedigree is implemented.

### **III. Inference**

There does not appear to be a universal definition of inference. NCPA takes inference to mean that a transported container has a label that identifies the items within, but the recipient is not required to physically identify that each contained item matches up with the list of items. The recipient of the container is, however, allowed or required to “infer” that the container contains the listed items.

The California law requires that E-pedigree tracks each dangerous drug at the smallest package or immediate container distributed and received and that there must be a unique identification number established at the point of manufacture that is uniformly used.<sup>2</sup> Allowing for inference appears to be a concession that “smallest package serialization” is not obtainable. Where unit level serialization is not possible and inference is instead needed, NCPA does not believe that the recipient of the container – including pharmacists – should be required to receive the container and accept any liability that might arise from accepting a container whose packing list does not match the products contained therein.

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<sup>1</sup> *P.L. 110-085, Sec. 913, amending Chapter V of the Federal Food, Drug, and Cosmetic Act at new 21 U.S.C. 505D(b)(3)*.

<sup>2</sup> “A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and relieved by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.” *Section 4034(d)*.

“...uses a unique identification number, established at the point of manufacture... that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.” *Section 4034(i)*.

NCPA questions whether true safety is adequately protected by inference. However, if the Board sees the need to have inference then a pharmacist and other recipients of “inferred” containers should be held harmless for the contents of the container.

#### **IV. Grandfathering**

NCPA supports a clean and easy to remember “grandfathering” rule – permitting non pedigree drugs manufactured before the final implementation deadline to be moved and sold up to one year after the implementation date. At that time, pharmacies should have at least a six month window in which to return any non-pedigree product to wholesalers, distributors or manufacturers for credit.

#### **V. Conclusion**

NCPA appreciates this opportunity to discuss the national interests of independent pharmacy in California E-pedigree issues. Extending the implementation date is just one step in the E-pedigree process, and NCPA looks forward to continued dialogue with the Board on these issues.

Because of the inability at this point to achieve interoperability, the costs involved, the effect on independent pharmacies and the potential for confusion and harm to patients/consumers, NCPA requests this Committee to recommend to the Board that it exercise its discretionary powers pursuant to Section 4163.5 to extend the implementation date to January 1, 2011, with additional time for pharmacy compliance.

NCPA also has the following requests:

- 1) that the Board only implement inference with a pharmacy hold-harmless provision
- 2) that “grandfathered” non-pedigree drugs may be distributed up to one year after the implementation date followed by six or more months in which to return any pre-pedigree products for credit