

**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/
NCPA submission for the Board's January 23 – 24, 2008 meetings**

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 technology¹, 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.² 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 –

¹ *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)*.

² “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)*.

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.

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



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January 9, 2008

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**Re: Board of Pharmacy Meeting (Jan. 23-24, 2008)
E-Pedigree Comments**

To the Members of the California State Board of Pharmacy:

Novartis Pharmaceuticals Corporation ("Novartis") submits this letter in response to the California Board of Pharmacy's ("the Board's") request for comments on the feasibility of complying with California's electronic track and trace and unit-serialization requirements for prescription drug products sold in California by January 1, 2009. This letter serves to reinforce discussions held between Novartis representatives and the Board's executive staff on September 5, 2007.

Novartis, along with its affiliated companies, is a leader in offering innovative drugs to patients in California for serious or life-threatening medical conditions in a wide variety of therapeutic areas, including cardiovascular, oncology, neuroscience, and infectious disease. We share the Board's dedication to patient safety and strongly support efforts to protect patients by enhancing the security of the pharmaceutical supply chain. For the past three years, we have taken proactive steps and expended significant time and resources to determine how best to generate electronic pedigrees and apply unit-serialization to each of our prescription drug products. In addition to the complexities of implementing unit-serialization across 53 drug product families and 45 packaging lines, we have had to resolve, and are still in the process of resolving, tremendous technical and logistical challenges.

For these reasons, Novartis has adopted a phased-in implementation approach which is based on a variety of factors related to the risk of counterfeiting and diversion to each product. Based on our projected timelines, three of our brands will be in full compliance with California's requirements by January 1, 2009, and we are committed to continuing to implement unit serialization to our remaining products as quickly as possible. However, our best estimate is that substantial additional time and effort will be required to bring our entire product line into full compliance. We therefore request that the Board exercise its authority under the California Business and Professions Code and extend the January 2009 deadline.

In support of our request, we articulate why Novartis is unable to meet the 2009 deadline, the efforts Novartis has taken to date, the technical and logistical

challenges associated with implementation, the continuing steps needed after 2009 to achieve full compliance. Most importantly, we explain how the public would be better served by extending the deadline.

I. COMMENTS

Novartis is part of a multinational family of companies that develops, manufactures, and supplies drug products to patients around the world. In the United States alone, we market 53 products that are packaged in more than 300 packaging configurations, manufactured on 45 drug packaging lines (including 23 packaging lines operated by contract manufacturers), located at 15 different sites in six countries.

A. Non-e-pedigree Initiatives

Because of the breadth of our operations, Novartis has undertaken several major supply chain security actions, other than e-pedigree initiatives, to protect our products' supply. For instance, we have implemented an extensive transportation security protocol under which all products have unique packaging configurations, text, and graphics, and we are actively pursuing other overt and covert product authentication features and methods. Most of our products are shipped via dedicated, direct delivery, sealed modes of conveyance, such as trucks and cargo containers, and we use a limited number of carefully vetted carriers who are not permitted to contract their services to shipment brokers. An electronic track device is affixed to all dedicated truck shipments for active 24-hour surveillance. For added security, Novartis engages personnel for covert surveillance of random shipments to assure that these shipments are not diverted. Novartis also tries to manage the distribution supply chain through contractual arrangements with customers (i.e., wholesalers). Further, procedures are in place to stop any suspicious orders before they are filled or shipped.

Novartis also is a certified member of the Customs-Trade Partnership Against Terrorism (C-TPAT), a voluntary supply chain security initiative between businesses and the U.S. Customs and Border Protection to improve the international drug supply chain and strengthen U.S. border security. Through this initiative, business partners are asked to ensure the integrity of their security practices and communicate and verify the security guidelines of other business partners within the supply chain. As such, Novartis uses only C-TPAT certified carriers and supply chain partners. We do not route products intended for the U.S. market through suspicious ports of entry, and we do not ship products through Free Trade Zones, which typically have relaxed restrictions and therefore are an increasingly popular pathway for the entry of counterfeit drug products.

B. Substantial Efforts to Comply

For the past three years, Novartis has actively worked to implement an e-pedigree solution in preparation of the impending requirements in California. We recognize that the Board has accepted the GS1 EPCglobal Drug Pedigree Standard and that several vendors have indicated software programs are available to help companies

comply with the California requirements. Although this may be the case, in our experience, the implementation of unit-serialization and electronic track and trace has been significantly more complex than simply purchasing and executing a software program. A unit-serialization and electronic pedigree program is unique not only to each company, but also to each manufacturing facility, packaging line, and product. Further, like other large pharmaceutical companies, Novartis is in the process of the daunting task of retrofitting multiple packaging lines for a large portfolio of products, and integrating such changes cohesively with security measures currently in place and with the electronic standards and capabilities of trading partners.

To date, we have expended \$10 million and leveraged the resources of 45 full-time employees to develop unit-serialization and an electronic track and trace program. Given our substantial investment, it would be both imprudent and impossible to implement an immediate full-scale operational change without thoroughly testing the performance standards of the proposed technology. For instance, unreliable read rates or programming reliability could lead to production disruptions, which in turn may prevent our important therapies from reaching patients in California, who rely upon our life-saving therapies and maintenance drugs (e.g. leukemia treatment and high blood pressure medication). As we explain below, we are very concerned that, were Novartis required to go to unit-serialization on January 1, 2009, we would have to take multiple manufacturing lines out of production, which would result in shortages of critical drugs.

We have adopted a risk-based, phased-in approach to implement unit-serialization and electronic track and trace technology. We believe that this approach will move us toward full compliance with the California requirements and protect patient safety early in the process, while assuring that patients in California receive a non-interrupted supply of all Novartis prescription medications.

1. Risk Assessment

In 2004, we began a process to identify, review, and analyze each drug product relative to the potential for counterfeiting, and then applied our evaluation to develop a risk-based implementation plan. We prioritized our pedigree-related compliance efforts using eight weighted risk-based criteria to focus on drug products most vulnerable to counterfeiting and diversion:

1. Life-saving treatments and treatments for which there is no viable alternative, which are at high risk of counterfeiting;
2. Previous history of counterfeiting or diversion, and the future probability of counterfeiting or diversion;
3. Market demand issues with stockouts due to interrupted supply or variability in market demand;

4. A high volume of sales in the U.S. or high unit cost, which are indicators that a product may be attractive to counterfeiters or easier to introduce into the market;
5. Ease of duplicating a drug product;
6. Status of a product's life cycle (i.e., whether the product was recently approved, or whether sales are expected to diminish because of impending patent expiration)
7. Current implementation of product security measures, such as authentication features; and
8. Prevalence of internet drug sites unlawfully selling a drug product;

2. *Program Design and Challenges Identified*

In taking initial steps to change our manufacturing systems, we quickly reached the conclusion that the complexity of our U.S. operations precludes the option of dedicating certain manufacturing facilities or packaging lines to drugs bound for California. As noted, 45 packaging lines spread across 15 sites located in 6 countries manufacture drugs for distribution, and all U.S. products are shipped to customers through a central distribution point. Thus, regardless of the countries in which particular products are manufactured, to comply with the Board's requirements, eventually unit-serialization and electronic track and trace have to be applied to all products for sale in the United States.

We elected to apply the first phase of our program to three "high-risk" drug products (including controlled substances), and selected a packaging line with a slower rate of production to serve as a test model for application of unit serialization. We also decided that we would only implement unit serialization that included the use of both radio-frequency identification (RFID) tags and two-dimensional data matrix bar codes, the ability to print the bar codes on the drug label, and the capability to record and pass on the encoded information to trading partners. By encoding a serial number in the RFID tag, which itself is separately serialized, and in the two-dimensional bar code, we can provide an added layer of security from counterfeiting or diversion. For the same reason, it was important that Novartis internally control the process of encoding RFID tags with serial numbers and printing bar codes.

After making these critical decisions, however, Novartis discovered that its equipment manufacturers lacked the knowledge necessary to affix RFID tags and print two-dimensional bar codes on labels. Thus, we engaged Systech International, a provider of packaging performance management solutions, including RFID and bar code technology, for its expertise. Working in conjunction with our printing equipment suppliers, Systech supports our use of "middleware" – software that integrates

information contained in different applications across a network. Working together, we undertook the following steps:

- Our printing equipment manufacturer designed and built printing equipment for use on the dedicated Novartis manufacturing line. This process took 27 weeks.
- The “middleware” software was integrated into the printing equipment, which took 10 weeks.
- The re-configured printing equipment was tested for 4 weeks, and delivered to Novartis’s manufacturing facility for installation.

In addition to these RFID and bar code printing issues, we have faced hurdles in setting up a system to record the assigned serial numbers. Novartis uses SAP systems for recordkeeping, but the SAP modules that existed when we began this process lacked the sophistication to record the serialization information from the packaging line. We worked with SAP to enhance their AII (Auto-ID Infrastructure) module that stores serialized number ranges for each container or outer carton. This number will be forwarded through “middleware” to the software that controls the packaging line, encoded in the RFID tag, and printed on the label. The information will be scanned again for confirmation before it is relayed to our SAP module, which will record the assigned number including the item to pallet relationship, with safeguards in place to reject duplicative serial numbers.

As designed, this information will be held until a purchase order is filled by our distribution center, which is equipped with antennas that will re-read the RFID tags to record specific information about the outgoing product (e.g., item, quantity, serial number). Our system is set up to alert Novartis if any confirmation of shipment delivery is not received within a certain time period, which will trigger an internal investigation.

Novartis is currently working with several trading partners to assure that they are equipped with the necessary equipment to retrieve the encoded RFID and bar code information. One potential roadblock is the lack of consistent standards among trading partners. All three major wholesalers are accepting the EPCglobal ePedigree standard. Two of the wholesalers will accept this over the currently used industry accepted standard communications protocol referred to as ‘AS2’; the third has requested the communications protocol to be ‘web services’, which is not currently supported by Novartis.¹

¹ A related concern is whether downstream customers (e.g., retail pharmacies) will have the necessary scanners and readers to retrieve encoded information at all locations in California. Based on our experience, substantial investment will be required for retailers to obtain and implement the use of the necessary equipment.

Members of the California Board of Pharmacy
January 9, 2008

And, our phased-in approach will continue until all 53 products and 22 internal, as well as 23 packaging lines at contract manufacturers are provisioned for unit serialization. Rolling out unit-serialization and electronic track and trace technology to our contractors adds an additional level of complexity – especially in the absence of a U.S. serialization standard. Along the way, we intend to periodically re-assess and adjust our risk assessments accordingly based on new data and counterfeit risks. Regardless, our best projections anticipate that an additional \$75 million and several years will be required to bring the entire product line in full compliance.

* * * *

In summary, Novartis agrees that adopting unit-serialization and electronic track and trace technology will improve the drug supply chain and protect patient safety, and we are committed to complying with the California requirements. We have taken significant steps to meet California's requirements, but we believe that additional time is required to fully overcome the substantial logistical hurdles faced by large manufacturers in meeting these requirements. Further, we believe that the January 2009 deadline could harm patient safety in the long run. A full-scale implementation of the California requirements, without confirmation and validation that our proposed unit-serialization methods operate efficiently and at the standards we and the Board expect, may result in production disruptions. Thus, patients may be deprived of important therapies or may pay higher costs to obtain such drugs. For these reasons, we respectfully request that the Board authorize an extension of the deadline.

Thank you for considering our comments. Please feel free to contact us if you have questions or need additional information.

Sincerely,



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Worldwide Pharmaceutical Operations

Via Federal Express

January 8, 2008

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

To the Members of the California State Board of Pharmacy:

Pfizer Inc. respectfully responds to the California State Board of Pharmacy's ("the Board's") invitation to comment on an agenda item for the Board's January 23-24, 2008, meeting in San Diego. Namely, Pfizer wishes to comment on the discussion item regarding readiness for the January 1, 2009 implementation/compliance date for electronic pedigree set forth in the Business and Professions Code sections 4034 and 4163. In short, Pfizer strongly recommends that the Board extend the compliance date for these sections until January 1, 2011.

Pfizer shares the California Board of Pharmacy's concern for patient safety and is committed to addressing issues that impact the safety of the U.S. pharmaceutical distribution system. Pfizer has therefore been an active participant in the Board's discussions regarding sections 4034 and 4163.

As Pfizer has indicated in past discussions with the Board, the company fully supports manufacturer-initiated electronic pedigrees by January 1, 2009. Nevertheless, it is not feasible for Pfizer to implement item-level serialization for all of the company's products by the January 1, 2009, compliance date. Indeed, based on our experience in implementing pilot programs, our best estimate with respect to the time required for Pfizer to implement such item-level serialization for all prescription products is five to seven years. Since the Board currently does not have the discretion to implement select provisions of the California e-pedigree law and therefore cannot separate the e-pedigree requirements from the need for item-level serialization of all products, Pfizer supports the Board extending the compliance date for sections 4034 and 4163 to January 1, 2011. We

continue to encourage the Board to support a risk-based and phased approach for the deployment of item-level serialization.

For your convenience, and for the purposes of responding to the Board's *Template for Submissions Regarding Implementation Date of California ePedigree Laws (Bus. & Prof. Code, § 4163.5)* ("*Template*"), we have attached Pfizer's June 20, 2007, presentation to the Enforcement Committee. That presentation provides evidence demonstrating the specific and significant impediments to implementing item-level serialization for all products. The presentation also sets forth the numerous initiatives that Pfizer has undertaken to secure the supply chain. For example, Pfizer now has two widely used products in the U.S. market utilizing EPC serialization and RFID. First, Viagra[®] (sildenafil citrate) is uniquely serialized to the item level, using RFID and a 2D barcode on every bottle and is supported by an online authentication tool for authentication of the EPC serial number found on the Viagra label. RFID has also been incorporated into the case and pallet labels of Viagra. Pfizer has also begun shipping Celebrex[®] (celecoxib) that incorporates a passive radio frequency device encoded with a unique EPC into its case and pallet level shipping labels. In addition, Pfizer has extended a broad invitation to its trading partners to participate with Pfizer in e-pedigree pilot programs and currently has four active e-pedigree pilots underway with four trading partners. We believe that Pfizer is at the forefront of industry's efforts with respect to serialization and e-pedigree.

Based on Pfizer's actual experience to date with serialization and e-pedigree implementations, it is clear that additional time is required across the supply chain to deploy the necessary systems and infrastructure to support the exchange of pedigree and serialized information. Each organization that receives or sends a pedigree may have different pedigree solutions and solution providers, various legacy IT systems and significantly varying electronic commerce capabilities. Therefore, establishing and testing the necessary data exchange functionality with each trading partner can take weeks/months. In December 2007, we began to exchange our first production pedigrees with one trading partner and for one serialized product; this was the result of six-plus months of effort between the solution providers, trading partner and Pfizer. We continue to address several outstanding issues necessary to ensure the consistent and efficient exchange of this information.

Additional time is also required to further advance serialization plans. Each of the two serialization projects Pfizer has undertaken have taken a year to implement with significant dedicated resources assigned to these projects and many open issues yet to be addressed. Although significant progress is being made in the standards development area, important work still remains. Pfizer is committed to continuing to devote the necessary resources to further develop our serialization plan, to work with industry to deploy and test interoperable solutions that support the exchange of pedigree information, and to support the ongoing standards work being done by GS1. However, the reality is that it will not be feasible for Pfizer to complete these efforts before January 1, 2009.

Also in response to the Board's *Template*, Pfizer respectfully submits for the Board's consideration comments and testimony the company provided to the U.S. Food and Drug

Administration ("FDA") in February 2006. (Copies attached.) These documents similarly outline both the specific obstacles to implementing item-level serialization for all products and the significant and numerous steps that Pfizer has taken to help combat counterfeiting.

As indicated in the Board's *Template*, it is the "first priority of the Board to protect the California public." Pfizer believes that it would not be in the public's best interest to mandate item-level serialization of all products by the unattainable compliance date set forth in sections 4034 and 4163. If this requirement is implemented before Pfizer or the rest of the industry is able to comply, it could result in Californians being unable to obtain critical medicines because industry will be unable to supply the state's citizens with medicines that meet the state's requirements, specifically, drugs serialized at the item level.

CONCLUSION

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement, and employment of technology. In the long-term, and on the technology front, item-level serialization has the potential to be an important part of the anti-counterfeiting and product integrity efforts. However, implementation of the technology for all products throughout the distribution chain is not attainable by January 1, 2009.

Pfizer is grateful for the opportunity to provide these comments to the Board, and looks forward to continuing to collaborate with the Board and other stakeholders on this important issue.

Sincerely,



Tom McPhillips
Vice President
US Trade Group

Enc: 3 Attachments



Patient Safety and Channel Security

**California Enforcement
Committee**

June 20, 2007

Discussion Points



- Background
- Actions to date
- Work in Progress
- Item-level Serialization
- Future Vision
- Summary



Background

- Pfizer shares the California Board of Pharmacy's concern for patient safety and is committed to addressing issues that impact the safety of our US pharmaceutical distribution system
- As a result of Pfizer's experience with counterfeit product (Viagra, Lipitor, etc) it is clear there is no easy or single solution to the counterfeiting problem
- A multi-faceted approach involving business practices, legislation/regulation, enforcement and technology is necessary to address this issue
 - ◆ Cross-industry collaboration and cooperation is essential

Actions to Date



■ Business Practices

- ◆ Required Pfizer-authorized wholesale customers (ADR's) to purchase Pfizer products directly from Pfizer or other Pfizer-authorized wholesalers
- ◆ Steps have been taken to discourage repackaging of Pfizer products
- ◆ Distributor audits have been implemented
- ◆ Resources have been dedicated to product integrity work teams and initiatives

Actions to Date



■ Legislation and Regulation

- ◆ Pfizer has been very active in promoting public policy at both the federal and state level to deter counterfeiting
- ◆ At the state level, Pfizer has called for stricter laws regarding the licensing of wholesale distributors and greater oversight of repackaging operations
- ◆ Pfizer has supported the implementation of a pedigree process
- ◆ At the federal level, Pfizer has played an instrumental role in raising awareness of the risk importation poses to our supply chain, has supported implementation of PDMA, and the need for a uniform set of pedigree requirements



Actions To Date

■ Enforcement

- ◆ Increased investment in Global Security anti-counterfeiting resources and lab (analytical testing) capabilities
- ◆ Developing and providing leads to global enforcement agencies, FBI, FDA (OCI), etc on an ongoing basis
- ◆ Supporting investigative efforts
- ◆ Monitoring the market and internet for suspicious activity
- ◆ Aggressively pursuing criminal enterprises suspected of counterfeiting our products and cooperating with law enforcement to successfully prosecute those involved

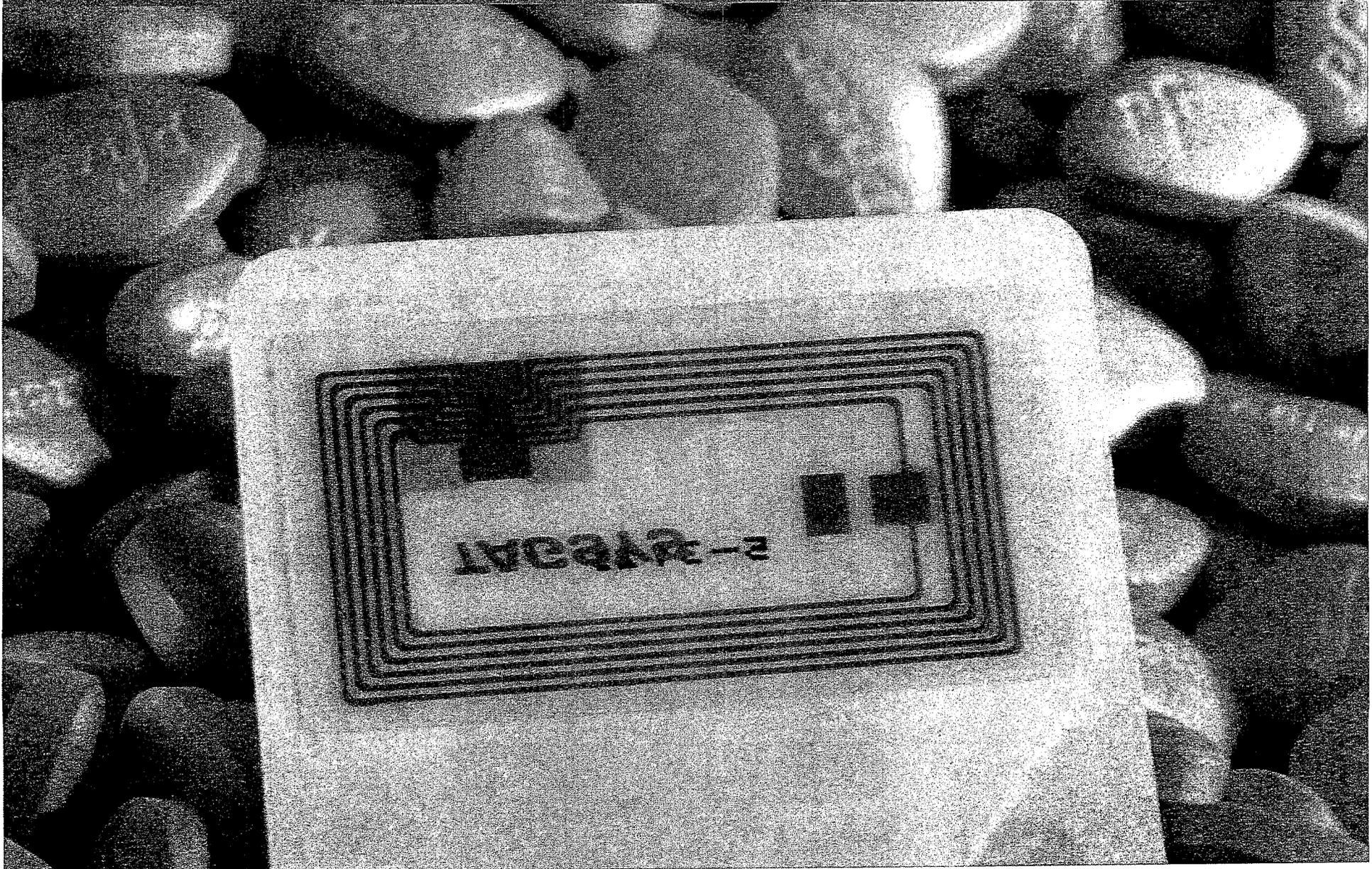


Actions to Date

■ Technology

- ◆ Overt anti-counterfeiting technology (color-shifting ink) has been incorporated into the packaging of “at risk” items
- ◆ Covert technologies are also used on a select basis on packaging and products
- ◆ RFID technology (and serialization) has been incorporated into the packaging of our US Viagra bottles, cases, and pallets
 - One year to implement at a cost of approximately \$5 million (initial implementation costs)
- ◆ Viagra authentication service implemented– allowing others in the supply chain to verify the authenticity of the serialized number found on Viagra packaging.

RFID and Viagra



RFID Tagged Viagra





Viagra Label

Store at 25°C (77°F);
excursions permitted to
15-30°C (59-86°F)
[see USP Controlled
Room Temperature].

Dispense in tight
containers (USP).

DOSAGE AND USE

See accompanying
prescribing information.

*Each tablet contains
sildenafil citrate equivalent
to 100 mg sildenafil citrate.



This package contains
a radio frequency device.

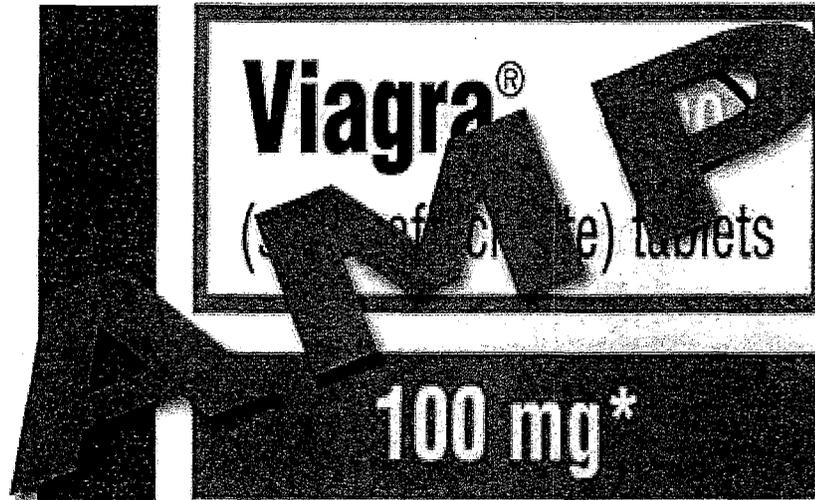
05-5487-30-5



NDC 0069-4220-30

30 Tablets

Rx only



Distributed by

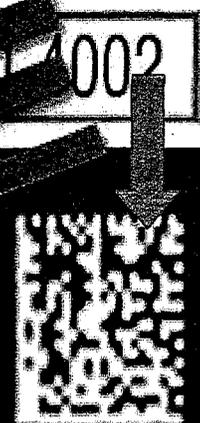
Pfizer Labs

Division of Pfizer Inc, NY, NY 10017



N3 0069-4220-30

8703245



PROD003
EXP 1 APR 04

RFID Item-Level Tagging





Serialization Lessons Learned

- As a result of our experience with Viagra and our current efforts with Celebrex, this is what we know:
 - ◆ Serialization is complex and costly
 - During a one-year period as many as 75 Pfizer colleagues and several external consultants were involved with the Viagra implementation
 - ◆ The one-time serialization implementation costs do not vary significantly regardless of the chosen data carrier (RFID or 2D)
 - ◆ The majority of the cost incurred lies in the provisioning and commissioning of the unique serialized number and applying this serial number to packages moving at speed on packaging lines
 - ◆ Effective process controls are essential to ensure the accuracy and integrity of the serialization process
 - ◆ Significant modifications are also required at distribution points to capture and associate serialized information with outbound customer shipments
 - ◆ Enhanced order assembly and shipping accuracy will be required in a serialized and pedigree environment to minimize disruption and returns
 - ◆ Each implementation is unique



Work in Progress

Significant 2007 Initiatives:

- E-pedigree implementation & testing – Viagra
- RFID implementation – Celebrex case-level
- On Track – industry pilots
- PhRMA Supply Chain Security Technical Group
- Rx SafeTrack – track and trace vision
- Standards Development and Industry Adoption
“Roadmap”



Work in Progress

- E-pedigree Implementation and Testing – Viagra
 - ◆ Our solution provider has been selected and funding secured for Viagra pedigree testing and implementation
 - ◆ Interested trading partners have been identified and we are working with their solution providers to address data requirements
 - ◆ An electronic signature capability is being implemented at each of our US logistics centers
 - ◆ Testing of Viagra e-pedigrees to begin by end of June
 - ◆ Systems interoperability to be tested with solution providers chosen by trading partners

Work in Progress



- RFID Implementation – Celebrex case-level
 - ◆ 4 packaging lines involved at one site in Caguas, PR
 - ◆ Different line automation and floor space options than Viagra
 - ◆ Faster line speed and greater case volume than Viagra
 - ◆ Many competing priorities for line time; must not disrupt supply
 - ◆ Effort to implement projected at 1 year and a cost of approximately \$4 million (initial implementation cost)



Work in Progress

■ On Track

- ◆ Pilot work to address various issues including RFID implementation, end-to-end e-pedigree testing, 2D bar code serialization and utilization, cost/benefit
- ◆ Participation from Manufacturers, Wholesale Distributors, and Retailers (chains and others), and solution providers



Work in Progress

- PhRMA Supply Chain Security Technical Group
 - ◆ Technology, Business Process and Legislative teams
 - ◆ Discussion Topics
 - Serialization
 - Data Carriers
 - Electronic Pedigree
 - Track and Trace
 - Authentication
 - Other Good Distribution Practices
 - Cost/Benefit
 - ◆ White Paper Due in Fall



Work in Progress

- Rx SafeTrack (formerly Call to Action)
 - ◆ Cross-industry group tasked with defining a vision for track and trace and a possible date when a track and trace process could be implemented
 - ◆ Leadership and commitment being provided by an Executive Council comprised of 9 industry CEO's.
 - ◆ Recommendations due October 2007



Work in Progress

■ Standards Development and Industry Adoption

- ◆ Significant effort underway with EPCglobal members defining user requirements for critical areas necessary to support serialization
 - Serialization standard
 - Item-level tagging
 - Track and Trace
 - Decommissioning, etc
- ◆ Industry Adoption Roadmap currently being shared with industry trade associations as a starting point for discussions surrounding serialization and e-pedigree



Pfizer Item-level Serialization

The magnitude of the effort.....

- 65 packaging lines at 21 sites (including 10 contract manufacturers) supplying product to the U.S. market
- Over 600 individual SKU's sold in the U.S.
- \$95 – 100 Million estimated cost to implement serialization capability on packaging lines and in logistics centers (RFID or 2D); ongoing cost not included
- Each implementation is unique and complex due to varying line speeds, line automation equipment, floor space availability, and the competing priorities for line time; must not disrupt supply to patients
- Best estimate of time required to implement item-level serialization for ALL products (5 -7 years) once funding and resources are secured; unclear business value (for ALL items)
- Today we have 1 product (5 SKU's) serialized at the item-level and we are an "early adopter"

Item-level Serialization and Pedigree



■ Open Issues

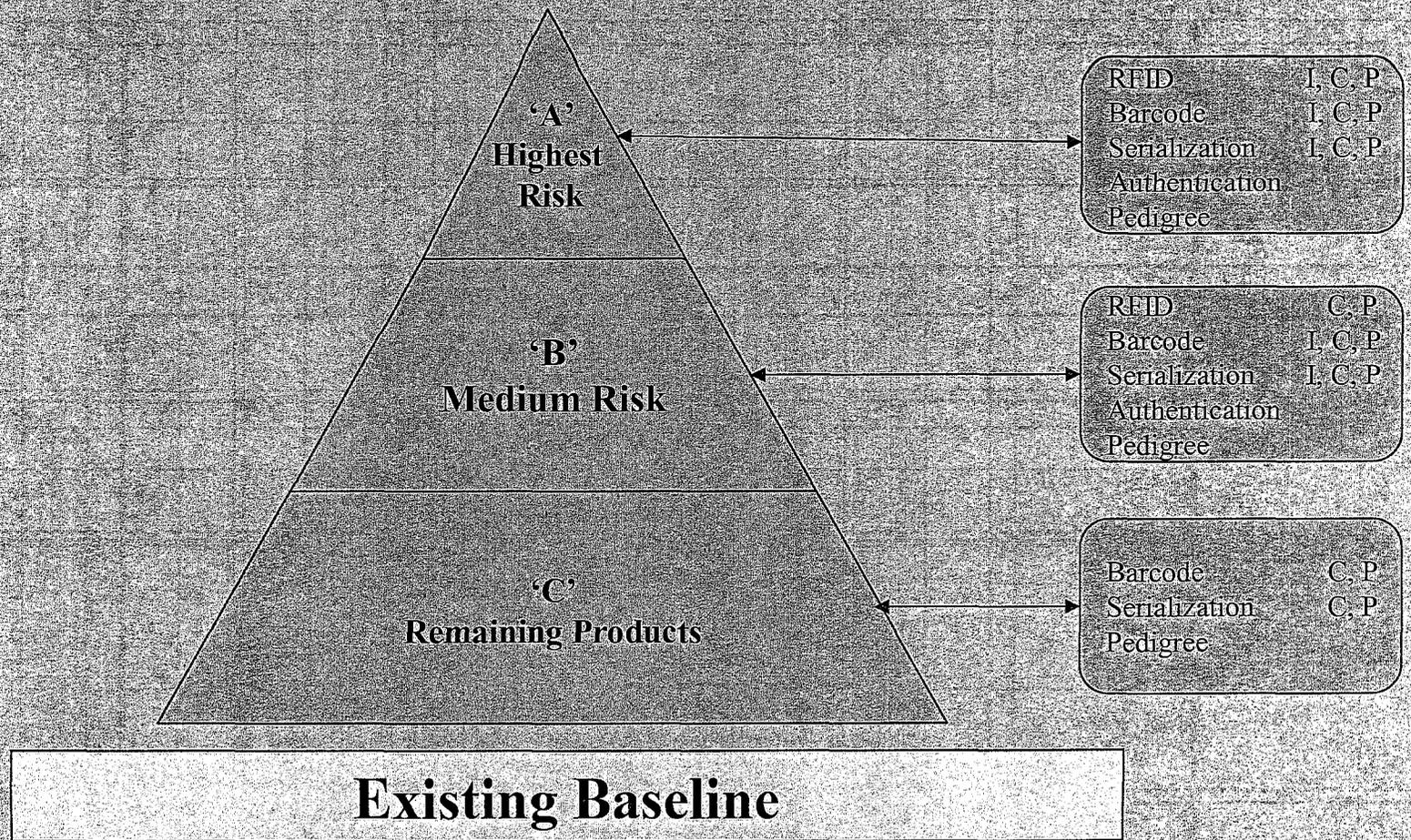
- ◆ Need for ratified standards, conformance testing, certification, etc.
- ◆ Need for guidance from the FDA regarding
 - Validation and process controls required to manage uniquely identified items
 - Recall conditions (if any) when serialization “exceptions” occur
 - Acceptable symbology and text to be used on product labeling and packaging
 - Use of RFID to serialize products such as biologics
- ◆ Need a uniform and consistent set of requirements; varying pedigree requirements at the state and federal level
- ◆ Implementing regulations are necessary to guide implementations and minimize rework
- ◆ Need for industry to agree on a path forward and move together to implement



Future Vision

- A risk-based and phased approach to the deployment of e-pedigree, serialization, RFID and 2D technology
- E-pedigree deployment by 2009
 - ◆ Begins to build much of the infrastructure necessary to support serialization and a future track and trace capability
- Robust (and interoperable) pedigree and track and trace systems would be deployed to support the inclusion of serialized information once serialized product is available.
- Pharmaceutical manufacturers would implement their serialization strategies beginning with an assessment of their product portfolio against various risk factors
- Level of technology application would be driven by risk

A Risk-based Approach



Key : I – Item Level, C – Case, P – Pallet



E-Pedigree and Patient Safety

How does electronic pedigree enhance patient safety?

- Electronic pedigree information can be secured in a way that makes it less susceptible to falsification than today's paper-based documents
- The requirement to "certify" information found on the pedigree is accurate (before passing product in the supply chain) should heighten due diligence regarding the source and previous ownership of the product
- Electronic information regarding who has taken ownership of specific products provides an audit trail to facilitate investigations
- Electronic pedigrees add a barrier for counterfeiters who must not only counterfeit the product but now must also breach the secure exchange of electronic information about the movement of that product
- Electronic pedigree information is theoretically more readily retrievable when needed to support investigations, etc.
- Electronic pedigree requirements that begin with the manufacturer and require the participation of all segments of the supply chain close many of the gaps that exist in today's process
- Electronic pedigrees may enable (at a minimum) lot level tracking of product shipments that does not exist today for many



Summary

- Many steps have been taken during the past 4 years to enhance patient safety by further securing the supply channel
- Significant industry-wide efforts are underway today to further address channel security and the role serialization will play going forward
- Item-level serialization is complex, requires extensive investment and collaboration, and will take many years to implement for all products
- Electronic-pedigree implementation offers additional channel security benefits and can be implemented in the near-term
- A risk-based approach to serialization applies enhancements to products where higher risk exists and focuses resources

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Tom McPhillips
Vice President
U.S. Trade Group

February 24, 2006

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Anti-Counterfeit Drug Initiative Workshop and Vendor Display
(Docket No. 2005N-0510)**

Dear Dockets Management:

On behalf of Pfizer Inc, I respectfully submit these comments to Docket No. 2005N-0510.

EXECUTIVE SUMMARY

As the world's leading pharmaceutical manufacturer, Pfizer remains strongly committed to providing patients with safe and effective medications of the highest quality. We share the FDA's concern for the risk to patient health posed by counterfeit drugs, and welcome the opportunity to work with the FDA and other stakeholders to develop effective mechanisms for preventing the insinuation of counterfeit drug products into the U.S. drug distribution system.

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement, and employment of technology. Pfizer has undertaken initiatives in all of these areas.

On the technology front, electronic track-and-trace systems, such as radio-frequency identification ("RFID") and electronic product codes ("EPCs"), represent a particularly promising means for enhancing the security of the medication distribution system. To learn more about how to implement such an approach in the United States, Pfizer has undertaken an RFID/EPC pilot program for Viagra. Under this program, great insights have been gained into the potential for RFID. This pilot program also continues to provide a much greater appreciation of the issues yet to be resolved.

More specifically, the Viagra pilot program has taught us that a fully integrated pharmaceutical track-and-trace system that relies on mass serialization of all items is not likely to

be widely available in the near term. The industry must first determine whether a track-and-trace system can or should be implemented for select or all medicines. The role that mass serialization will play in this process must also be determined. Pfizer believes that a timetable for widespread adoption of technology such as RFID cannot be established until these and other critical issues are addressed.

However, because of the paramount concern over patient safety, the battle against counterfeits cannot wait. Pfizer therefore continues to support the implementation of pedigree (chain of custody) requirements. To this end, Pfizer has and will continue to be a staunch supporter of model wholesale licensing and pedigree legislation being enacted in the states. This model legislation requires the use and authentication of pedigrees for medicines that leave the "normal distribution channel." The model legislation supports the use of electronic pedigrees ("e-pedigrees") when the widespread adoption of e-pedigrees becomes technologically viable.

Pfizer's near-term vision for an e-pedigree is one that does not depend on the mass serialization of individual items. Rather, at least in the near-term, the e-pedigree would create an electronic file of a medicine's movement through the distribution system. Such an approach would provide for the tracking of pharmaceuticals by lot. The approach would also address concerns about the burden of passing paper pedigrees, and may ultimately provide additional protection against counterfeiting of the electronic document itself through the use of digital signatures. In theory, when tracing a medicine's history, this electronic information would be more readily retrievable than today's process. Pfizer believes that there would be merit for pharmaceutical manufacturers to initiate the pedigree when such an electronic process is fully viable.

Pfizer also supports Federal efforts to combat counterfeiting. Pfizer recognizes that the implementation of a "universal" pedigree could help alleviate concerns over potential conflicting state requirements. And because any available weapon against counterfeits should be deployed, Pfizer supports lifting the stay of the Prescription Drug Marketing Act ("PDMA") regulations.

Pfizer notes, however, that the PDMA broadly exempts authorized distributors of record ("ADRs") from passing pedigrees to customers. This is a concern given the past history of counterfeits entering at the ADR level. The PDMA and implementing regulations should be amended to address this broad ADR exemption. And ultimately the PDMA and regulations should be updated as the widespread adoption of e-pedigrees and electronic track-and-trace technologies become feasible.

Finally, Pfizer supports the adoption on both the Federal and state level of stiff penalties for counterfeiting. It is also critical that the Federal government and state governments have dual authority to rigorously enforce those penalties.

SPECIFIC POINTS ADDRESSED IN PFIZER'S COMMENTS:

These comments will specifically address the following points:

- Pfizer's experience with the company's RFID/EPC Viagra pilot program.
- The obstacles to widespread adoption of RFID.
- The role FDA can play with the implementation of RFID.
- The timetable for RFID implementation.
- The setting of standards.
- Pfizer's continued support of the use of pedigrees.

Pfizer Viagra Pilot Program

Pfizer Pilot: Capabilities Created – Applied Technology Assessed

Program Announcement – A little more than a year ago, Pfizer announced the commitment that by the end of 2005 Pfizer would; (1) begin shipping Viagra in the United States with RFID/EPC tags; and (2) create an authentication capability for use by wholesalers and pharmacies.

As promised, on December 15, 2005, Pfizer's first RFID tagged Viagra was shipped to our U.S. customers. Pfizer's authentication capability was made available a few weeks later. All Viagra produced for sale in the United States now contains an RFID tag on its container.

Viagra was selected as it is Pfizer's most frequently counterfeited product and because it allowed Pfizer to minimize the number of teams, facilities, and packaging lines involved. A key objective of Pfizer's RFID pilot program is to learn more about the technology and the business processes that such an approach, including mass serialization and RFID technology, requires.

New Processes Developed – Pfizer's RFID pilot program for Viagra required the creation of many new capabilities. For example, Pfizer created a mass serialization process. This is a process that allows for the generation and assignment of a unique number (electronic product code) to each bottle, case, and pallet of Viagra.

Pfizer also decided to develop the ability to write and read EPC numbers at a high rate of speed. The capability was therefore established on existing packaging lines to write and read two bottles every second; this is the equivalent of over 7,000 package labels per hour. A backup system involving the application of a two dimensional ("2D") bar code to the label with the exact same EPC as the RFID tag was also created.

Once all of this was done, Pfizer equipped its logistics centers to capture the EPC information when product is shipped. Finally, Pfizer developed and implemented an authentication capability so that wholesalers, retailers, and pharmacists could authenticate the EPC.

Assessment – The Viagra RFID pilot was a complex project, involving over 70 Pfizer colleagues working thousands of hours and with costs approaching \$5 million to achieve Pfizer’s goal. Viagra consists of only five dosage/package combinations and is a very small percentage of our total units produced. Pfizer’s program was pursued in a way to be scaleable, while maintaining productivity. Pfizer takes great pride in the fact that the company was able to maintain production throughput within 5% of prior rates, comply with GMP requirements, and not compromise quality.

Pfizer Pilot: Key Decisions

A number of key decisions needed to be made during Pfizer’s Viagra pilot program. The decisions ranged from the choice of frequency to efforts to ensure privacy.

NDC Number Not Used – Pfizer’s decision not to incorporate the NDC number into the EPC numbering scheme was based primarily on the absence of industry standards and patient confidentiality concerns. Pfizer understands that the decision not to include the NDC may create operational efficiency issues in the distribution channel. Pfizer also appreciates that encrypting the NDC may help address patient privacy concerns in the future. These are issues requiring further study.

Frequency Considerations – Pfizer chose to use 13.56 Mhz (High Frequency) tags on bottles and 915 Mhz (Ultra High Frequency) tags on cases and pallets based on the following:

- ***Analysis of the basic physics characteristics of HF and UHF.*** The primary belief here was that HF tags at the item level would address tag readability concerns with mixed tote shipments of Viagra along with other liquid formulation products and products packaged in foil.
- ***Benchmarking use of RFID across similar industries.***
- ***Existing knowledge of UHF deployment and the need to effectively manage the interference issues created by UHF read ranges.*** This was a concern in our Logistics Centers as well as on our packaging lines where tags were being written to, and read while, in close proximity to each other on high speed packaging lines.
- ***The types of hardware and tags available on the market to achieve tagging at each level.*** The issue here was primarily one of finding reliable tags small enough and suitable for tagging pharmaceuticals at the item level. Performance of item level and case level tags and the related hardware was also an important consideration.
- ***Input from others in the supply chain.***

Two Dimensional Bar Codes and Other Label Additions – Pfizer also decided to include a 2D bar code as redundant, back-up technology to the RFID tag. The 2D bar code was included in an effort to address potential RFID tag readability issues and minimize exception handling needs. In addition, the decision was made to disclose the use of RFID on the Viagra label. Pfizer consulted with FDA to determine the appropriate placement and content of the disclosure statement.

Pfizer Pilot: Next Phase

Pfizer's Viagra pilot program has provided initial lessons about the application of RFID/EPC tags within Pfizer's "four walls." The pilot program will also provide further insights into the viability of the widespread adoption of RFID.

Pfizer realizes this is not just about applying an RFID tag. There needs to be an exploration about how best to handle the data generated by RFID and about exception reporting. It is also essential to gain greater insight into the needs of distribution channel participants. The considerable costs associated with RFID must be further explored. The acceptance, performance, and utility of the tags in the market must also be assessed.

The next phase will require a high level of collaboration and feedback amongst trading partners. To this end, Pfizer has been engaged in discussions with several of our supply chain partners to understand their plans for authenticating Viagra. Pfizer is encouraged that, during the first quarter of 2006, many of our supply chain partners have plans in place to begin authenticating Viagra at select sites.

OBSTACLES TO WIDESPREAD IMPLEMENTATION OF RFID

There must be continued collaboration to obtain real world experience with RFID and mass serialization throughout the distribution channel. This will require time and a significant investment before RFID is ready for widespread implementation.

As Pfizer moves forward, the company will be seeking feedback on the performance and utility of RFID-tagged products under normal day-to-day use. Through this, Pfizer hopes to gain a greater understanding of the benefit and effect of the use of these new technologies with a select or total system usage.

Consensus must also be achieved on data access issues and sharing of information. In particular, access to data by manufacturers will be an essential element of tracking the distribution of medications. Research is also needed on the feasibility of tagging all pharmaceuticals such as biologics and liquids. Finally, and yet just as important, decisions must be made on RFID/EPC standards and the use of appropriate tags in a cost effective manner that provides robust information.

All these factors, along with credible marketplace data from our Viagra RFID pilot, will be considered when developing our future strategy for securing the supply chain and enhancing patient safety. And as we have consistently stated, technology alone will not address the issue of counterfeiting.

FDA'S ROLE IN IMPLEMENTING RFID

Pfizer believes that FDA should continue to actively participate and, where appropriate, facilitate the discussions on the feasibility of implementing RFID. FDA's February 8-9,

2006, Anti-Counterfeit Drug Initiative Workshop and Vendor Display is an excellent example of the vital role that FDA can play in this area.

We believe that it is premature to establish a firm deadline for the implementation of track-and-trace technologies until the experience of Pfizer and other companies conducting pilots can be fully assessed. To that end, we believe that industry should take the lead in determining how technology can be applied both in the near-term and the long-term. By participating in this dialog, FDA can help to assess RFID and provide future guidance on this issue.

TIMETABLE FOR RFID IMPLEMENTATION

As noted above, numerous issues must first be addressed before a specific timetable is set for the widespread adoption of RFID. Critical among these issues is the utility and performance of RFID tags under day-to-day use. Certain key questions such as how the data will be shared, and whether all pharmaceuticals will be tagged, must be resolved. Standards must also be established and the feasibility of tagging all pharmaceuticals such as liquids and biologics must be assessed. Costs represent another important issue that must be fully understood.

Pfizer anticipates that it may be possible to implement the tagging of a limited number of pharmaceuticals within three to five years. However, it will likely take several additional years beyond that to adopt RFID for all prescription medications. The required investment in this technology will be large for all distribution channel participants and especially the manufacturers.

THE SETTING OF STANDARDS

Pfizer supports the process used by EPCglobal to establish standards that are specific to the pharmaceutical industry and driven by business requirements. However, to be successful, there must also be broader participation by the retail and hospital pharmacy. While standards are under development, guidelines on critical issues such as privacy, EPC numbering, and frequency should be developed to assist others undertaking pilots.

UNIVERSAL PEDIGREES

Given that the widespread implementation of RFID may be many years off, Pfizer supports current efforts to require the implementation of pedigrees. Pfizer also recognizes that a “universal” pedigree is the ideal. But it must be a pedigree associated with strong rules that are enforceable and a system that is able to ensure that the medication distribution system is not breached.

State Initiatives

Pfizer has been and will continue to be a staunch supporter of model wholesale licensing and pedigree legislation being enacted in the states. There are a number of key provisions in the model legislation that offer practical solutions to the immediate challenges of ensuring patient safety by combating counterfeits.

Strong Licensing and Bond Requirements – A key element of the model legislation is a strict licensing and bonding requirement for wholesale drug distributors. The goal is to make sure regulators know who is moving lifesaving medications that ultimately reach the patients who need them.

Electronic Pedigrees – The model also requires the study of e-pedigrees by the appropriate state regulatory body. Based on the findings of the study, and with input from key stakeholders, the implementation date for a mandated e-pedigree for all products would occur no sooner than December 31, 2007.

Normal Distribution Channel – Another key element of the model legislation is a requirement for creation of a pedigree only when a medication leaves the “normal distribution channel.” Generally speaking, the “normal distribution channel” involves the distribution from the manufacturer to the wholesaler or chain warehouse to the pharmacy to the patient. Pfizer regards this as important since medications that leave this “normal” system are most susceptible to the introduction of counterfeit medications.

Authorized Distributor of Record – The model recognizes that there should not be a broad exemption for authorized distributors of record. This is because, in certain cases, ADRs have been the entry point for counterfeits.

States Success – Pfizer is extremely pleased that a growing number of states have been successful in passing pedigree laws and applaud the efforts of those states actively engaged in efforts to pass similar legislation.

The Stay of the PDMA Regulations Should be Lifted

Pfizer is also a staunch supporter of Federal efforts to combat counterfeiting. A “universal” pedigree could help alleviate the worry over different or conflicting state requirements.

However, we are concerned that the currently stayed PDMA regulations broadly exempt ADRs from passing pedigrees to customers. We also recognize that e-pedigrees, and ultimately effective electronic track-and-trace technologies such as RFID, will be far more effective than the PDMA’s paper pedigree system at ensuring the integrity of the pharmaceutical supply chain.

Pfizer therefore supports amending the PDMA and PDMA regulations so that they are more fully aligned with the model pedigree legislation discussed above. Most notably, the broad ADR exemption should be addressed. The PDMA and regulations should also be updated as the widespread adoption of e-pedigrees and electronic track-and-trace technologies become feasible.

Nevertheless, Pfizer recognizes that the final PDMA regulations, issued in 1999, would be helpful to provide some stop-gap protection. The stay should thus be lifted. Although paper pedigrees are vulnerable to falsification and vulnerable to disuse, they aid in enforcing diligence in supply transactions. A pedigree reveals the number of times a drug product has changed hands, and the identities of those involved.

Given the limited amount of product meeting the requirement of PDMA for a pedigree, this information by itself may raise suspicions regarding authenticity or potential quality issues. Moreover, the pedigree requires the exercise of appropriate diligence to ensure the accuracy of its information, and to evaluate the circumstances of the drug’s distribution history. And of course, the pedigree can be helpful in facilitating investigations and recalls.

New and Enhanced State and Federal Penalties

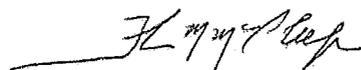
Pfizer believes that enhancing the penalties for counterfeiting might achieve additional deterrence. Heightened penalties, and the ability to enforce the penalties, should be shared by the Federal and state authorities.

CONCLUSION

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement, and employment of technology. In the long-term, and on the technology front, track-and-trace technologies have the potential to be an important part of the anti-counterfeiting and product integrity efforts. In the short-term, Pfizer supports the continued implementation of pedigree (chain of custody) requirements.

Pfizer is grateful for the opportunity to provide these comments to FDA, and looks forward to continuing to collaborate with FDA and other stakeholders on this important initiative.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom McPhillips", written over a horizontal line.

Tom McPhillips

FDA
Anti-Counterfeit Drug Initiative
Workshop
Public Meeting
February 8 and 9, 2006

Thomas McPhillips
Vice President, U.S. Trade Group
Pfizer Inc



Overview

- **Share FDA's Counterfeiting Concern**
 - Counterfeit drugs present a significant risk to patient health
- **Must Address Counterfeiting on Many Fronts**
 - Enhanced business practices;
 - Regulatory and legislative solutions;
 - Heightened enforcement; and
 - Employment of technology.
- **Pfizer has Undertaken Initiatives in all These Areas**



Overview

- **Provide comment on:**
 - Pfizer's Viagra RFID pilot program
 - Obstacles to RFID implementation
 - Role of FDA
 - RFID adoption timetable
 - Standards setting process and mass serialization
 - Universal pedigree requirements and legislation



Pfizer RFID Pilot

- **Viagra RFID Initiative:**

- Pilot program aimed at shipping RFID/EPC tagged Viagra and creating an authentication capability by the end of 2005.
- Viagra selected because it is Pfizer's most frequently counterfeited product.
- All Viagra produced for sale in the U.S. now contains an RFID/EPC tag.



Pfizer RFID Pilot

- **Key objective of pilot program:**
 - Learn more about mass serialization and RFID technology and the business processes its use requires.



Pfizer RFID Pilot

- **Capabilities created:**
 - **Mass serialization capability**
 - **Allows:**
 - Generation and assignment of unique number to each bottle, case, and pallet of Viagra
 - Writing information to high or ultra-high frequency RFID tags
 - **EPC reading and writing capabilities**
 - **Allows:** High speed application on existing packaging lines
 - **2 dimensional bar code alignment**
 - **Allows:** Same number assignment for EPC and RFID tag
 - **Capture and track tag and write/read performance**
 - **Ability to capture EPC information upon shipment from our logistics centers**
 - **Authentication capability for wholesalers and pharmacies**



Pfizer RFID Pilot

- Key decisions during Viagra pilot:
 - Choice of frequencies
 - Read and write to tags on-line vs. pre-written
 - No NDC in the EPC numbering scheme
 - **Privacy first**
 - Redundant two dimensional bar code
 - Disclosure on label of use of RFID



RFID Implementation

- **Much to learn and evaluate**
 - Not just about applying a tag
- **Objective of our next phase:**
 - How to handle data and exception reporting
 - Learn more about wholesalers and pharmacies needs
 - Understand business process implications and
 - Define ongoing costs



RFID Implementation

What Else is Needed?

- Continued collaboration to obtain real world experience with RFID and mass serialization throughout the distribution channel
 - Significant investment required
- Feedback on performance and utility of RFID-tagged product under normal day-to-day use
- Understanding of benefit and effect of targeted or total employment of mass serialization/RFID
- Resolution on data access and sharing
- Research on feasibility of tagging all pharmaceuticals
- Standards decisions and cost effective, robust tags



How can RFID be implemented?

Role of FDA

- **FDA as Facilitator** – FDA should continue to actively participate and, where appropriate, facilitate discussions on feasibility of implementing RFID.
- **Industry as Serialization Leader** - Industry should take lead on how serialization is to be applied both near and long-term.



How can RFID be implemented?

Timetable

- **Timetable** – Numerous issues must be addressed before a specific timetable is established.
 - **Key Questions:**
 - How will data be shared and who will have access?
 - Do all pharmaceuticals need to be serialized and tagged for anti-counterfeiting purposes?
 - How does the technology perform? Can costs be reduced?



How can RFID be implemented?

Timetable

- **Phase 1**: Tag only “**high-risk**” items
 - Adoption possible in near future.

- **Phase 2**: Tag **ALL** items with RFID
 - Several additional years will be required with a very substantial investment.



RFID Implementation

Standards Setting

- **EPCglobal Process**
 - Support the process used by EPCglobal
 - Established standards that are driven by business requirements and specific to the pharmaceutical industry
- **Broader Participation Needed**
- **Guidelines Needed Now**
 - While standards are under development, guidelines on issues such as privacy, EPC numbering schemes, and frequencies should be developed.



Universal Pedigree

- **Electronic Solution Not an Immediate Fix**
 - Implementation of electronic track and trace system may be many years off
 - However, we have an immediate need
- **Solution Needed Now**
 - Pedigrees (chain of custody) are necessary in the interim
 - Ideally, there should be one way to do this



States Addressing Issue Through Legislation

- **Key components:**
 - **Stricter Licensing and Bonding Requirements**
 - **Inclusion of Normal Distribution Concept**
 - Pedigrees should be required when the drug leaves the “normal distribution channel.”
 - System could apply more broadly when electronic system operational.



States Addressing Issue Through Legislation

- **States Have Made Tremendous Strides in Enacting Pedigree Laws**
 - A few select examples include Arizona, California, Florida, Indiana, Iowa, New Jersey, New Mexico, Nevada, Oklahoma, and Texas.
- **Continued Pfizer Support**
 - Pfizer supports these initiatives



Marjorie E. Powell
Senior Assistant General Counsel



2008 JAN 10 AM 10:54

January 9, 2008

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

RE: Template for Submissions Regarding Implementation Date of
California ePedigree Laws (Bus. & Prof. Code, § 4163.5)

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments to the California Board of Pharmacy in response to its "Template for Submissions Regarding Implementation Date of California ePedigree Laws (Bus. & Prof. Code, § 4163.5)," posted on the Board's web site.

PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$39.4 billion in 2005 in discovering and developing new medicines. Industry-wide research and investment reached a record \$51.3 billion in 2005. PhRMA's comments apply to the research-based pharmaceutical companies, which supply the newer medicines, and account for approximately one-third of all prescription medicines dispensed in the United States; generic manufacturers supply the other two-thirds of all medicines dispensed

PhRMA commends the Board of Pharmacy for providing guidance on what information it needs to consider a request that the Board of Pharmacy delay the implementation date, and PhRMA formally requests such a delay. The extensive dialogue which the Board of Pharmacy's Enforcement Committee has had with the pharmaceutical distribution chain over the past many meetings provides a strong basis from which the Board can consider the question of a possible delay in the implementation date, within the context of patient safety. PhRMA agrees with the Board of Pharmacy's concern for counterfeit drugs and recognizes that implementation of electronic tracking technologies for high risk products can be an important step to further secure the supply chain.

PhRMA submits the following information, gathered from its members (the companies that research and develop new medicines), discussions with other entities in the pharmaceutical supply distribution chain and their trade associations, discussions with participants in the standard setting process, and from listening to presentations at meetings of the Enforcement Committee of the Board of Pharmacy.

Pharmaceutical Research and Manufacturers of America

In October 2007, as requested by the Board of Pharmacy Enforcement Committee to enable Committee members to understand the efforts of manufacturers to comply with the California law and the problems that manufacturers had encountered, and to gather information and to develop its public policy positions, PhRMA conducted a confidential survey of its member companies on their activities and mechanisms to track the distribution of pharmaceutical products in the supply chain. U.S. antitrust laws prevent disclosure of the identity of companies responding to the survey; that information has not been shared with PhRMA staff or member companies. Company-specific information has been aggregated to protect its confidential nature. The responses from this PhRMA member survey, along with the information derived from the sources briefly described above, form the basis of the information in this request for delay.

Partial compliance is achievable during 2009

Many manufacturers will be able to provide ePedigree at the lot level during 2009. In addition, some manufacturers will also be able to provide item-level serialization for some medicines during 2009. Companies with a small number of products may be able to provide item level serialization for all of their products; however, PhRMA estimates that only a small portion of all prescription drugs that are commercially distributed in California will have serialization at the item level by January 1, 2009.

As noted in previous discussions, it is clear that, for multiple reasons related to development of technologies and FDA regulatory requirements for manufacturers, manufacturers of prescription drugs will not be able to fully comply with the requirement to provide item level serialization for all prescription drugs by the January 1, 2009 deadline. These reasons include issues such as:

- Lack of development of necessary standards and technologies;
- Absence of certified vendors;
- Vendor inability to service all manufacturers, wholesalers and distributors for all products, due to limited vendor capacity;
- Absence of necessary FDA regulations to guide manufacturers on critical issues such as required labeling submissions, necessary validation activities and critical stability studies; and
- Inability of down-stream partners to read and authenticate serialization information across multiple serialization systems.

Moreover, as a policy matter, PhRMA does not believe that all products require item-level serialization. PhRMA believes, consistent with the views of the FDA's Counterfeit Drug

Task Force, that a risk-based approach to identifying products at highest risk for counterfeiting is the most effective means to further secure the pharmaceutical drug supply. Manufacturers should make individual decisions regarding which products in their portfolio are at highest risk of counterfeiting and take necessary steps to adopt appropriate serialization technologies for those products.

PhRMA believes the Board of Pharmacy should recommend a phased in implementation approach. A simple delay to 2011 could decelerate activities towards compliance throughout the prescription drug supply chain. A phased in approach avoids this possible loss of momentum. In addition, it is important to create an environment where pilots and phased implementations are encouraged rather than postponed. As the Enforcement Committee has recognized, pilots provide an opportunity to identify and resolve problems which occur during implementation, without threatening the functioning of the distribution chain. These learnings can be leveraged to make sure that implementations occur in a minimally disruptive fashion. In addition, a hard start date would undoubtedly be disruptive to the entire supply distribution chain as it would impose significant operational changes for every member of the distribution chain, which could negatively limit access to medicines.

Finally, a phased in approach provides a means to address, based on experiences with high risk medicines, at least some of the difficult issues that the Enforcement Committee has raised at recent meetings. For example, a phased in approach could allow for the “grandfathering” of medicines that were manufactured, packaged, and shipped to a wholesaler or retailer prior to implementation of the pedigree. Those products could still be distributed under a phased in approach, which may be especially important for medicines serving small patient populations, where a disruption in supply may present unique problems; one witness at the December 2007 Enforcement Committee meeting mentioned that a treatment for a bite by a particular snake is manufactured only every few years.

Progress is currently being made by PhRMA members

PhRMA members and many others within the distribution system are nonetheless currently working on a number of activities related to the serialization of drug products:

- Initiating pilots focused on implementation of ePedigree, including those with and without item-level serialization;
- Participating in pilot tests to determine what changes are needed to internal and joint business processes;

- Encouraging FDA to issue all of the numerous regulations that will allow manufacturers to include item-level serialization on product labels or packaging, will clarify the stability studies that must be performed on pharmaceutical products in packaging containing certain types of serialization technologies, and the validation procedures required to support serialization;¹ and
- Evaluating changes to production and labeling lines to serialize, validate serialization, and seek FDA approval for changes to approved New Drug Applications, as appropriate.

A more detailed review of these activities and the current status and future plans is shown in Attachment II, which reviews the results of a PhRMA survey of member activities.

Technology issues related to interoperability still remain open

The California statute requires that the system for conveying the pedigree, including the item-level serialization number, for each prescription medicine shipped within the state must be interoperable among all members of the distribution system. The mechanisms eventually adopted by manufacturers must be compatible with, and provide information that can be read by, the mechanisms used by wholesalers and retailers, including chain and independent pharmacies and hospital pharmacies, to be an effective system. No one technology has been accepted by all parties within the supply chain; indeed, no one technology currently available meets the needs of all entities in the distribution system. Standards are still being developed, and the technologies that meet those standards will need ratification and subsequent implementation once the standards are finalized. California's statutory requirement and the multiple meetings and other activities of the Board of Pharmacy have encouraged the development of standards and the certification of vendor systems. However, the standards development process takes time, and it can only be pushed so fast. Moreover, once standards have been developed, vendors will need to be certified to those standards and processes built around those technologies for all supply chain partners to follow to create an interoperable system.

A delay or a phased in approach would provide both incentive and time for the development of standards. It will also enable the Board to track the progress of key standards and business process changes. This will provide an accurate assessment of which standards can be fully developed in time for vendors to be certified and for all parties within the supply chain to adopt, implement, test, and begin operating with the new technologies. Standards that must still be developed include, but may not be limited to:

¹ Necessary FDA guidance to manufacturers centers on three areas: labeling, stability, and validation. Specific questions that FDA must answer are set out in the letter to FDA dated January 9, 2008 and included as Attachment I to this petition for delay.

- RFID high-frequency item-level serialization;
- Serial number format for RFID;
- Discovery configuration and installation; and
- Discovery services.

These standards must also address complex issues surrounding data integrity, interoperability, and compatibility across the supply chain.

While many standards or guidelines must still be developed, the most important factor which will limit the industry's ability to comply will be the industry-wide coordination that will be required across the entire supply chain to implement an interoperable system to exchange serial numbers, pedigrees and associated transactions, i.e., shipments, receipts, returns, etc. This implementation of this industry wide interoperable system could have the business impact similar to the impact that Y2K had on this business sector.

Y2K required every company to modify, test and verify that its company's systems could still function after the date January 1, 2000. However, Y2K was controlled within each company's "4-walls". The California pedigree law requires every company's systems at all sites to be interoperable internally and industry wide, and fully operational and compliant on January 1, 2009. First, there is not enough time for every company to modify its systems to be compliant by January 1, 2009. Second, the interoperable system cannot be developed, tested, verified and deployed and verified as FDA compliant across the entire industry by January 1, 2009.

Proposed milestones

In addition to the completion of all of the standards described above, and the issuance of the FDA guidance on each of the topics described in the attached letter to FDA, it will be critical for the Board of Pharmacy to coordinate with the FDA in light of the FDA's new legislative mandate to develop a new standardized numerical identifier at the package or pallet level, in order to assure that both sets of requirements will be consistent in all respects. Additional milestones that would be helpful in the interim period between 2009 and 2011 include:

- Board issuance of guidance, in consultation with FDA and pharmaceutical supply chain stakeholders, on factors to consider in evaluating whether a medicine is at high risk of being counterfeited;
- The establishment by manufacturers of item-level serialization for products identified at high risk of being counterfeited;

- The individual adoption of processes and systems by downstream trading partners for receiving and confirming, with item-level serialization for medicines identified to be at high risk of being counterfeited by downstream trading partners; and
- The individual adoption of processes and systems for receiving and confirming non-serialized e-pedigree by downstream trading partners for medicines identified at lesser risk of counterfeiting.

Why a delay will benefit public safety

Many patients rely on consistent access to prescription medicines; however, a strong possibility exists that many medicines intended for distribution in the state of California will not contain item-level serialization by January 1, 2009. Further, many entities within the prescription medicine distribution system will not be able to read and convey pedigree information with item-level serialization by January 1, 2009. Unless the Board takes action to delay the implementation date, every entity within the supply chain would need to determine for itself whether to distribute medicines in California without an interoperable, electronic item-level serialized pedigree on January 1, 2009. It is impossible to predict how individual supply chain entities may react if they found themselves faced with a looming compliance deadline that they knew they were unable to meet. Based on the enforcement risks, some entities within the supply chain may decide not to distribute some medicines, resulting in the very real possibility that patients in California would not have access to needed medicines and possibly putting patients at greater risk if they attempt to get product outside of normal pharmacy transactions.

A delay will prevent the above situation from occurring. A phased in approach would prevent this situation as well as provide additional benefits. It will both prevent the potential supply chain disruption that January 1, 2009 would represent, and also encourage the implementation of patient safety technologies where possible. This would allow the Board of Pharmacy and the pharmaceutical supply chain to benefit from incremental patient safety benefits as implementations move forward as well as determine the correct blend of laws, regulations and technologies to achieve the patient safety goals we share.

Conclusion

For all the above reasons, PhRMA respectfully requests that the Board of Pharmacy delay implementation of the deadline for item-level serialization and work with all members of the distribution system on a logical phased in approach. In addition, in light of the Board of Pharmacy's knowledge about these issues, PhRMA encourages the Board of Pharmacy to collaborate with the manufacturers and other parties in the supply chain to contribute to

California Board of Pharmacy
Request for delay of epedigree date of January 1, 2009
January 9, 2008
page 7

FDA's efforts to develop and issue needed regulations, to ensure the adoption of needed commercial standards for interoperability, to inform all the members of the distribution system, particularly the smaller members with more limited resources, about the requirements, and to develop regulations to ensure a smooth transition to a fully interoperable electronic system that does not result in major difficulties in assuring that patients receive the medicines they need in a timely and efficient manner.

Sincerely,

A handwritten signature in cursive script, reading "Marjorie E. Powell". The signature is written in dark ink and is positioned to the right of the word "Sincerely,".

Marjorie E. Powell

Attachments

Attachment I: PhRMA Summary of Survey Results

Attachment II: PhRMA Letter to FDA dated January 9, 2008

Attachment I to PhRMA Submission to California State Board of Pharmacy
Summary of Survey Results
January 9, 2008

In October 2007, as requested by the Board of Pharmacy Enforcement Committee to enable Committee members to understand the efforts of manufacturers to comply with the California law and the problems that manufacturers had encountered, and to gather information and to develop its public policy positions, PhRMA conducted a confidential survey of its member companies on their activities and mechanisms to track the distribution of pharmaceutical products in the supply chain. Twenty-one members of PhRMA responded to the survey. U.S. antitrust laws prevent disclosure of the identity of companies responding to the survey; that information has not been shared with PhRMA staff or member companies. Company-specific information has been aggregated to protect its confidential nature.

E-Pedigree without Serialization

PhRMA's survey results revealed that more than 2/3 of our member companies are in the planning phase for non-serialized electronic pedigree. Of the remaining respondents, the majority are currently conducting e-pedigree pilots. A small number of companies, less than 10% of the respondents, have implemented non-serialized e-pedigree for all of their products in commercial distribution.

PhRMA's members report that, based on their pilot studies, pharmacy involvement in non-serialized e-pedigree pilots is extremely limited; wholesaler participation is greater but still limited.

Serialization

PhRMA's survey indicates that the impact of item-level serialization for manufacturers would be enormous. Based on our survey, more than 2000 medicines of the research-based prescription drug industry are affected, with each manufacturer having an average of 113 affected products. A total of 431 packaging lines in 162 plants are impacted, with an average of 25 packaging lines in 8.5 different plants impacted. Our manufacturers estimate that nearly 900 internal company personnel would be involved in any commercial serialization, with an average of 53 people per company.

The PhRMA survey results reveal that the research-based pharmaceutical manufacturers' experiences with serialization pilots are in the preliminary stages. Multiple companies are conducting serialization pilots at the case, pallet and item level, and the majority of these pilots involve limited product tagging. The majority of respondents conducting serialization pilots at the item level are using 2D barcode technology. The majority of serialization pilots involving tagging at the case or pallet level are using UHF/RFID technology. Eighty-two percent of the serialization pilots involving wholesalers and/or

pharmacies affect no more than 25% of the volume of that product in the commercial marketplace.

The PhRMA survey results also reveal that planning and conducting serialization pilots is a time and resource-intensive process. The majority of the pilots our member companies are involved in are taking 12-18 months to plan and implement, and the majority have an expected duration of 12-18 months. Thus, a serialization pilot at the case, pallet or item level takes approximately 3 years from planning to completion. The cost to conduct these pilots ranges from approximately \$200,000 for a limited scope serialization pilot to anywhere from \$1 million to \$15 million for one pilot.

PhRMA's survey results also reveal that each implementation is unique. Taking into account the significant time and resources necessary to plan and conduct pilots, it is clear that each implementation of item-level serialization will be time-consuming and resource-intensive, and could face unexpected challenges and delays at any time. Survey estimates of the time to serialize all products range from approximately 1 year per product to 5-7 years. Moreover, the cost estimates for serialization are staggering. PhRMA's survey results suggest that the costs to serialize all medicines of the research-based pharmaceutical companies in commercial distribution range between \$5-\$10 million at the low end all the way up to \$200 million.

Alan Goldhammer, PhD
Deputy Vice President,
US Regulatory Affairs



January 9, 2008

Ilisa B.G. Bernstein, Pharm.D., J.D.
Director of Pharmacy Affairs
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852

Dear Ms. Bernstein:

Section 913 of the Food and Drug Administration Amendments Act of 2007 requires the Agency to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. As part of this requirement, FDA is to work towards the development of a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing and repackaging. PhRMA is following this matter with great interest as our Supply Chain Security Technical Group has been examining the use of new technologies to better protect patients from exposure to counterfeit drugs. PhRMA has commented to the FDA on several occasions in the past on this matter and continues to participate in ongoing activities with other supply chain partners.

As FDA is aware, the California Board of Pharmacy is charged with implementing a law that requires pharmaceutical manufacturers to serialize pharmaceutical packaging down to the lowest level so that an electronic pedigree system can be established within the state to track and trace such products. PhRMA has made several presentations to the Board's Enforcement Committee regarding industry's readiness to meet their January 1, 2009 time frame. One of the issues that we raised with the committee was the need for additional clarification from FDA regarding certain regulations and policies. These are outlined in the remainder of this letter.

Two technologies are presently under consideration for serialization of pharmaceutical packaging, 2-D bar codes and radio frequency identification (RFID) tags. Both have advantages and disadvantages. 2-D bar codes can be printed on packaging, the technology has an agreed upon standard and is robust. However, bar codes require line of sight reading. RFID tags do not require line of sight reading but the standards are still evolving and their application to packages may slow down operations. Both technologies will require changes in labeling and packaging operations that are the subject of current Good Manufacturing Practice regulations. Although the FDA has issued a compliance policy guide for company initiated studies using RFID (http://www.fda.gov/oc/initiatives/counterfeit/rfid_cpg.html), further clarification of regulatory responsibilities is required for products entering commerce where the encoded serial number might be used for regulatory compliance (e.g., meeting the California requirement, initiating a recall, etc.). Furthermore, PhRMA recommends that this guidance be extended to studies involving the use of other data carriers as such research is currently underway.

Pharmaceutical Research and Manufacturers of America

950 F Street, NW, Washington, DC 20004 • Tel: 202-835-3533 • FAX: 202-715-7090 • E-Mail: agoldhammer@phrma.org

The following regulations are especially pertinent:

- o 21 C.F.R. part 314 and section 505 of the Act, except for field alert report requirements.
- o 21 C.F.R. Part 11.
- o 21 C.F.R. parts 210 and 211 and section 501(a)(2)(B) of the Act (current Good Manufacturing Practices).
- o 21 C.F.R. part 207 and section 510 of the Act (Registration and Listing).
- o 21 C.F.R. § 314.70 and section 506A of the Act.

These regulations pose the issues in the following categories that require FDA guidance and/or interpretation .

1. Labeling

- a. Does the addition of a serial number and/or data carrier warrant a labeling submission to FDA? If so, what type of FDA filing will be required -- a pre-approval supplement, a change being effected or a reference in an annual report? Does the type of required submission vary depending on the manner in which the serial number is applied or the data carrier used? For example, printing a serial number or bar code can be accomplished by pre-printing, on-line printing, or by application of a sticker containing the relevant information.
- b. Is quality of print, bar code or RFID readability considered a cGMP requirement? Is application of serial numbers and data carriers defined as a cGMP process?
- c. Will NDC bar code requirements allow for use of 2D bar codes?
- d. Will packaged product be subject to a recall in the event of an exception reading of the serial number in the field? Who is responsible if the RFID tag is damaged when in commerce after the packaged unit leaves custody of the pharmaceutical company?

2. Stability

- a. What studies will be required to evaluate the impact of RF on products such as proteins? What type of filing will be required to submit these study results to FDA -- pre-approval supplement, change being effected, or a notation in an annual report?
- b. What studies will be required to assure leachables do not impact product when a tag is placed on a potentially permeable container (e.g. PE/Liquids)? What type of filing will be required to submit these study results to FDA?

3. Validation

- a. Must all components of system utilizing e-signatures be fully compliant with 21CFR Part 11? This is an important issue with respect to establishing an electronic pedigree system requiring signatures from trading partner representatives.
- b. Must all systems used to support serialization efforts be validated if not impacting current validated states? What levels of validation does FDA expect from trading partner systems (e.g., wholesalers, retailers)?

Ms. Bernstein
January 9, 2008
Page 3

PhRMA looks forward to FDA's response to these issues so that our companies might have a better understanding of the Agency's thinking about all the regulatory compliance issues. Our companies are engaged in a number of pilots involving packaging labeled with RFID and/or 2-D barcodes. Several products are currently in commerce.

Do not hesitate to contact me regarding clarification of the issues set forth in this letter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alan Helleman".

December 19, 2007
Reference No.: SAS07073

VIA FIRST CLASS MAIL

Mr. William Powers
President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

Dear Mr. Powers,

On behalf of the Plasma Protein Therapeutics Association (PPTA), I am writing to request that you exercise your statutorily granted discretion as codified in the California Business and Professions Code and delay implementation of the substantive aspects of California's Pedigree requirements until January 1, 2011. Patients that rely upon life-saving plasma-derived and recombinant analog therapies (collectively, "plasma protein therapies") cannot risk any disruption to their access to care. In this instance erring on the side of caution by delaying implementation and putting access to care first for the chronically ill patient populations treated with plasma protein therapies should be paramount.

PPTA is the primary advocate for the world's leading producers of plasma-derived and recombinant analog therapies. Plasma protein therapies, which include albumin, blood clotting factor, alpha-1 proteinase inhibitors and intravenous immunoglobulin, among others, are lifesaving therapies used to treat a variety of rare diseases and serious medical conditions for a very small, often compromised patient population in the United States. The complexity of biologics must be taken into account when considering a law directed at comprehensive prescription drug distribution. PPTA members are committed to ensuring the safety and availability of these medically needed life-sustaining therapies.

The California Business and Professions Code defines Pedigree as "a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system ensuring compatibility throughout all stages of distribution." CAL BUS. & PROF. CODE § 4034(a). We would like to note at the outset that as the primary association representing the leading manufacturers of plasma protein therapies, PPTA is committed to maintaining the integrity of the distribution channel in California and, more broadly, globally. We take the potential of counterfeit therapies very seriously and individual companies have taken numerous concrete steps to guard against such threats as patient safety. PPTA manufacturers view patient safety as their highest priority.

PPTA is concerned, however, that the interoperability requirements, as codified in Section 4034 might lead to disruptions in the supply channel should the January 1, 2009 implementation date be maintained. Specifically, we believe that many downstream providers, particularly those in

rural parts of the state will not be able to comply with the pedigree requirements resulting in difficulties accessing therapies for patients who depend upon them to lead normal healthy, productive lives. Therefore, an adverse impact on patients who utilize plasma protein therapies may be an unintended consequence of attempting to ensure the integrity of the distribution channel. PPTA respectfully requests that the Board keep this issue in mind when considering the January 1, 2009 implementation date.

Section 4034 defines "interoperable electronic system" as "an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug." CAL BUS. & PROF. CODE § 4034(i). We believe that downstream providers, such as some individual pharmacies referenced in the statute may not be able to comply with these requirements resulting in potential disruptions to access. It should be noted that we believe that interoperable system is essential to ensuring the integrity of the channel. Our concern is that such a system may not feasibly be in place 12 months from now.

For the purpose of a standard for product serialization, PPTA supports a requirement for manufacturers to apply a unique numerical identifier to each prescription drug package, as defined as the unit of sale in which a drug may be received by a pharmacy or other entity authorized to acquire or possess prescription drugs. PPTA believes that the timing for compliance with this requirement must take into account the technological hurdles including engineering changes, and emerging labeling technologies.

While there are several counterfeit-resistant technologies successfully employed by the Bureau of Engraving and Printing as well as radio frequency technology, nanotechnology, and encryption technology available for manufacturers to use, PPTA believes the technologies used to identify and track prescription drugs must be selected at the discretion of the manufacturers in order to best ensure the safety and efficacy of the drug. The selected technology should eventually be linked to an interoperable health information technology system database by its numerical identifier. The timing of such linkage must be consistent with the engineering changes required for implementation.

PPTA greatly appreciates the opportunity to comment on the implementation of the California pedigree law. PPTA hopes to be part of the dialog with the Board as it continues to work with the issues associated with implementation of this important law for the residence of California. Should you have any questions, or if you require additional information, please do not hesitate to contact me at (202) 789-3100 or by email at rfaden@ppta.org.

Very truly yours,



Ryan M. Faden, JD, MPH
Assistant Director, State Affairs



January 9, 2008



2008 JAN 14 PM 3:46
California State Board of Pharmacy
1625 N. Market Boulevard, Suite N219
Sacramento, CA 95834

Dear Members of the Board of Pharmacy:

On behalf of Safeway, I would like to provide a summary of our Company's strategic approach to the development of our ePedigree solution as requested by the Board.

Safeway's roadmap towards full compliance with California ePedigree requirements will begin with a pilot test at a store during summer 2008. This pilot will be a joint project with McKesson Drug, our current pharmacy drug supplier.

Various ePedigree tracking solutions will be used by the drug manufacturers, i.e. RFID (HF & UHF) or 2-D bar codes. Accordingly, we will work diligently with our wholesaler partner during the pilot to interface with their solution methodology to achieve a compliant model.

Key objectives of the solution design and pilot test will include:

- Testing various communications systems and technologies within the pilot project
- Designing and implementing a direct data link between the McKesson distribution center and the Safeway data center
- Installing a data repository at a Safeway data center to store all ePedigree transactions for compliance auditing purposes.
- Interfacing Safeway's pharmacy system with ePedigree information
- Operating ePedigree-capable scanners located at the pilot test store connected and providing data to the inventory module of Safeway's pharmacy system.
- Identifying and addressing key areas to create an effective operating platform to receive and provide ePedigree information
- Creating dataflow of information and all processes within the pilot project.

Once the pilot demonstrates a successful solution for ePedigree to comply with the various requirements, Safeway will implement this functionality in our California-based locations. However, the implementation system plan is not capable of completing all California stores before January 2009.

Safeway believes that it is acting in good faith to meet the requirements of the California ePedigree Laws and will fully meet those requirements within a reasonable timeframe.

Sincerely,

Ron Bingaman,
Safeway Pharmacy Director



2008 JAN -B AM 11:57

January 7, 2008

California State Board of Pharmacy
1625 N. Market Boulevard
Suite N219
Sacramento, CA 95834

Members of the California State Board of Pharmacy,

Takeda Pharmaceuticals North America, Inc. appreciates the opportunity to weigh in on the timelines set forth for the implementation of electronic technologies to track, at the serialized individual unit level, the distribution of prescription drugs within California. Specifically, we ask that you consider extending the date for compliance of the electronic pedigree requirements via the board's authority pursuant to Section 4163.5 of the Business and Profession Code.

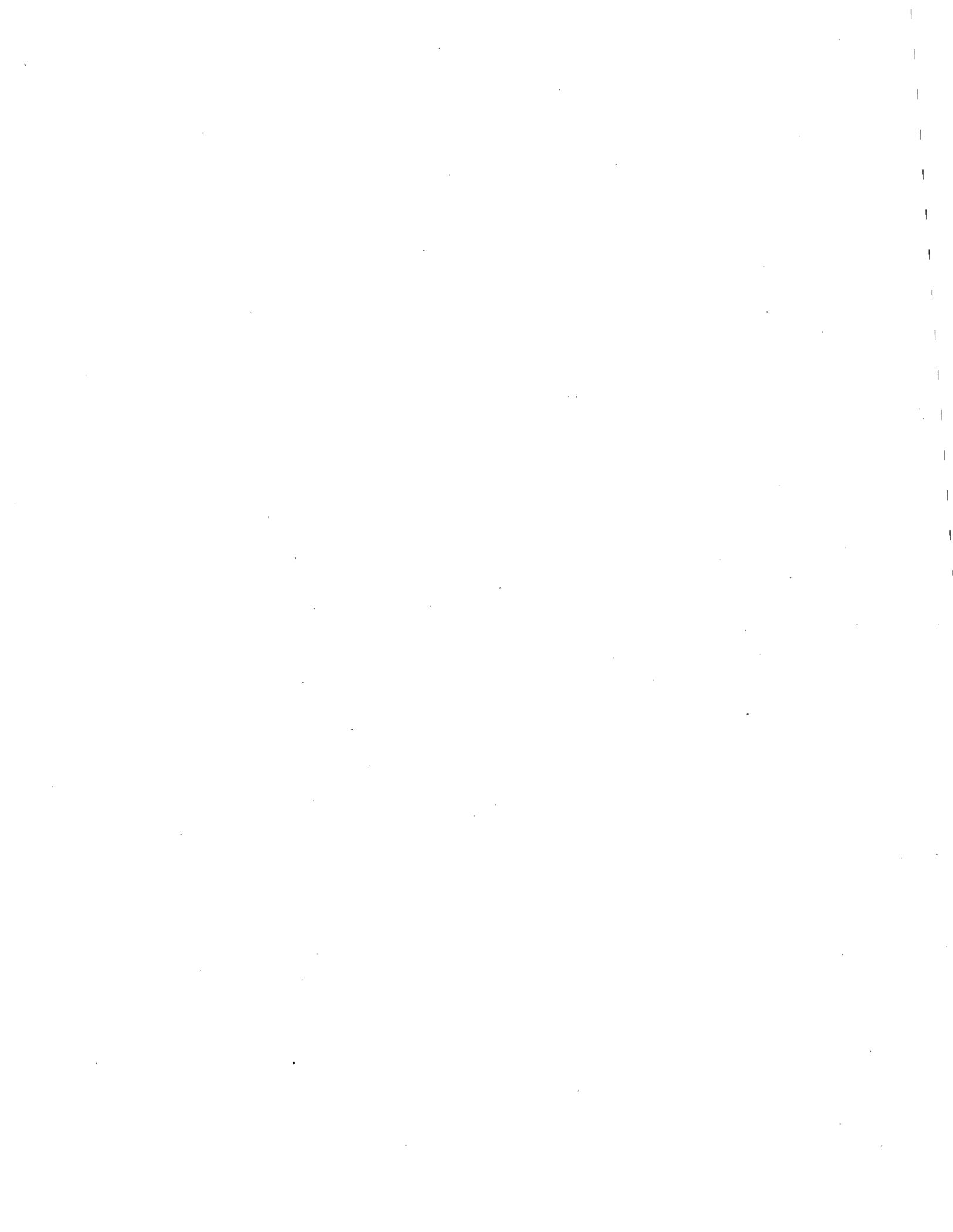
Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. Furthermore we share your commitment to protecting the integrity of the pharmaceutical supply chain within California. To that end, Takeda has implemented policies and procedures to achieve that goal. However, it is unlikely that we will be able to comply with the January 1, 2009 deadline for all of our products across all therapeutic categories.

Thank you for your consideration. We look forward to continuing our work with you to protect and enhance the health and well being of Californians.

Sincerely,

A handwritten signature in cursive script that reads "Doug Busscher".

Doug Busscher
Director Supply Chain
Takeda Pharmaceuticals North America, Inc.
One Takeda Parkway
Deerfield, IL 60015





STATE BOARD OF PHARMACY
2008 JAN -9 PM 3:08

Thomas J. Lynch, J.D., Ph.D.
Senior Vice President
Compliance, Regulatory Affairs and Public
Policy
Talecris Biotherapeutics
PO Box 110526
Research Triangle Park, NC 27709
Tel: 919-316-6510
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January 8, 2008

California State Board of Pharmacy
1625 N. Market Boulevard, Suite N219
Sacramento, CA 95834

**Re: Business and Professions Code sections 4034 and 4163
California ePedigree Laws**

To the Members of the California State Board of Pharmacy,

Talecris Biotherapeutics Inc. ("Talecris") appreciates this opportunity to comment on the proposed Implementation Date for the California ePedigree Laws (Bus. & Prof. Code, § 4163.5). *In the interest of patient safety, Talecris respectfully urges the Board to extend the date for compliance with the ePedigree requirements to January 1, 2011.*

Talecris Biotherapeutics Inc. ("Talecris") is one of the largest producers and marketers of plasma-derived protein therapies in the world. We develop, produce, market and distribute therapies that extend and enhance the lives of people suffering from chronic and acute, often life-threatening, conditions, such as immune deficiency disorders, alpha-1 antitrypsin (AAT) deficiency, infectious diseases, hemophilia and severe burns. Our heritage of patient care innovations in therapeutic proteins dates back to Cutter Laboratories, which began to produce plasma-derived products in the early 1940s, and its successor companies, including Miles Inc., Bayer Corporation and Bayer Healthcare LLC.

Talecris is committed to protecting those whom we serve. However, we believe that it will not be feasible to implement electronic technologies to track at the serialized individual unit level the distribution of prescription drugs in California by January 1, 2009. Failure to extend the current deadline would place patient safety at risk by jeopardizing access to medicines for Californians who depend on our prescription drugs for treating life-threatening conditions. The risk of denying these patients access to their medicines far outweighs any risks that may exist in the current system.

Our therapies are biologics, which require special handling, storage, and shipping conditions. The complexity of biologics must be taken into account when considering a law directed at comprehensive prescription drug



Thomas J. Lynch, J.D., Ph.D.
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Fax: 919-316-6675

distribution. Talecris, along with other members of the Plasma Protein Therapeutics Association (PPTA) participated in a study with the U.S. Food and Drug Administration (FDA) to determine impact of RFID on biologics.

During the PPTA-FDA Liaison meeting held on Friday, October 12, 2007, the FDA stated the current testing was complete, that the RFID may have impacted the product and that while the product was still within specification, more stability studies were necessary. The FDA was in the process of contacting manufacturers and requesting permission to publish the study. Importantly, the FDA encouraged the industry to conduct additional tests and share that information with the Agency and public.

The FDA's observations that RFID may have impacted the product and that more stability studies were necessary demonstrate the necessity for an extension of the ePedigree compliance date so that these important tests can be conducted.. The additional studies called for by the FDA will require extended testing of multiple products, which would include experimental exposure to RFID emission(s) relevant to the technology to be employed, and extended analytical testing of the exposed product during its shelf-life (2-3 years for many biological products). Talecris is currently working with several vendors to assist us in performing additional testing. Although the RFID exposure portion of the testing could be completed over the next several months, the subsequent product testing including stability studies that are required would not be completed until much later. Test results are critical in moving to the next steps in the ePedigree technology selection and implementation process. Requiring implementation of RFID technology before the impact of that technology on the safety of biologic products was resolved would place California patients at unknown health risk, contrary to the public interest.

Finally, it is worth noting that FDA has jurisdiction over drug products' packaging and labeling. If the FDA were to determine that the incorporation of RFID technology was a change requiring prior Agency approval for some products (or classes of products), the regulatory process could add additional time before the technology could be adopted.

From our tamper-evident packaging to our cold chain supply innovations and finally to select distribution partnerships, Talecris continues to work toward the safest, most efficient way to get our products into the hands of those who need them. Talecris will continue to evaluate ePedigree technologies and work towards a solution that best serves patient safety.



Thomas J. Lynch, J.D., Ph.D.
Senior Vice President
Compliance, Regulatory Affairs and Public
Policy
Talecris Biotherapeutics
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Tel: 919-316-6510
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In sum, Talecris urges the Board to exercise its authority and extend the date for compliance with the ePedigree requirements to January 1, 2011.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Lynch", written over a horizontal line.

Thomas J. Lynch, J.D., Ph.D.
Senior Vice President
Compliance, Regulatory Affairs and Public Policy





STATE OF CALIFORNIA
BOARD OF PHARMACY

2008 JAN -9 AM 11:06

January 8, 2008

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

Re: Request for Exemption from ePedigree Implementation/Compliance Laws

Dear Members of the Board:

Tercica, Inc. is submitting for the Board's consideration this letter regarding the January 1, 2009 implementation/compliance date for the California ePedigree Laws. For the reasons set forth below, we are requesting a total exemption from implementation/compliance, and alternatively, a delay until January 1, 2012 for implementation/compliance.

Tercica is a small (120 employees) biotechnology company that sells two drugs. Increlex is used to treat very short children with severe primary insulin like growth factor deficiency (approved by the FDA in December 2006), and Somatuline Depot is used to treat adults with acromegaly (approved by the FDA in August 2007). Both drugs serve extremely small "orphan" (as defined by the FDA) populations (i.e., approx. 6,000 and 12,000 respectively nationwide). Currently, only about 120 children in California use Increlex, and fewer than ten patients use Somatuline Depot (however, we expect this to increase). Increlex is distributed directly to children's families through only specialty pharmacies---never through retail pharmacies. Similarly, we expect the vast majority of Somatuline Depot will be distributed through specialty pharmacies, although there will be the possibility (unlike with Increlex) for some retail sales as well.

We do not manufacture either drug ourselves. Accordingly, for us to implement/comply with the ePedigree laws we will need to work with third-party manufacturers. This will be extremely costly and burdensome. It will also be a major time and cost impediment to our drug formulation and re-formulation efforts and attempts to lower the costs of manufacturing and packaging our two drugs.

1. TERCICA SHOULD BE GRANTED AN EXEMPTION FROM THE ePEDIGREE LAWS.

We strongly believe that exempting Tercica from implementation/compliance with ePedigree Laws would not be detrimental to the public interest. As a small innovative company, and with our products in the early commercial phases of their life-cycle, we do not make a profit, and do not expect to become profitable until 2010 at the earliest. Implementation of an ePedigree system would place a tremendous burden on our limited cash resources, which are already fully allocated exclusive of such a major investment. With the vast majority of our patients receiving their drug directly from specialty pharmacies, we believe that the ePedigree would provide little or no benefit to them given the low risks of a specialty distribution supply chain.

2. IF NOT GRANTED AN EXEMPTION, TERCICA SHOULD BE GRANTED A DELAY IN IMPLEMENTATION/COMPLIANCE WITH THE PEDIGREE LAWS.

If the Board does not grant our request for an exemption, we would like to be granted a delay until January 1, 2012 for implementation/compliance. In sum, we believe that Tercica will be unable to meet the January 1, 2009 compliance date. However, Tercica would have a better opportunity to achieve implementation/compliance, if allowed at least three additional years to complete the implementation of the required technologies. Allowing this delay would enable complete validation of all electronic systems, which enhances the assurances for product tracking and chain of custody control.



Below is a summary of our analyses and efforts toward implementation/compliance:

- a. Tercica's planning phase for implementation is adversely complicated and time consuming due to the number of third parties and high costs involved: Tercica has only recently launched its two pharmaceutical products, both sterile injectable drugs. Both are supplied via a complicated logistical chain of third-party manufacturers, storage facilities, wholesalers, and specialty pharmacies. All operations at Tercica are outsourced thru this complex network of third-party service providers. Planning for implementation of electronic pedigree has begun but the coordination of all third parties for implementation and standardization of electronic systems has been, is and will be extremely complex and resource-consuming. The ePedigree project, particularly if RFID technology is chosen, is very expensive with unclear benefits compared to traditional manual systems. As a small company with very limited financial and human resources, Tercica is hard-pressed to accelerate these activities and thus an additional three years is necessary in order to achieve full compliance.
- b. An extension of three years to January 1, 2012 may enable Tercica to complete planning and implementation for electronic pedigree of its products, specifically validation: Tercica recognizes that validation of the electronic system will be a long and complex process due to the multiple, independent sites involved and varying capability for sophisticated electronic data acquisition, storage, retrieval, archiving, and training. The implementation of technology for sterile injectable drugs is particularly complicated, as compared to oral drugs. Furthermore, any electronic system will involve substantive changes to product labeling which obligates the company to apply for and receive FDA-approval prior to implementation. Thus the plan must allow time for prototyping and validation of the new devices so that success is ensured prior to FDA submission. Typically, design, implementation, validation, and regulatory approval of such systems is a multi-year project. In Tercica's case, the project will span at least four independent companies, including a company outside of the United States. As an example, the initial milestone of gaining contractual agreement with all parties on the type, capabilities, and required infrastructure support of an electronic pedigree system is expected to take more than six months.
- c. Safety of electronic pedigree is a function of quality assurance and comprehensive validation and only thru a delay in implementation to January 1, 2012, can such assurance be achieved: Tercica believes that the protection of the public health gained by application of the electronic pedigree law is inherent in the system accuracy and assurance of error-free operation throughout the product chain of custody, from manufacturer to storage facility to wholesaler/distribution centers, and ultimately to the specialty pharmacy. To achieve the necessary level of assurance electronic systems requires extremely complex and sophisticated validation protocols for critical operating parameters of both software and hardware, such as data signaling, capture, storage retrieval, security, archival, transmission, and retrieval. Implementation without comprehensive quality assurance is counter-productive to the long-term goals of patient safety and patient health.

For all the reasons stated above, we hope that you strongly consider granting Tercica an exemption from implementation/compliance with the ePedigree laws. In the event that you determine that no exemption may be granted, we hope that you grant us a delay in implementation/compliance until January 1, 2012.



Please do not hesitate to contact us if you would like for us to meet with the Board or staff.

Very truly yours,

A handwritten signature in black ink that reads "John Scarlett". The signature is fluid and cursive, with a long horizontal stroke extending from the end of the name.

John Scarlett, President and CEO
Tercica, Inc.

cc: Stephen N. Rosenfield, General Counsel
Richard King, Chief Operating Officer
Andrew J. Grethlein, Senior Vice President, Pharmaceutical Operations



TEVA PHARMACEUTICALS

THE STATE OF CALIFORNIA
BOARD OF PHARMACY

2008 JAN -9 AM 11:19

January 8, 2008

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

Re: Implementation Date of California Pedigree Laws

Dear Members of the Board:

Teva Pharmaceuticals USA, Inc., the leading source of generic pharmaceuticals for the United States market, commends the Board's efforts to help ensure the safety of California's patients under the Pedigree Laws. Teva's mission is to provide patients with safe and efficacious pharmaceuticals of the highest quality at a low cost.

In anticipation of the current January 1, 2009 implementation date of the Pedigree Laws, Teva is engaged in ongoing discussions with stakeholders throughout our supply and distribution chain. We are currently at the early stages of implementing pilot studies with a number of them. The threshold hurdle we face in adopting a Pedigree solution is determining specific track-and-trace technology that will actually work, be cost-effective and interoperable among our fifty outsourced product suppliers, our approximately seventy unique, internal production lines and our hundreds of customer ship-to points, several of which are located in California. We have solicited and received from Pedigree solution vendors multiple implementation proposals, which vary widely in the use of specific tagging technology (i.e., RFID, 2D), cost and time to implement. Although we are working aggressively to find common ground with our stakeholders to ensure that the Pedigree solution we adopt will work throughout our supply and distribution chains, more time will be required before we can identify a practical and interoperable technology we believe will successfully accomplish the goals set forth in the Pedigree Laws.

Even assuming that Teva would have until January 1, 2009 to test, retrofit and validate each of its internal packaging lines and validate track-and-trace processes at its primary distribution facility at which approximately one million saleable units of pharmaceutical products are handled each day, it would not be possible for most of Teva's >1,200 SKUs to become compliant with California's Pedigree law within that time. Moreover, our customers, in order to ensure adequate inventories of Pedigree-compliant product by the current implementation date, are requesting that Teva and other manufacturers supply Pedigree-compliant product to them by as early as May 2008. Such a timeline is impossible for Teva to meet.

Administrative Offices:

1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090
Phone: 215.591.3000 Fax: 215.591.8600 www.tevausa.com



TEVA PHARMACEUTICALS

In light of the foregoing facts, Teva requests that the Board delay the implementation of the Pedigree Laws until January 1, 2011.

Additionally Teva requests that a grandfather clause be put into effect for inventory held in the supply chain. In the absence of such a delay, and not being able to utilize existing inventory, Teva, and presumably a large number of other pharmaceutical manufacturers, wholesalers and distributors, will be legally precluded for a period of many months from supplying into California a wide variety of pharmaceutical products. Furthermore, we would like the Board to consider allowing inference as a means of utilizing pre-established and validated parent-child relationships as a means of facilitating distribution. Such a concept would allow Teva to utilize pallet and case-level serialization for processing of 3rd party manufactured product without considerable disruption to distribution processes. In the absence of inference, Teva will experience significant processing delays in our distribution center, ultimately impacting the availability of our product to the market. Such a drastic reduction in the availability of pharmaceutical products to the citizens of California is clearly at odds with the stated first priority of the Board to protect the California public.

Again, Teva supports the Board's efforts in securing the pharmaceutical supply chain, and overall goal of ensuring the safety of the citizens of California. We believe that postponing the implementation date of the Pedigree Laws, the grandfathering of inventory in the supply chain and allowing inference will enable continued supply of affordable, lifesaving generic medicines.

Regards,

A handwritten signature in black ink, appearing to read "Michelle L. Keller".

Michelle L. Keller
Product Safety and Integrity Manager
Teva Pharmaceuticals USA, Inc.

Administrative Offices:

1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090
Phone: 215.591.3000 Fax: 215.591.8600 www.tevausa.com

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January 8, 2008

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

SUBJECT: Implementation Date of California e-Pedigree Laws
(Bus. & Prof. Code s. 4163.5)

Dear Members,

Thank you for the opportunity to comment on the implementation of the e-Pedigree requirements for California pharmacies. These comments are submitted on behalf of the University of California (UC) Health System and its academic medical centers (AMCs) located at Davis, Los Angeles, Irvine, San Diego, and San Francisco campuses. The UC Health System fully supports the intent of e-Pedigree legislation to protect California's health care consumers and appreciates the leadership of the California State Board of Pharmacy to implement the e-Pedigree requirements. Your efforts will help ensure that all segments of the pharmaceutical delivery process – manufactures, distributors, hospitals, clinicians and pharmacies – promote the highest possible pharmaceutical product quality, including ensuring authenticity. While we share your goal of documenting pharmaceutical authenticity as quickly as possible, the complexity of this change compels us to respectfully request that the Board exercise its authority to extend the implementation date to January 1, 2011.

The UC clinical enterprise is the fifth largest healthcare delivery system in California and the leading provider of certain specialty services and medical procedures. Specifically, the UC clinical enterprise offers services that are essential to the health and well being of all Californians including a broad array of highly specialized services, often available only in our health system, and serves as a health care safety net for many low-income medically vulnerable Californians.

I want to underscore that our goal is completely consistent with your Board's – to provide the highest quality patient care, including delivering the safest pharmaceuticals available. It is within this spirit that we raise various practical implementation concerns.

Among the most complex of the e-Pedigree implementation issues is coordination with our supply chain. The UC Health System receives its pharmaceutical supply from a major

BOARD OF PHARMACY
2008 JAN -9 AM 11:23

distributor that can not currently deliver e-Pedigree information to our pharmacies. The distributor has been alerted to our concerns and has been advised of our need to receive the information necessary to meet the e-Pedigree standards as quickly as possible. As a practical matter, it's imperative that our effort to secure this information from the distributor happen collaboratively to ensure the supply of the drugs needed to treat our patients is maintained. There are no immediate alternative sources for the UC Health System.

Moreover, our distributor has identified various technical issues related to the standardization of lineage coding, unit dose segmentation, and pedigree reporting that requires much coordination and resolution between the distributor and the manufacturing industry. Resolving these issues is essentially a prerequisite step for our meeting the e-Pedigree standards.

Lastly, the technical and resource intensive nature of updating our information systems and developing processes to capture and hold pedigree data and track incoming pharmaceutical products is formidable. We fully understand and respect that the Board has requested specific milestones, which will make it possible for us to meet a 2011 implementation date. At this point, because we do not have the necessary authenticity information from the distributor, and unit dose coding from the manufacturer, we regrettably are not in a position to outline milestones for the Board.

Our goal is to work as diligently as possible to meet the Board's requirements in a manner that does not interrupt the flow of life-saving drugs to California's hospitals. An implementation date of January 1, 2011 will help ensure this result.

I would be delighted to schedule a meeting of key UC Health System pharmacy and information technology leaders to meet with Board members or your staff to discuss these issues.

Thank you for your consideration. We are available to answer any questions and discuss this matter further. I can be reached at 510-987-9062 or smunoz@ucop.edu and Michael Thompson of my office can be reached at 510-987-0586 or mthompson@ucop.edu.

Sincerely,



Santiago Muñoz
Associate Vice President
Clinical Services Development

C: UC Pharmacy Directors

Wal-Mart Rx Serialization Requirements

California's 2009 e-pedigree Requirement

November 9, 2007

“Wal-Mart Supplier Questions to Address Regarding Serialization”

1. What date will you be ready to test e-pedigree serialization on products to pallet level, case level, and product level?
2. What date will you be ready to implement a complete e-pedigree solution on all products?
3. How do you plan to provide (transmit) the e-pedigree to all participants in the supply chain?
4. If you plan on using something different from the list above, briefly explain how you plan to be compliant.

Wal-Mart Stores, Inc. time line is to have all pharmacy products being shipped in California to comply with the state e-pedigree requirements under these approved methods by October 1st, 2008 to ensure quality implementation of e-pedigree prior to January 2009.

If you have technical questions about the above processes please contact Glen Luna at glen.luna@wal-mart.com

For questions on warehouse procedures contact Tom Hervey at Thomas.hervey@wal-mart.com

For merchandise specific questions contact Andrika Jackson at andrika.jackson@wal-mart.com

Wal-Mart Rx Serialization Requirements

California's 2009 e-pedigree Requirement

November 9, 2007

Wal-Mart believes that the best way to serve its customers is to continue to develop new and innovative technologies that improve supply chain efficiency, enhance product quality and safety, and save customers money. We do that through strong partnerships with our supplier community. Our ongoing commitment to implementing EPC technology is part of our shared dedication to meet the changing needs of our customers.

Toward that goal, we would like you to share your company's plans to comply with California's new "e-pedigree" requirement, which takes effect in January of 2009. This preparation will ensure that product deliveries are not interrupted. We have listed below the compliance options Wal-Mart will be prepared to work with for the e-pedigree requirement. Please review these options and provide your answers to the four (4) planning questions to Andrika Jackson at andrika.jackson@wal-mart.com by Wednesday, November 21st, 2007.

"Wal-Mart Serialization Requirements"

- A unique serialized number at all levels of packaging (item, inner pack, warehouse pack, case, master pack, pallet)
- An item level Drug Pedigree meeting standards, data schemes, and data carriers approved by EPC global and GS1
- A serialized **ASN** of pallets to purchase order, cases on a pallet, and items in a case. These serialized numbers should be arranged hierarchically for each purchase order or shipment.
- EPC as the primary data carrier
- Item Marking: EPC as primary data carrier with 2D bar code backup redundancy
EPC standard: UHF Gen2, using SGTIN-96 data format
Barcode backup standard: 2D (data matrixECC200), or DataBar, using AI(01) GTIN + AI(21) serial number
*** The serialized barcode is required in addition to the existing UPC Barcode*
- Case Marking: EPC as primary data carrier, with linear bar code backup redundancy
EPC standard homogenous product: UHF Gen2, using SGTIN-96 data format
EPC standard mixed product: UHF Gen2, SSCC-96 data format
linear backup standard: SSCC-18 (GS1-128), homogenous or mixed cases
- Pallet Marking: EPC as primary data carrier, with linear bar code backup redundancy
EPC standard: UHF Gen2, SSCC-96 data format
linear backup standard: SSCC-18 (GS1-128)





2008 JAN 10 AM 10:47

January 9, 2008

California State Board of Pharmacy
1625 N. Market Boulevard, Suite N219
Sacramento, CA 95834

To the Members of the California State Board of Pharmacy,

As a manufacturer and supplier to the pharmaceutical supply chain, and most importantly to the patient population, Watson understands and concurs with the California Board of Pharmacy regarding the critical need to ensure a safe and secure supply chain. During the December 5th, 2007, California Board of Pharmacy Enforcement Committee Meeting, Watson went on record reviewing our support to date as well as compliance to meet all other states Anti-Counterfeit Drug Pedigree legislative requirements including the state of Florida, completion of E-Pedigree application/vendor selection and implementation timeline for 2008, completion of a two year RFID pilot program, continued progress on our long term serialization strategy prioritizing high risk products, and research of interoperable components and investments made toward these new technologies.

In summary, we committed to continue progressive steps towards California's legislative requirements, but also asked the California Board of Pharmacy to exercise its authority pursuant to Section 4163.5 of the Business and Professions Code to extend the date for compliance with the electronic pedigree requirements. Watson does not believe that it will be possible to implement all of the electronic track and trace components required to serialize each product at the smallest unit of sale level by January 1, 2009. Some of these challenges are due to a lack of solidified standards still under development that will assist with Track and Trace, Data Exchange Discovery, and Global Data Synchronization. The lack of these standards makes it prohibitive for all members of the Healthcare Supply Chain to implement interoperable systems, providing a unified solution.

Watson believes that failure to extend the deadline would place patient safety at risk due to possible supply chain interruption of generic medicines needed for millions of Californians who depend on these lower cost alternative prescription drugs to prevent and treat many conditions. It is Watson's view that the risk of patients not having access to their medicines is greater than the risk associated with the existing system.

Watson will continue to participate and work with industry councils and regulators to solidify interoperable, validated standards that will lead to a permanent solution to ensure a safe and secure supply chain.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Diane Miranda".

Diane Miranda
Vice President, Sales Operations & Distribution

360 Mt. Kemble Avenue, Morristown, New Jersey 07962

973-355-8300