

Comments re: Inference

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@LISTSERV.DCA.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, November 21, 2012 9:00 AM
To: PHARM-GENERAL@LISTSERV.DCA.CA.GOV
Subject: E-Pedigree Inference Comments

Last call for comments on Inference:

The Board continues to seek detailed information from members of the pharmaceutical supply chain to build the elements for a possible regulation dealing with inference. These comments would be appreciated and most useful if received before the December 4th Enforcement Committee Meeting. To facilitate the expectations of the Board in requesting these comments, we are re-releasing the information provided below. Thank you and see you on December 4th.

At its September 11, 2012 meeting, the Enforcement Committee of the Board considered the submissions received in response to the "Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units Drug Pedigree Law" released/published July 23, 2012. A copy of the "Opportunity" document describing the parameters for submissions in support of a possible rulemaking is attached.

That request for information set a deadline of September 1, 2012 for such submissions. However, the discussion at the September 11, 2012 Enforcement Committee meeting made clear that greater specificity and greater participation by all segments of the supply chain is desirable to support a possible rulemaking.

Accordingly, the Board is extending the deadline for submissions in response to the "Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law" to a new deadline date of **November 30, 2012**. Once again, please submit in hardcopy.

Any new or supplemental submission should pay careful attention to the descriptions of the information that would be helpful to the Board that are given in the attached.

In particular, submitting parties are directed to items 3, 4, and 6 in the attached, and to the detailed information outlined in those items.

The intended sequence is that any submitting party:

- (a) identify the means and methodology, in as much detail as possible, that it will deploy to meet the pedigree requirements, including certification requirement(s);
- (b) where an inference is requested, identify as specifically as possible the particular transaction(s) to which the inference is to be applied (e.g., a wholesaler requests an "inbound inference" that, upon receipt of sealed cases from a known and demonstrably reliable manufacturer trading partner, that are homogenous both in product/SKU and lot number, it be allowed to "infer" that the case identifier is accurately linked to the individual package serial numbers, so that it can receive and certify receipt of the individual items based on that parent-child relationship without opening the sealed case prior to accomplishing "receipt" of product)

and suggest regulatory language that can accurately and specifically describe the limited transaction(s) in question;

(c) supply data on how many units and/or percentage of the business that would be subject to this transactional inference, thereby helping to define potential increase in risk/decrease in unit-level tracking that is inherent in this inference; and

(d) describe and support with as much data as possible the perceived benefit of this inference, whether in terms of how much additional cost would be incurred and/or is being avoided by use of this inference, what is the increased risk that is avoided by not having these cases opened, or in other terms.

Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law

Pursuant to Business and Professions Code section 4163.3 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants' ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, § 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than September 1, 2012.

§ 4163.3. Legislative intent; maintaining integrity of pedigree system; use of inference

(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Section 4163.3 affirms the base requirement of the California pedigree law that all participants in the dangerous drug supply chain will “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.” Accordingly, the subsequent direction to the Board, to issue regulations defining circumstances under which it would be permissible to substitute an inference as to the contents of an aggregate container for verification and validation of that container’s individual unit contents, is similarly limited. Any allowance for inference(s) cannot unacceptably increase supply chain risk(s).

To meet this standard, the Board must base any regulation permitting inference on supply chain information and data demonstrating that use or reliance on inference in specified settings and/or under particular transactional circumstances will not unacceptably increase supply chain risk(s).

At its public meetings, the Board has repeatedly stated its willingness to receive this information. This notification confirms that the Board will accept written submissions from interested parties, in support of or in opposition to permitting inference under specified circumstances, to develop the record necessary to any Board rulemaking on the subject of inference and/or certification.

Necessary Information in Submissions

Any submission by an interested party¹ should include at least the following:

1. Identifying and contact information for the submitting person or entity.
2. A description of the submitting party’s interest in this subject, including the submitting party’s role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.
3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level,” including specification of the means and methodology for certification.
4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.

6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

8. A proposal for the allocation of any liability that may be incurred due to use of inference.

Where and When to Submit

All written submissions should be mailed or delivered to Executive Officer Virginia Herold, Board of Pharmacy, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. Materials received on or before September 1, 2012 will be considered by the Board in developing a possible rulemaking. These submissions will be considered at the Enforcement Committee meeting on September 11, 2012, and/or at the full Board meeting on October 25-26, 2012.

1 The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of inference(s). Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of inference(s).



<https://www.dca.ca.gov/webapps/pharmacy/subscribe.php>



ISSUE DATE: July 23, 2012

**Opportunity to Submit Information Necessary to Possible Board Rulemaking
On Inference and Certification of Individual Package Units – Drug Pedigree Law**

Pursuant to Business and Professions Code section 4163.3 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants' ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, §§ 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than September 1, 2012.

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- (b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.
- (c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.
- (d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.
- (e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Section 4163.3 affirms the base requirement of the California pedigree law that all participants in the dangerous drug supply chain will “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.” Accordingly, the subsequent direction to the Board, to issue regulations defining circumstances under which it would be permissible to substitute an inference as to the contents of an aggregate container for verification and validation of that container's individual unit contents, is similarly limited. Any allowance for inference(s) cannot unacceptably increase supply chain risk(s).

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1. Identifying and contact information for the submitting person or entity.
2. A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.
3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to "verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level," including specification of the means and methodology for certification.
4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).
5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.
6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

¹ The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of inference(s). Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of inference(s).

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.
8. A proposal for the allocation of any liability that may be incurred due to use of inference.

Where and When to Submit

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August 31, 2012

Executive Officer Virginia Herold
Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

RE: Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law; ISSUE DATE: July 23, 2012

Dear Madam:

Amgen discovers, develops, manufactures, and delivers innovative human therapeutics. A biotechnology pioneer since 1980 headquartered in Thousand Oaks, CA, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. (For more information, visit www.amgen.com)

Amgen is pleased to be afforded the opportunity to provide comments on the *Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law*. Amgen endorses the Board's commitment to ensuring the safety of patients and the drug supply. Amgen is committing major resources to the implementation of its serialization projects in order to play its part in building an interoperable system. While Amgen has not finalized all of the details of its serialization system, and many aspects of this system are proprietary and confidential, it offers the following comments:

- Aggregation and Inference are critical operational and inventory management elements in making serialization and interoperability a more cost-effective and impactful method to protect patients and the drug supply.
- As part of good manufacturing practices, Amgen actively takes precautions to ensure quality is maintained throughout the production and distribution of goods to our wholesalers and other authorized distributors. For example, our quality management system requires that equipment, information systems, and processes are tested and validated prior to their use for production. Automated verification is also built into the packaging process to confirm correct information is printed on the products and their secondary packaging. Sampling during production is performed to further verify that quality is sustained. Applicable staff are trained on and use standardized procedures where appropriate as part of this quality management system. We intend to use the quality management system to ensure serialization and aggregation attributes, like any other quality attributes, meet Amgen standards and comply with all applicable laws and regulations.
- Amgen recommends that regulators provide guidelines for the use of inference. However, these guidelines should not specify how an aggregation and inference process should be performed or what the acceptance criteria should be. Manufacturers and other supply chain members should be



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One Amgen Center Dr. MS 28-3-B
Thousand Oaks, CA 91320
www.amgen.com

allowed to determine how to perform quality checks and establish the appropriate criteria, in line with their existing quality practices.

Again, Amgen wishes to thank the Board of Pharmacy for receiving its comments on the important issue of inference.

Amgen is committed to work proactively with the Board of Pharmacy to enhance regulatory and compliance systems to secure the drug supply chain. We share the Board's concern about the public health impact caused by diversion and counterfeiting and strive to meet our corporate mission of serving every patient, every time.

Sincerely yours,

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Lewis T. Kontnik
Director, Brand Protection

APOTEX

ADVANCING GENERICS

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BOARD OF PHARMACY
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August 24, 2012

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

Dear Members of the California Board of Pharmacy,

Apotex welcomes the opportunity to comment on the Board's request for information regarding the pharmaceutical supply chain's use of inference in carrying out the requirements of California's electronic pedigree law. Apotex believes an end-point model would most efficiently achieve the public policy objectives of an electronic track and trace system at the state and/or federal level, and that, under such a model, aggregation and inference would not be necessary. Unlike an end point system, however, California's law requires the tracking and tracing at the unit of sale level. Under any such system requiring confirmation of serial numbers at each movement through the supply chain, it is essential, for efficiency and cost containment purposes, that inference be allowed. Requiring the scan of each unit will increase the cost of pharmaceuticals and introduce significant disruptions in product movement through the supply chain with potentially adverse impact on the public's timely access to affordable medicine. Accordingly, Apotex strongly encourages the California Board of Pharmacy to permit the use of inference under its electronic pedigree law as currently proposed.

Apotex would also like to take the opportunity these comments provide to express its concerns about the ability of the entire supply chain to meet the deadlines for compliance with California's electronic track and trace law. While Apotex will be ready to meet these deadlines, our ongoing preparations leave us with the view that the complexity of the task continues to pose significant challenges for compliance of the supply chain as a whole under the proposed deadlines. For example, there are some concerns that the effort required to establish e-pedigree connections to our customers will not occur in a timely manner to support the established deadlines. It is feared that, the time each connection is expected to take in conjunction with the anticipated last minute rush will leave some customers unable to conduct business under the new law. The sheer number of connections required in the greater supply chain is also a concern. Apotex therefore urges the Board to keep an open mind on the compliance timeline question as the Board continues to participate in the continuing discussions at the federal level about establishing a national system. Should such a system fail to be enacted this year, Apotex would similarly urge the Board to keep an open mind on the compliance timeline in any such discussions the supply chain should raise with the state.

1. Apotex Corporation (Corp) is the US Company that markets the products of Apotex Inc., the largest Canadian-owned manufacturer of prescription drugs. Apotex Inc. sells a portfolio of approximately 300 affordable medicines to 115 countries around the world. Through its sales and marketing offices in Weston, Florida, and operations center in Indianapolis, Indiana, Apotex Corp. is committed to providing safe and affordable generic medicines to the US market.
2. Apotex plans to address e-pedigree requirements via serialization of unit of sale, inner pack, case and pallet utilizing GS1 standard 2D Data matrix barcodes. Given that barcoding is a line of site technology, we plan to utilize inference to allow for aggregation of child serial numbers to parent serial numbers for inner pack, shipper case and pallet aggregation. Aggregation to higher pack formats would be electronically tracked and included in Advanced Ship Notice (ASN) and some Electronic Product Code Information Service (EPCIS) communications.

Apotex has partnered with industry leading solution providers to ensure appropriate, validated solutions are implemented to support the serialization and aggregation of our product, as well as the internal storage, tracking of serialized product to our customers down in the supply chain using Drug Pedigree Messaging Standard (DPMS) and EPCIS and to allow for tracing from our Third Party Suppliers.

Apotex is requesting a regulatory allowance for the use of inference from the Board. As described in our response to question 3, Apotex intends to use inference to aggregate child serial numbers for inner pack, shipper case, and pallet aggregation. Although we are not submitting regulatory language at this time, Apotex fully intends to work actively with all stakeholders on efforts to develop such language.

4. As described in the opening paragraph of these comments, Apotex is strongly in favor of the use of inference in any track and trace system that imposes unit-level tracking requirements. Inference is required to preserve efficiencies in the US Pharmaceutical Supply Chain while minimizing additional operational costs we expect to incur if inference is not permitted.
5. Inference is a mechanism that enables healthcare entities to conduct business in a manner that leverages best practices to meet the challenges associated with the distribution of serialized products. Inference enables the results of transactions conducted at the parent (case) packaging level to be automatically cascaded to all of the contents of that level automatically, without having to scan each individual unit packed within the parent. Apotex feels that inference is but a part of the solution. Combining inference with validated serialization systems and revised Standard Operating Procedures would balance the need for efficiency with the underlying value of security.

If inference and aggregation are not accepted in practice, the US pharmaceutical supply chain would be forced into unit level verification at every exchange of ownership. This would, no doubt, lead to a severe and unacceptable increase in effort to process drugs through the supply chain. Subsequently, it would dramatically increase the potential for delays in patients obtaining much needed medicines. Additionally, in order to attempt to maintain throughput, many of our downstream partners would be forced to expend a significant amount of energy, time and resources, in sum, leading to an increase in costs which would need to be passed to the end consumer.

Since 2D barcoding has become the data carrier of choice for serialized products, line of sight will be required. If inference is not an accepted practice, it would be very costly to the supply chain and ultimately to the consumer. Having to manually scan each unit of sale shipped and received would result in a dramatic increase in man hours and would expect to lead to supply interruptions caused by the added delays at all levels of the supply chain.

It is our opinion that the acceptance of inference adds no additional risk to the security of product while helping to ensure minimal supply disruptions by maintaining a required level of efficiency in the Supply Chain. Utilizing inference would reduce the need for additional manual handling of units which by its nature could lead to unnecessary human error and additional costs incurred as a result of the additional handling.

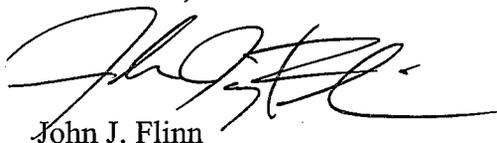
It is felt that inference allows for balance in the Supply Chain by maintaining efficient delivery of product down to the end consumer while allowing the various partners to stay true to the intent of the legislation to ensure a more secure Supply Chain for the enhanced safety of all Americans.

6. Apotex is in the process of finalizing its implementation program. While it is understood this new technology will require changes to Standard Operating Procedures, it is too early to identify the magnitude and specifics of the changes required. We can infer however, that the majority of any SOD changes will be found in the operating of packaging and distribution systems as well as the exchange of information with Third Party partners and customers.
7. Apotex does not feel there should be any allocation of liability. Inference, along with serialization, is intended to provide for an increase in security while minimizing disruption in the pharmaceutical supply chain. Whilst all supply chain partners appear to be working diligently to implement serialization and e-pedigree solutions, we all do so in good faith. In the unlikely event there is a challenge due to inference, we feel this would need to be handled on a case by case basis, allowing for flexibility to resolve the issue at hand. Instituting liability language, in our viewpoint, would undermine the cooperative spirit of the newly secured Supply Chain in the US. Further, it is felt that free market should determine liability, once again, on a case by case basis.

At this time, Apotex would like to take the opportunity to have the Board provide further clarification on grandfathering of existing stock during the transition period. We would also strongly suggest the Board formally support the widely expected use of EPCIS as the primary messaging standard for epedigree. By providing clearer direction on these two critical items the supply chain can focus on implementing the needed systems to support the looming deadlines.

We appreciate the opportunity to provide our perspective on these issues and will continue to work collaboratively with our various trade organizations to support increasing security in our supply chain.

Thank You,

A handwritten signature in black ink, appearing to read 'John J. Flinn', written over a horizontal line.

John J. Flinn

Vice President Commercial Operations
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August 30, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

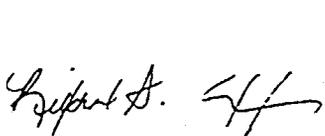
Dear Ms. Herold:

The undersigned organizations (BayBio, BIOCOM, and CHI) are California's leading life science associations, representing more than 2,400 biotechnology, pharmaceutical, medical device, diagnostics, research tools, and bioagricultural companies. California is home to the oldest, largest and most productive life science clusters in the world, employing more than 268,000 people statewide. The total economic impact of the life sciences in California is greater than either Hollywood's vaunted entertainment industry or our world renowned wine industry. We appreciate the opportunity to comment on the Board's "Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law" in our role as general representatives for many companies who would be the source point for much of the supply which will enter the system discussed.

Inference is an absolutely critical component to a viable and effective track and trace system. In order to produce a system that does not interrupt and delay the access to medications and other therapies for patients, regulations should encourage use of inference to the maximum extent possible. BayBio, BIOCOM and CHI are concerned that a system without strong utilization of bundling and inference will inevitably create supply stream bottlenecks, delaying the delivery of medications to the consumer and placing great numbers of patients at unnecessary risk. Additionally, it will likely require significant increases in workforce to manage the greatly increased administrative workload. The specific proprietary methods to be used to establish pedigree across our combined memberships will vary, and so we are unable to comment on specific means and methodology to be used by our members. The mere fact that this variance will exist illustrates the complexity faced by our member companies, downstream suppliers, and the Board of Pharmacy in ensuring a fully interoperable system.

Another issue we would like to bring to the Board's attention on behalf of our memberships is that of liability. Manufacturers should not be liable for the actions of those not under their direct control. Once a product has been transferred from the manufacturer's jurisdiction, a manufacturer cannot reasonably be expected to be able to insure or affect its safety and security. Provided all relevant statutes and regulations have been adhered to and packaging is not compromised, liability should follow the product and be conveyed to the parties accepting the product throughout the supply chain. A manufacturer cannot be reasonably held responsible for the actions of downstream participants with whom they have no direct contact or control over independent supply chain actors.

BayBio, BIOCOM and CHI greatly appreciate the opportunity to submit comment in this matter. If we may answer any questions on behalf of our respective associations, please feel free to contact us at the numbers or email addresses below.



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VIA EMAIL (Virginia.Herold@dca.ca.gov)

September 6, 2012

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (July 23, 2012)

Dear Ms. Herold:

Please accept this letter as Cardinal Health's response to the Board of Pharmacy's Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law, published July 23, 2012. Headquartered in Dublin, Ohio, Cardinal Health helps pharmacies, hospitals, ambulatory surgery centers and physician offices focus on patient care while reducing costs, enhancing efficiency, and improving quality. Cardinal Health is an essential link in the health care supply chain, providing pharmaceuticals and medical products to more than 60,000 locations each day. The ability to use inference in meeting the obligations under the California pedigree law will be a critical process in maintaining efficiency for Cardinal Health and our customers.

Overview of California pharmaceutical distribution business

Cardinal Health has two pharmaceutical distribution centers in California. Our locations in Elk Grove and Valencia service over 3,000 customers; providing pharmacies, hospitals, ambulatory surgery centers and physician's offices with access to over 57,000 items including 20,000 prescription (dangerous) drugs.

The below statistics highlight the approximate volume of annual operational activities for our two California pharmaceutical distribution centers. These numbers illustrate the magnitude of serial number management that will be required for compliance with California pedigree law:

- Receipts: 55 million pieces; 2 million cases
- Shipments: 55 million pieces (75% of which are Rx) contained within 4 million totes
- Returns: 3% of pieces originally shipped

Cardinal Health has been engaged in pilot activities to support implementation of the California pedigree law for more than five years. One of our California distribution centers is currently engaged in pilot activities with several drug manufacturers to build effective controls to comply with the law while ensuring business efficiencies.

Inference definition

Inference can be defined as a conclusion drawn from evidence or reasoning. For the purposes of pedigree, inference is a process that supply chain partners use to electronically match expected receipts and shipments with the physical product actually received or shipped without physically reading each unique serial number within a packaging unit.

Cardinal Health believes that inference, when used responsibly in the receiving and shipping processes, will support efficient operations and will not increase the risk of diversion or counterfeiting within the pharmaceutical supply chain.

Circumstances where inference is necessary

California pedigree law evidences the legislative intent in statute. The Legislature intended that all participants in the supply chain “verify and validate the delivery and receipt of dangerous drugs against those [electronic] pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.” See B&PC §4163.3(a). Inference is an essential operational process that must be allowed in order to comply with the law. The Legislature recognizes this as they included §4163.3(b) the requirement that the Board of Pharmacy, by regulation, shall “define the circumstances under which participants in the distribution chain may infer...”. See §4163.3(b). To aid the Board in drafting those regulations, the following circumstances are those which Cardinal Health would like to utilize inference:

- Distributor’s receipt of sealed full case(s) when electronic data has been received from the supplier prior to receipt of the physical product. The electronic data received must provide the unit to case relationship.
- Distributor’s receipt of full pallet(s) when electronic data has been received from the supplier prior to the receipt of the physical product. The electronic data received must provide the unit to case and case to pallet relationship.
- Distributor’s shipment of sealed full case quantities when electronic data has been delivered, prior to the recipient’s receipt of the physical product, from the distributor. The electronic data must provide the recipient with unit to case relationship.
- Inference shall not be allowed on receipt of a product through the returns process.

Cardinal Health requests that the Board of Pharmacy draft regulations allowing inference in these above circumstances.

Because Cardinal Health strives to fulfill customers’ needs immediately, we ship daily (sometimes twice daily) to customers. These order quantities tend to be single units. Data over a one year period for six serialized NDCs shows that although 70% of products were received

during this period with inference, 98% of units (serial numbers on an individual unit) shipped were physically read upon receipt, shipment, or both. The 2% of units not scanned at the unit level are scanned at the case level. Both receipt and shipment serial numbers for these case level scans are recorded as transferring ownership based on verification of the original electronic transmission provided by the supplier. See chart below for actual pilot statistics in 2011:



Procedures to use inference

Cardinal Health has established documented procedures in our distribution center engaged in pedigree pilot activities. Although these procedures may be revised with increased product volume, the major components of the procedures will remain the same and are as follows:

- Supplier must provide electronic transmission via AS2 secured transaction (using either a serialized Advanced Ship Notice, DPMS pedigree, or EPCIS transaction) that provides hierarchy for serialized products
- Procedures are defined to determine which suppliers can be trusted to provide accurate and complete data:
 - Physical verification of a defined number of consecutive receipts
 - 100% match of electronic transmission with physical serial numbers received
 - No manual intervention other than product scans
 - Approval of trusted status by local compliance manager
 - Signed documentation of process compliance
- Random audits performed to ensure ongoing accuracy of electronic transmissions
 - Conducted according to ANSI/ASQZ1.4-2008, using Special Level S-1 and the single sampling plan for normal inspections

Safety of inference

Prescription drug manufacturers have overt and covert methods for securing their products. One of the overt methods is the case seal or tape. The security of the case is compromised when that seal is broken and product continues to move in its original carton through the supply chain. California regulation requires that all materials be examined upon receipt or before shipment. See CCR 1780(d). Our distribution centers examine product to ensure there is no evidence of tampering, such as a broken seal on a manufacturer's case. The ability to infer the contents and leave the cases sealed either until the entire case is sold or until a single unit is needed for a customer, would create a more secure supply chain.

Operationally, inference is preferred because opening every case in an effort to read the individual units would have a significant negative impact on productivity and may lead to overall increased cost to distribute in California. In addition, the use of inference expedites the receiving process, resulting in product being readily available to ship to dispensers that have patients in need of those prescription drugs.

Liability

Each trading partner should be responsible for information they represent as true and for the consequences that result if such information is found to be false or erroneous. Consideration should be given to whether the error was intentional or due to human error or mistake, as well as the seriousness of the resulting consequence.

Parties should be liable for their own actions, but mitigating factors such as properly vetting trading partners, due diligence, long-standing relationships, and past experience (good or bad) with a certain entities should be taken into consideration when determining any liability resulting from reliance on inference as a result of manufacturer provided product and shipment information.

Conclusion

The safety and security of our nation's pharmaceutical supply is one of Cardinal Health's top priorities. We take this responsibility very seriously, as a safe and reliable drug supply is central to our customers' business and critical to the health and well being of patients. We are committed to complying with pedigree laws, including serialization requirements, in the most efficient manner possible. If you have any further questions, please do not hesitate to contact us.

Sincerely,



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August 29, 2012

Virginia Herold
Executive Officer, California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Herold;

Thank you for the opportunity to comment on the Drug Pedigree Law as it relates to inference and certification of individual package units.

As licensed healthcare practitioners in California, we support the Board's decision on moving forward with Pedigree Law to protect the public from counterfeit medications and minimize drug diversion. Furthermore, we concur with the California Society of Health-System Pharmacists (CSHP) Policy on E-Pedigree and Tracking of the Medication Supply Chain (see Attachment 1). While many of the processes for ordering, receiving, and inventorying of pharmaceuticals are shared across pharmacy practice settings (community, hospital, retail, etc.), the Pedigree Law will create unique challenges and opportunities for hospital pharmacists. We wish to elucidate the specific implications of the Pedigree Law on inpatient pharmacy practice.

To facilitate electronic inference, it is expected that all firms fulfilling orders of dangerous drugs in aggregate containers will assign serial numbers to their containers as below:

- The aggregate is identified with a unique serial number and each unit/item in the aggregate is also identified with a unique serial number. For example, if medications are received in a pallet, then each pallet will have unique serial number, each tote on the pallet will have a unique serial number, and each unit in the tote will have its own unique serial number.
- All serial numbers are associated with the aggregate in a hierarchical relationship.
- Electronic communication identifies each item in the aggregate.
- Pharmacies will have assurance that the integrity of the aggregate has remained intact since leaving the last supply chain partner and can confirm the integrity of the aggregate has not been compromised.

1) Risks Associated with Open Cases

We support a regulatory allowance that would allow individual pharmacies to choose to infer the contents of aggregate containers for the purposes of certification of delivery or receipt of individual package units for all dangerous drugs. Inference supports patient safety, security and efficiency in the supply chain distribution process (i.e., products move faster in the supply chain). Opening containers to verify the individual package can lead to:

- Delayed delivery of medications to patients
- Introduction of error into the system
- Tampering
- Theft
- Product mix-up

The security and integrity of medications may be compromised if security seals or tamper evident packages are not left intact. For example, open packages of controlled substances may lead to tampering or theft.

2) Statistical Sampling

We support statistical sampling of incoming shipments from trusted members of the supply chain rather than conducting 100% inspection of all incoming items to assess the presence and integrity of the products. We do not support regulatory language which would require pharmacies to perform sampling for chemical analysis of medications; rather, sampling should be limited to product or package confirmation. We would recommend each Pharmacist in Charge (PIC) be responsible for delineating within their own Standard Operating Procedures (SOPs):

- Frequency and amount of sampling performed.
- Situations in which 100% of the shipment should be inspected if there is reason to be suspicious about the integrity of an incoming shipment.

Manufacturers and distributors/wholesalers should have additional responsibility for conducting more frequent statistical sampling (based on the Acceptable Quality Level [AQL]) and periodic chemical analysis before medications are shipped to pharmacies. Pharmacies should not be liable for receiving counterfeit or mishandled medications during transportation.

3) Technology and Manual Pedigree

We anticipate the Board will receive comments from other supply chain participants and technology vendors with specific hardware, software, and data carrier recommendations to facilitate the passing of electronic pedigree information among supply chain participants. We believe the system used for tracking E-Pedigree should be harmonized with internationally recognized standards for such an identifier (e.g., Radio Frequency Identification (RFID), Serialized Global Trade Item Number (SGTIN)). We urge the Board to recognize there will be situations which will require manual tracking of pedigree information (e.g., during hardware/software downtime, emergency situations). We suggest each hospital should define within their SOPs their process for manual pedigree tracking. Ideally, in the future, one machine-readable code would contain a product's expiration date, lot number, and NDC number which would be then tracked through pedigree.

4) Exception for Using Electronic Pedigree (Risk Assessment)

While the comments above are specific to the use of inference of aggregate package contents, the situations in which an electronic pedigree must be passed between supply chain participants impacts and will be impacted by the decision to use inference. Because of the difficulties associated with passing an E-pedigree, the relationships hospital pharmacies have with the entities below, and the minimal risk of tampering, fraud or errors, we recommend against the use of electronic pedigrees in the following situations:

- The ability for pharmacies to procure essential medication from another pharmacy to avoid patient harm (i.e., emergency loan and borrow)
- Sales/transfers to another pharmacy under common control
- Sales/transfers to authorized providers (e.g., sales to private doctors' offices)
- Medication shipments approved by the FDA and received from outside of the United States due to critical drug shortages (e.g., methotrexate from Europe)
- Reverse distributor transactions (e.g., for expired and recalled medications)
- Compounded medications from contracted pharmacies that have a quality assurance program built in as part of their contracted relationship with the pharmacy (e.g., outsourced parenteral nutrition compounding company)
- Existing medication inventory

Finally, we would appreciate the opportunity to address these issues at an upcoming Board meeting.

Founded in 1962, CSHP represents over 4,500 pharmacists, student pharmacists, pharmacy technicians, and associates who serve patients and the public through the promotion of wellness and rational drug therapy. CSHP members practice in a variety of organized healthcare settings – including, but not limited to, hospitals, integrated healthcare systems, medication therapy management clinics, home healthcare and ambulatory care settings.

If you have any questions and/or comments, please do not hesitate to contact me or CSHP Legislative and Regulatory Analyst Jonathan Nelson at (916) 447-1033 ext. 105 or jonathan@cshp.org.

Sincerely,



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Attachment 1

California Society of Health-System Pharmacists (CSHP) Policy on E-Pedigree and Tracking of the Medication Supply Chain

CSHP advocates for improved processes to assure the integrity of medications throughout the supply chain, specifically to eliminate or minimize the persistent and increasing threat from counterfeit, misbranded, adulterated, or diverted drugs.

1. Support the California State Board of Pharmacy in development of a comprehensive electronic pedigree system to track and trace the passage of medications through the entire supply chain.
2. Require the technology and process implemented be compatible with national and international standards so as not to impede the supply of medications.
3. Require the technology(s) adopted must be a single, shared interoperable system to allow health-systems to receive medications from all sources in a single process.
4. Advocate that the technology developed has the future ability to extend the validation of the pedigree to the level of patient administration throughout the continuum of care.
5. Assure that health-systems be an active participant in the development of technology, process design and implementation.
6. Advocate that the implementation deadlines for the supply chain be a phased in approach allowing health-systems time to implement after the deadlines for manufacturers and distributors.
7. Require that "grandfathered" inventory be addressed in the implementation plan to minimize inventory losses.
8. Advocate for a streamlined process to allow medication returns and "emergency" borrowing of medications within the documentation process.

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento, CA 95834

August 30, 2012

Dear Board of Pharmacy,

Re: Inference and Certification of Individual Package Units – Drug Pedigree Law

EMD Serono, Inc., the U.S. biopharmaceutical subsidiary of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical group, would like to thank the California Board of Pharmacy for their dedication to protecting the citizens of California through their tireless pursuit of electronic pedigree legislation. Like the California Board of Pharmacy, EMD Serono's goal is to protect patients from unauthentic products and we continue to take an active role in ensuring the safety and integrity of our products.

The industry moves approximately 9 million units per day* making unit level serialization without inference extremely challenging. EMD Serono thanks the California Board of Pharmacy for the opportunity to participate in the creation of practical inference guidelines. As many industry members have stated in previous letters and board meetings, if the industry is required to scan each individual unit throughout the supply chain, the additional burden would be devastating to the industry.

Description of EMD Serono's interest in serialization / inference

In 2002, EMD Serono implemented a secured distribution model including a track and trace program for Serostim® [somatotropin for injection], a recombinant human growth hormone. Shipments of Serostim® are restricted to contracted pharmacies that participate in this program. Each Serostim® unit is uniquely serialized and can be tracked to the patient level. In 2003 the FDA stated that the Serostim® tracking program is an effective solution.

Since the California Board of Pharmacy proposed the electronic pedigree and serialization legislation in 2004, EMD Serono has been diligently working on implementing an interoperable system using the GS1 standards and initiating pilot programs with wholesalers. Currently, EMD Serono has two pilot programs underway with two of its three major wholesalers.

Description of the means and methodology that have been deployed by EMD Serono

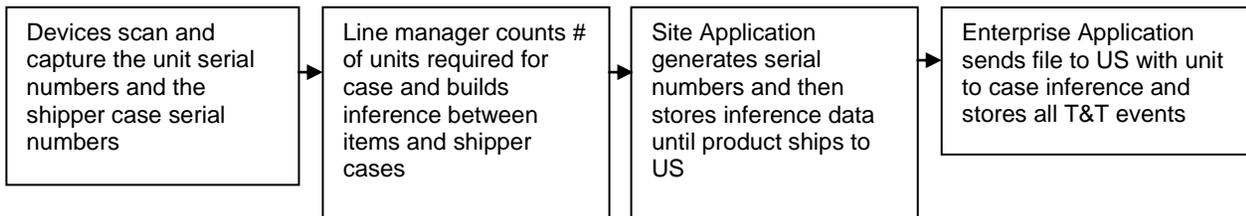
As noted in previous submissions to the California Board of Pharmacy, in order to implement serialization, EMD Serono had to establish a cross-function team including: Supply Chain, IT, Packaging, Manufacturing, Quality Assurance, Regulatory Affairs, Government Affairs, Legal and Procurement. This global team was successful in completing the following projects:

- Packaging modifications to add 2D barcodes and serial numbers,
- An application to capture and track all serial number events,
- State license processing and validation upgrades to include on the ePedigree,
- An upgrade to our 3PL interfaces to capture all data fields required for the ePedigree
- And finally the ePedigree solution.

All projects were completed by 2008 and we continue to make enhancements and phase in serialization. Currently we have eight out of eighteen major products serialized and plan to have all products serialized by 2015. The current system design is made up of four levels.

- Level 1: Devices and Printers
- Level 2: Line Controller
- Level 3: Site Application
- Level 4: Enterprise Application

As you see in the flow below, each level is essential to the serialization process.



Product marking at MFG	Each unit has a 2D barcode with the sGTIN encoded. (In 2015, each unit will have the sGTIN, lot and expiration date encoded into the 2D barcode.)
Data capture and Uniqueness check	Each unit is read immediately before being packaged into the case to ensure the following; 1) There are no duplicate serial numbers 2) The correct serial numbers are placed into the case 3) The correct item serial numbers are aggregated with the correct case serial number

Aggregation file building at MFG	All aggregated unit and case serial numbers are stored in the system as a “manufactured lot”
Product shipped to 3PL	A file with the unit to case association is sent to the 3PL for verification upon receipt.
In-bound at 3PL	Product is received and placed into quarantine until all verifications are complete, including quality and quantity checks.
Out-bound from 3PL	Product is scanned on the outbound, captured and passed via an electronic pedigree to the downstream trading partners.
Other inbound at 3PL	Product which is moved to retain or reject is captured and stored as product that will never ship to trading partners.
Returns	Product returns are captured as returned and sent for destruction. (Redistribution of returns is extremely rare and would need to go through extensive quality checks prior to placing product back to stock.)

EMD Serono has taken a number of steps to ensure the correct serial numbers are placed into the correct case. For example, our system logic will not allow a case to be completed and sealed until the serial numbers match the total case quantity. In addition, our manufacturing sites make sure item serial numbers are only scanned once the items are placed into the shipper case and also ensure the correct case label is applied to the correct shipper case.

Furthermore, our cases are packaged using branded tape. Therefore, any case that has been opened will be apparent. Less than full case quantities will invalidate the case serial number, requiring the case to be opened and all items within scanned individually.

Our final check is with our 3rd party logistics company. Upon arrival the product is placed into quarantine until all necessary quality and quantity checks are complete. For serialized product the quantity is validated against the serialized aggregated file received from the manufacturing site. If there is a discrepancy, each unit is scanned on the inbound to ensure the file is correct prior to shipping product to our trading partners. In addition, we have a final check on the outbound, which ensures there are no duplicate serial numbers within the file.

Reasons that inference is necessary and advantageous

Each supply chain step, starting from the goods outbound from the manufacturing site, requires identification of the shipped or received items. This operation cannot be managed without inference:

Having no inference would mean that every single item should be read/scanned individually, which would represent hundreds of thousands of scanning operations. Not only would this dramatically slow down the goods movements at each node, but it would also significantly increase the risk of error in the scanning operations.

We therefore believe that inference clearly decreases risks of diversion of counterfeiting, and is necessary and advantageous in order to

- Ensure the ability to track all individual serial numbers of a shipment within a reasonable time frame
- Maintain a seamless flow of goods through the supply and distribution chain
- Decrease the risk of error in the code reading operations and thereby minimizing the opportunity of counterfeit product entering the legitimate supply chain.

EMD Serono has taken great strides in serialization and has taken great efforts in ensuring the integrity of case inference. We have system checks, manual checks, clear Standard Operating Procedures and multiple checks prior to shipping product to our trading partners. In addition, in February 2012 our global team kicked off a new project to enhance the systems to reduce manual checks and further streamline the processes for global efficiencies.

As mentioned above, EMD Serono applauds the California Board of Pharmacy and other relevant Federal and State agencies for their continued efforts to ensure that measures remain in place by law to prevent counterfeiting and diversion throughout the United States. We have and will continue to work closely with the Federal and State authorities to ensure that our genuine medicines will reach patients for whom they are intended and will continue to advocate for a national standard. EMD Serono remains committed to assessing, testing and incorporating potential new technological advances in product tracking and distribution as they become practically available.

Date of Submission

August 30, 2012

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* Source: HDMA

RESPONSE TO CALIFORNIA BOARD OF PHARMACY

RE:INFERENCE

Thank you for the opportunity for GPhA to comment on inference and its role in compliance with the California Pedigree Law. The generic pharmaceutical industry is committed to providing safe and effective products to US consumers and believes that maintaining and improving the safety of the US supply chain are important components of achieving that goal.

The Generic Pharmaceutical Association (GPhA) represents manufacturers of generic drugs. Generic medicines now fill 80% of the prescription drugs dispensed in the US yet account for only 25% of the total cost. Over three billion of the four billion units sold in this country are generic. Given the enormous volume, compliance to the California ePedigree law by the mandated dates represents a large, complex and costly challenge to our members.

GPhA understands inference, within the context of the California law, to mean the ability of a downstream partner to infer, or assume, the contents (units) of an aggregate container (i.e., case or pallet) from information provided by the prior owner of the product, without necessarily opening that aggregate container. The ability to infer in this fashion, assumes that the prior owner has done aggregation, or created a parent-child data relationship (between the pallet - case – unit) and passed that data in a pedigree document to a downstream partner. Generic manufacturers are having great difficulty with meeting a certifiable aggregation requirement due to:

- Limits of aggregation technology and applications.
- Cost of aggregation.
- The value of manufacturer aggregation to increasing patient safety through increased supply chain security.
- Difficulties with data integrity and certification.
- Liability of data errors.

Aggregation Technology

The data carrier used by most, if not all, manufacturers planning to comply with California is the 2D barcode. 2D is readily available, has very high reliability and is relatively inexpensive. An interoperable system must enable downstream partners to infer the contents of aggregate containers. Because 2D barcode is a line-of-sight technology, establishing an accurate parent/child relationship between units, cases and pallets (i.e., aggregation) relies on cumbersome, inaccurate and expensive technology.

In a 2D scenario, manufacturer aggregation requires 360 degree visioning systems stationed in front of an automated case packing machine. Each serialized unit is scanned using optical character recognition technology as it is packed into a new case. This process varies from line to line depending on the presence of automated case packers, palletizers, different package types - i.e., tubes, cartons, bottles - which sometimes results in units needing to be turned, tilted or manipulated robotically to allow the

scan of the label at high speeds. Once the appropriate number of units has been packed into a case and that case is sealed, the system at the line level virtually creates that case with those specific units inside. In turn, when cases are stacked onto pallets, the cases typically must be hand-scanned, unless a palletizer is present. That step would complete the aggregation of units to cases, and then cases to pallets. The ability to get accurate scans while operating at production speeds, while also accounting for all of the different misfeeds, sampling for quality assurance, line stoppages, etc., makes this process cumbersome and very expensive. Errors are a certainty, potentially caused by any number of factors from packaging types and shapes, to equipment issues and technology limitations, to line exceptions.

The Value of Manufacturer Aggregation

75%-90% of cases, and virtually 100% of pallets are opened or divided and the units subsequently placed in a new aggregate container by the first supply chain customer, thereby obviating the manufacturers aggregation information for those affected units. The lion's share of generic Rx products are sold through the "big 3" wholesalers. Most of these cases are opened and the units piece-packed at the wholesaler for subsequent sale. The net effect of this repackaging after one "hop" in the supply chain is that units would likely need to be "re-aggregated" to their new containers at the wholesale/distributor stage in order to allow inference further down the supply chain.

Given this value proposition for manufacturers aggregation, it is important to look at the costs:

Costs for Manufacturers Aggregation (Industry estimate)

Assumptions:

- Assumes 2D barcode as data carrier
- This model does not include cost for line shutdowns, re-engineering due to speeds or space constraints.
- This model does not include cost for returns or shipment refusals due to lack of certification, etc.

Number of drug manufacturers serving the US market		425
Number of production / packaging lines - industry aggregate	\$	3,250
Typ. Cost per production / packaging line with serialization, but no aggregation	\$	125,000
Typ. Cost per production / packaging line with serialization and aggregation	\$	750,000
Typ. Cost of Database / EPCIS/ Pedigree and integration	\$	2,000,000

	<i>No aggregation</i>	<i>With aggregation</i>
Total cost of production / packaging lines	\$ 406,250,000	\$ 2,437,500,000
Total cost of database and integration	<u>\$ 850,000,000</u>	<u>\$ 850,000,000</u>
(One time) Simple CapEx subtotal	\$ 1,256,250,000	\$ 3,287,500,000
Annual OpEx (Maintenance / Updates)	\$ 251,250,000.0	\$ 657,500,000

So, the net value of a \$3.3 billion manufacturer investment, and annual maintenance of \$658 million in aggregation technology is the transmission of a parent/child relationship for only one step in the supply chain in most cases. GPhA believes that in order to allow the entire supply chain to infer the contents of aggregate containers (cases and pallets), it would be necessary for serialization of the new containers (totes, etc.) plus "re-aggregation" of the units to those totes, increasing the costs detailed above in total industry terms.

Difficulties with Certification Mandates in California's law

An important aspect of California's law is the certification of the accuracy of pedigree information with every change of title in the supply chain. Given the description of the manufacturers aggregation process as detailed above, GPhA believes that it would be very difficult, if not impossible, for a manufacturer to certify aggregation information for 100% of product. The available technology and processes are simply not 100% accurate in scale and at production speeds with different product and package types.

Another complication in the certification aspect of California's law is the common use of third party manufacturers. Under California's law, the ANDA holder in the case of a generic, is the manufacturer, meaning that company must create a certifiable pedigree. In the case of a contract manufacturer relationship, which all of the large generic manufacturers have, much of the industry will be in the position of certifying aggregation information that is not under the manufacturer's direct control.

Potential Liability for errors in inferred data

GPhA believes that the vision systems currently available for the aggregation of serialized units fall short of 100% reliability. Therefore, a certain percentage of system error is unavoidable for aggregated data regardless of standard operating procedures. Further, manufacturers cannot be held responsible for the operating processes and procedures of other supply chain participants and their handling of data. GPhA urges the board to take this into consideration and establish liability rules only to the company holding title to a product at the time of an incident.

Thank you very much for the opportunity to provide comments on inference. GPhA looks forward to participating in this process with the ultimate goal of an achievable, reliable and cost-effective system which results in a safer supply chain for all.



August 30, 2012

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (July 23, 2012)

Dear Ms. Herold:

On behalf of the Healthcare Distribution Management Association (HDMA) and its members serving California, I appreciate the opportunity to respond to the Board of Pharmacy's request for comments regarding inference and its use in the context of California's electronic pedigree law. The framework set forth by this law will result in operational and technological changes unlike any the industry has experienced to date. Inference will be an integral part of any implementation strategy for pharmaceutical distributors, and its allowance by the Board is necessary for distributors to meet the goals and requirements of the California law.

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Nearly 90 percent of the prescription drugs in the U.S. are stored, managed, and delivered by our primary distributor members. Every day, HDMA member companies collectively ensure that nearly 9 million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. In California, our members serve over 32,000 customers.

We appreciate and support the Board of Pharmacy's request for comments from individual companies. As you know, HDMA also has been significantly involved in the development of the California pedigree law and offers a unique and critical viewpoint on implementation. We hope that this perspective is helpful to the Board as it moves toward 2015 and beyond.



Background

Inference in the context of electronic pedigree and track-and-trace has essentially the same meaning as it does in the English language – an assumption that a proposition is true based on the occurrence of some other fact or assumption. For example, Wholesale Distributor XYZ received ten individual units in a sealed case (A) from the manufacturer of a product, along with a communication stating that these ten units were numbered 1 through 10 in case A. Because the manufacturer provided this information, and the same manufacturer sent Wholesale Distributor XYZ the case, XYZ can *infer* that what the manufacturer sent to it is what was stated by the manufacturer – without requiring Wholesale Distributor XYZ to open the case to confirm.

The concept of inference first emerged in discussions among pharmaceutical supply chain partners approximately five years ago, when the current iteration of the California pedigree law was being drafted by the Legislature. Historically, California’s law has been silent on the specific type of technology and/or data carrier required to satisfy the provisions of the law, but the concept of unit level track-and-trace was based originally on the capabilities of radiofrequency identification (RFID) technologies. In 2007 or 2008, it became clear that manufacturers overwhelmingly believed that unit level serialization was more practical and economically feasible through the use of two dimensional (2D) data matrix bar codes. Because 2D bar codes utilize “line of sight” technology, an individual must scan each bar code in order to capture product information.

On an average day, a typical HDMA member distribution center handles almost 2,000 customer orders, and picks (or processes) an average of 95,000 product units. Due to this high volume and the associated need for efficiencies of scale, scanning individual units on receipt is not always practical or economically feasible. The Legislature understood the need for supply chain members to avoid having to unnecessarily open every single case of product.

In recognition of this concern, the Legislature’s solution was the allowance for inference as described in California Bus. & Prof. Code § 4163.3. HDMA reads the statutory language regarding inference as requiring the Board of Pharmacy to issue regulations that define circumstances in which inference may be used. The need for inference still exists today, and without it, primary distributors will have incredible difficulty with implementation, potentially slowing movement of product and bringing the distribution chain to a halt in California.

Below are HDMA’s responses to a number of the Board of Pharmacy’s specific requests for information.

I. Process and Technology Recommendations

HDMA and its members have been working on implementation issues related to California’s pedigree law since before the 2008 law was enacted. Our members have engaged staff and

outside consultants in exploring existing and developing technology solutions in order to help them comply with the California law. Some members have also engaged in pilot programs that will help inform more specific solutions and data exchange between trading partners.

In addition, HDMA members have been participating in the development of GS1 standards and piloting use of those standards. Significant efforts have been put forth and progress has been made; though, there is still more work to be done before the standards are complete and ready for application throughout the supply chain.

It should be noted, however, that the ability of HDMA primary distributor members to comply with the California law is heavily dependent upon manufacturer compliance beginning in January 2016. A future that includes serialized product, use of track-and-trace technologies, and electronic pedigree data exchange is one that has been contemplated, but we cannot yet fully understand or anticipate how such changes will require modifications to our members' operational and logistics functions.

The impact of these changes extends beyond the boundaries of the state's day-to-day product demands, affecting the ability to move product within complex, national, distribution networks, and creating a need for new contingencies for moving product into the state during times of emergency or shortage. Without a critical mass of serialized product entering the supply chain, with unit-to-case aggregated product information (individual SNIs associated to case), distributors will have significant difficulty maintaining their current levels of efficiency, which may adversely affect the availability of drug products in California.

II. Circumstances In Which Inference is Necessary

As primary distributors, HDMA members will be receiving the vast majority of product shipments directly from manufacturers. HDMA believes that inference would be appropriate and should be permitted under the following circumstances:

- 1) Recipient places an order for product with the shipper, with whom the recipient has a business relationship; and
- 2) A sealed homogenous (same lot, same product) case is sent by the shipper directly to the recipient; and
- 3) The shipper and recipient have technology solutions to provide electronic business-to-business transactional security; and
- 4) The shipper sends – in advance of, or in conjunction with shipment – information about the items/contents of such case, including the items' serial numbers and pedigree information related to each specific case; and
- 5) The recipient receives the case and the product information from the shipper.

Although the frequency of receiving sealed homogenous cases as described above may vary depending on the manufacturer, product and customer orders, we anticipate that the vast majority of inbound shipments received by primary distributors consist of sealed homogeneous cases.

Please note that most individual units received by primary distributors using case inference will in fact be scanned individually as the units are prepared for shipment to the pharmacy setting. Exceptions to this procedure will occur when distributors ship to large volume customers, such as mail order pharmacies, regional or national pharmacy warehouses, warehousing health systems, or government agencies.

III. Safety Benefits / Advantage to Allowing Inference

Allowing inference by distributors as described above would help to facilitate implementation of the provisions of California's pedigree law. Most important, inference will enable compliance with the spirit and the intent of the law – to employ technology and processes in the supply chain to permit electronic track-and-trace for the first time. Simply put, without inference, such technologies and processes might not be successfully deployed. The use of inference by distributors will help to ensure that California providers and patients have continued access to life saving medicines, while increasing the security of the supply chain. It is anticipated that adoption of track-and-trace and electronic pedigree will create new procedural and logistical burdens for distributors; however, the allowance of inference will at least enable some efficiencies to be maintained.

Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain. As to the benefit of inference specifically, the use of inference in distribution centers will limit the number of open cases in a warehouse or on a receiving platform, thereby limiting the number of personnel handling product, and thus creating fewer opportunities for diversion, theft or contamination. If the scope of permitted inference is limited as described in section II above, HDMA does not believe that inference would be disadvantageous or introduce unacceptable increases in risk.

IV. SOPs and Statistical Sampling

As a preliminary matter, it is important to note that the statute does not require the Board to promulgate regulations addressing the content of Standard Operating Procedures (SOPs) covering the use of inference. The spirit of the governing statutory provision was to require each company to develop a compliance plan and SOP language compatible with its own processes and implementation plan.

HDMA Response to
California Board of Pharmacy
August 30, 2012

HDMA believes that each individual company opting to use inference should have the flexibility to tailor SOPs to its specific operations, while making such SOPs available to the Board of Pharmacy for review upon request.

If the Board believes that it is necessary to provide greater uniformity among supply chain members in their SOP development, HDMA suggests that the Board limit its guidance to several *general* factors or categories that could be considered in developing appropriate SOPs.

V. Allocation of Liability

HDMA suggests that each trading partner should be liable for the information that they introduce into the marketplace and for the actions/consequences that result if such information is found to be false or erroneous. Further, when assessing liability, the Board should consider whether the error was made with intent or due to mistake as well as the seriousness of the resulting consequence. (e.g., different treatment by the Board for systems malfunctions than for an intentional falsification or negligent assertion.)

For example, in the instance of a manufacturer stating that specific serialized items are shipped to a distributor, labeled with serial numbers 1-20 and contained in a manufacturer's sealed homogenous case, the manufacturer should bear responsibility for the accuracy of that information. For its part, the distributor should be responsible for complying with the state's requirements (including having appropriate SOPs), but the distributor should be able to rely on the information and assertions made by manufacturer, and should be held liable only for violations within its control.

In other words, parties should be liable for their own actions, but mitigating factors such as properly vetting trading partners, due diligence, long-standing relationships or experience with certain entities should be taken into consideration when determining any liability resulting from reliance on inference as a result of manufacturer-provided product and shipment information.

Conclusion

HDMA respectfully submits the above comments in response to the Board's request. The use of inference does not reduce the integrity of the pedigree system nor does it create an increase in the risk of diversion or counterfeiting. As we have stated, inference is a necessary part of implementation of California's pedigree law for distributors, as we expect manufacturers to be employing 2D bar codes to meet their serialization requirements. Without the ability to infer the contents of sealed homogenous cases based on information supplied about the products shipped within those cases, distributors would have severe difficulties complying with the requirements of California's pedigree law.

HDMA Response to
California Board of Pharmacy
August 30, 2012

Please contact me should you have any questions or need additional information. HDMA appreciates this opportunity to provide input and we look forward to working with you on this important issue.

Sincerely,

A handwritten signature in blue ink, appearing to read "Elizabeth A. Gallenagh". The signature is fluid and cursive, with the first name being the most prominent.

Elizabeth A. Gallenagh
Vice President, Government Affairs & General Counsel
Healthcare Distribution Management Association



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

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BOARD OF PHARMACY
2012 AUG 31 AM 11:52

August 29, 2012

Executive Officer Virginia Herold
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834

Re: §4163.3. Legislative Intent; maintaining integrity of pedigree system; use of inference

Dear Ms. Herold:

On behalf of the Health Industry Distributors Association (HIDA), I am submitting information necessary to possible rulemaking on inference and certification of individual package units as related to the California drug pedigree law. We respectfully request that the California State Board of Pharmacy (the Board) allow through regulation for supply chain trading partners to infer the contents of sealed containers from an associated serialized numerical identifier (SNI).

HIDA is the professional trade association that represents the interests of over 600 medical-surgical products distributor companies operating throughout the United States. Our members deliver life-saving healthcare products to more than 290,000 points of care including over 210,240 physician offices, 6,512 hospitals, 44,061 assisted living and nursing homes and 33,722 medical facilities. While our members primarily carry medical-surgical products they may also deliver low-risk, high-volume pharmaceutical products used in everyday medical interactions, such as topical anesthetics and flu vaccines.

As the implementation of the California electronic pedigree law approaches, a variety of HIDA distributor members have been challenged with establishing the definitive means and methodology needed to “verify and validate the delivery and receipt of dangerous drugs against electronic pedigrees at the unit level.” Specifically, the deployment of hardware, software, and processes associated with these functions (that is, verification, validation, and certification of dangerous drugs at the unit level) is difficult until more guidance is available from supply chain partners and the Board regarding compliance requirements. For example, the scope of a regulatory allowance for the use of inference for the purposes of certification of individual units of drug products will influence certain wholesaler decisions.

Regulatory allowance for inference is a necessity for wholesale distributors to maintain the efficiency of the supply chain. The prevalence of two-dimensional (2D) barcodes as the carrier technology for serial numbers, for example, will require “line-of-sight” scanning capabilities on the part of wholesale distributors to validate serialized numerical identifiers (SNI) on individual units. Opening sealed containers and scanning individual units to validate the contents of each and every container will add significant costs in labor, technology, and time to the supply chain. As such, inference should be allowed for supply chain participants in the following circumstances:

- Upon the receipt of product in a sealed container (e.g., pallet, case, package) with an associated SNI; and

- Upon the sale of product when the container's seal remains intact and when the contents within a container remain sealed with an associated SNI (e.g., a sealed case contained within a pallet).

Ensuring patient safety remains the priority of medical-surgical products distributors and the use of inference can be used toward that end. By preserving the original seal of a container, and in some cases tamper-evident packaging, downstream trading partners are provided an additional mechanism for assuring the contents are not illegitimate product.

Thank you for the opportunity to submit information on the need for inference in the healthcare supply chain. Please contact Ashley Palmer, palmer@HIDA.org or (703) 838-6113, if you have any questions regarding HIDA's comments to the Board.

Sincerely,



Linda Rouse O'Neill
Vice President, Government Affairs
Health Industry Distributors Association



WORLDWIDE GOVERNMENT AFFAIRS AND POLICY

August 31, 2012

Virginia Herold, Executive Officer
Board of Pharmacy
1625 N. Market Boulevard
Suite N219
Sacramento, CA 95834

Dear Ms. Herold:

On behalf of the Johnson & Johnson companies affected by the California Drug Pedigree Law, we appreciate the opportunity to provide information to the California Board of Pharmacy on the possible rulemaking on inference and certification of individual package units as it pertains to the California Drug Pedigree Law. Johnson & Johnson is the world's most diverse and largest health care company - actually a family of 250 companies producing pharmaceuticals, biologics, medical device and diagnostics and consumer health products, with operations in 60 countries (including 15 companies in California). Looking at only the pharmaceutical and biologics portions of the company, we are the eighth-largest pharmaceutical company and the fifth-largest biologics company in world.

1. Efforts of Johnson & Johnson Companies.

Johnson & Johnson companies take a variety of approaches to identify and mitigate the risks of counterfeit health care products. They include a range of product and packaging security measures that help distinguish the authentic product from a counterfeit, and aid in minimizing the potential for tampering. Affected companies within the Johnson & Johnson family are working earnestly to be in compliance with the California pedigree law when it becomes effective on January 1, 2015. This involves a significant undertaking to outfit our global packaging network with capability to apply the FDA's Standardized Numerical Identifier (SNI); upgrading our U.S. distribution centers to handle SNI labeled product; working with our external contract manufacturers to ensure they can apply SNI's to products that they manufacture for us; and upgrading our business and IT capabilities to support the new processes. As we are working to implement these capabilities needed to comply with the California pedigree law, we must also ensure that all our processes and systems are GXP compliant and that we maintain uninterrupted patient access to our products.

2. Use of Inference.

Fundamentally, Johnson & Johnson believes that inference is important to maintaining the uninterrupted supply of pharmaceutical products to patients and caregivers. We employ inference when moving product through our supply chain and fulfilling customer orders. Once SNI's have been applied to our products, we intend to maintain the association between the lot number and each individual SNI within that specific lot so that we are able to use inference in our distribution centers when we pick, pack, verify, and ship SNI labeled product to fulfill a customer's order.

We have a number of U.S. customers who distribute product to California-based pharmacies who will need processes and capabilities to exchange SNI's and business event related information. Our intent is to provide information to our trading partners via a system that conforms to GS1's Electronic Product Code Information System (EPCIS) standards.

3. Need for Regulatory Action.

While we fully expect that all legitimate companies interested in continuing to do business in California will seek to comply with the e-pedigree, there are substantial challenges in doing so. As such, it is critical to establish an interoperable electronic system that connects all trading partners and allows for the reliable and efficient exchange of e-pedigree data in order for companies to be able to comply with the CA law. In spite of the efforts being made by the Johnson & Johnson companies, as well as other industry leaders, California's law cannot be successfully implemented unless the Board and the FDA provide guidance and possibly regulations in several areas. These include:

a) Interoperable Electronic System Requirements and Regulations – over the last several years, the Johnson & Johnson companies have worked with the Global Health Exchange (GHX) and several trading partners to understand an option for sharing SNI related information. Although it is very preliminary, our work with GHX demonstrates the challenges with exchanging SNI related information between trading partners. We encourage the Board and the FDA to provide guidance to the industry by publishing regulations that define clearly the expectations for interoperability. Before the stakeholders within the pharmaceutical supply chain can successfully comply with the CA pedigree law, a number of key areas require resolution with respect to interoperability, including the following:

I. Interoperable Electronic System Specifications – Will a single industry solution or will multiple solutions be acceptable? What will be the planned architecture – e.g., centralized, semi-centralized, distributed/de-centralized? What are the data specifications that are required to ensure interoperability across trading partners – e.g., field lengths and formats?

II. Document Pedigree Model System (DPMS) vs. Electronic Product Code Information System (EPCIS) – Can a pedigree on request model using the EPCIS standards be used instead of the document based DPMS? Are physical pedigree documents required? What are the requirements for system availability? Can a pedigree document be electronically generated at the time of the inquiry? Are electronic signatures required to verify the authenticity of a product's pedigree?

III. Management and Accountability for the Interoperable Electronic System – Who is responsible for funding, managing and operating the interoperable system? Who is tasked with running the interoperable system on a day-to-day basis? Who is responsible for data integrity within the interoperable system?

b) **Phased Implementation and Enforcement Discretion** – Since California's pedigree law requires interoperability across the industry, we recommend that the Board formally state that it will exercise its discretion when enforcing the provisions contained across the phases and milestones as defined by the law, until the Board verifies that the majority of supply chain participants can exchange SNI related information.

c) **Liability** – With respect to liability, as stated previously, we intend to make information available through an EPCIS compatible system so that our trading partners can verify our product's SNI and the relevant business event information related to our products. We intend to certify the accuracy of the information related to our outbound shipments, and to certify the authenticity of an SNI on request.

However, we believe that manufacturers should not be held liable and, indeed, cannot be held liable for actions by our downstream participants, and for those participants who do not verify pedigree information. In particular, we should not be held liable to certify to the accuracy of a pedigree once legal title has been transferred to another entity.

We support the comments made in the submission by the Pharmaceutical Research and Manufacturers of America (PhRMA). Specifically, PhRMA's views related to liability and the challenges with achieving a "zero defect system" for the purposes of certification.

Thank you again for the opportunity to provide feedback on the Board's request for information on inference. If you have any questions or comments regarding the points raised in this letter, please feel free to contact me at (510) 248-2362.

Sincerely,



Nancy Noe
Manager, State Government Affairs & Policy

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CALIFORNIA
BOARD OF PHARMACY
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2012 AUG 30 PM 4:07

September 1, 2012

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (July 23, 2012)

Dear Ms. Herold:

On behalf of McKesson Corporation (“McKesson”), I appreciate the opportunity to respond to the State of California’s Board of Pharmacy (“Board”) request for comments regarding inference and its use in the context of California’s electronic pedigree law.

For 179 years, McKesson has led the industry in the delivery of medicines and healthcare products to drug stores. Today, a Fortune 14 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in healthcare settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 200,000 physician practices, and over 10,000 extended care facilities and 700 home care agencies. McKesson delivers medicines to the entire Department of Veterans Affairs system, as well as to a significant number of Department of Defense and other government facilities. McKesson is also one of the nation’s largest distributors of biotechnology and specialty pharmaceutical products and services for providers and patients.

Based on our expertise in pharmaceutical distribution and our history of providing recommendations to the Food and Drug Administration and selected states on technologies and standards to further secure the drug supply chain, we are pleased to provide comments on inference relative to the California drug pedigree law.

Below are responses to the information needed for possible Board rulemaking.

1. Identifying and contact information for the submitting person or entity.

Mr. Ron Bone, Senior Vice President, Distribution Operations, McKesson Pharmaceutical at 415-983-7613 or ron.bone@mckesson.com

Mrs. Ann Richardson Berkey, Senior Vice President, Public Affairs, McKesson at 415-983-8494 or ann.berkey@mckesson.com

- 2. A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.**

McKesson is a national pharmaceutical and medical supply wholesale distributor with two pharmaceutical distribution centers and two medical-surgical distribution centers located in the state of California. We have two pharmaceutical supply distribution centers located in Denver, CO and Olive Branch, MS which supply these California facilities.

Mr. Ron Bone has represented McKesson in GS1 Standards and Traceability standard setting efforts for the past eight years and has been participating regularly in federal and state discussions regarding serialization, traceability and pedigree.

- 3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to "verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level," including specification of the means and methodology for certification.**

McKesson seeks to protect the integrity of the pharmaceutical supply chain while ensuring the delivery of safe medicines to patients. We scrutinize our trading partners and hold trusted relationships with these manufacturers. Today, McKesson initiates the purchase of product through the issuance of a purchase order (PO) with the manufacturer. Upon receipt, we confirm the physical order and the data feed associated with that specific product order.

It is our expectation that manufacturers will provide products to McKesson with GS1 compliant 2D Barcodes. McKesson has deployed a GS1 compliant traceability solution in the two California pharmaceutical distribution centers and is installing the same solution in the rest of the distribution network. We are currently using this system in the pilot projects we are conducting with manufacturers and supplying feedback to GS1 on system enhancements that should be included in the standard. This system will compare the serial numbers from the data collected from the manufacturer to the serial numbers on the products picked for the customer. Only products that have a match in our data system will be allowed to be shipped to the customer. Any products that do not match will be isolated in a quarantine area for further investigation by the shipper.

- 4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard**

to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

Inference is an important element of any implementation strategy for pharmaceutical distributors and its allowance by the Board is essential to enable distributors to meet the goals and requirements of the California law.

McKesson intends to comply with all applicable laws and plans to utilize inference in its receipt and shipment of serialized product into our distribution centers. We encourage the Board to allow us to scan the case label of a manufacturer's sealed case and match that serial number to the data provided by the manufacturer. When we have a match, we want to be able to infer that the unit serial numbers (SNI) that the manufacturer linked to the case serial number are correct. We further want to ship this sealed case to a customer or to another McKesson distribution center using inference and without a requirement to break the sealed case and read the unit level serial numbers. The vast majority of our inbound shipments come to McKesson in the manufacturers' sealed cases.

In preparation for the practice of inference, McKesson will develop a detailed standard operating procedure (SOP) to ensure that the process meets specific criteria. As with all of our distribution processes, we employ Six Sigma methodology to minimize the occurrence of errors.

- 5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., noted above.**

We are not opposed to regulatory allowance for inference.

- 6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).**

Ensuring the integrity of the manufacturer's case is an important safeguard. A number of our larger customers will only accept product from us in the manufacturer's sealed case. In our distribution centers, the backup stock is kept in the manufacturer's sealed case until it is brought to the picking area and prepared for picking for the customer order. When a customer orders items at the unit level, we will compare the unit serial number with the number provided to us by the manufacturer to be sure we have a valid item. Only products that have a match in our data system will be allowed to be shipped to the customer. Any products that do not match will be isolated in a quarantine area for further investigation by the shipper.

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

The industry developed a document in conjunction with GS1 entitled "The Practice of Inference", which was published in 2010 and is available on the GS1 website. McKesson will base the development of its detailed standard operating procedure (SOP) for inference on this document.

8. A proposal for the allocation of any liability that may be incurred due to use of inference.

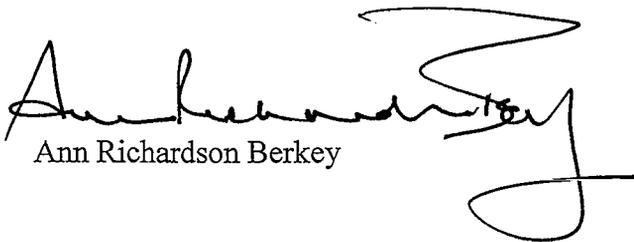
A distributor should not be held financially liable for the accuracy of the electronic data that they receive from their supplier. Since it is likely not the intent of the packager or manufacturer of the product to improperly record the aggregation of pieces in the case, these 'honest' mistakes should be communicated to the original packager or manufacturer so that discrepancies can be addressed. When these problems are detected and a supply chain partner discovers that the serial number on the product that they currently possess does not have a proper 'chain of custody' (for example, they do not have a record that shows that they should have this product), this discrepancy must be reported to the relevant parties, including regulatory bodies. Appropriate action should be taken to either correct the situation or return the product to the manufacturer of the product.

Any financial liability should be directed to protecting the supply chain and the detection and elimination of adulterated and counterfeit product.

On behalf of McKesson, we appreciate this opportunity to provide comments to the Board and to share our perspective regarding the use of inference to track prescription drugs. McKesson seeks to protect the integrity of the pharmaceutical supply chain while ensuring the rapid and safe delivery of medicines to patients.

We look forward to working with the Board as rulemaking on inference is further developed. Should you have any questions, please contact me or Ron Bone, Senior Vice President, Distribution Operations, McKesson Pharmaceutical, at 415-983-7613 or ron.bone@mckesson.com.

Sincerely,


Ann Richardson Berkey



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BOARD OF PHARMACY
2012 AUG 29 AM 11:40

**Opportunity to Submit Information Necessary to Possible Board Rulemaking
On Inference and Certification of Individual Package Units – Drug Pedigree Law**

The following comments are submitted on behalf of Medline Industries, Inc. We appreciate the opportunity to express our views on the importance of inference in the California pedigree system. Should the Board have any questions, please do not hesitate to contact Rob Calia at the contact information detailed below.

1. *Identifying and contact information for the submitting person or entity.*

Company: Medline Industries, Inc.
Primary Contact: Rob Calia
Address: One Medline Place
Mundelein, IL 60060
Phone: (847) 643-4249
Email: rcalia@medline.com

2. *A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.*

Medline manufactures and distributes more than 125,000 products (including prescription drugs) to hospitals, extended care facilities, surgery centers, physician offices and home care dealers. Medline has a network of 50 manufacturing and distribution centers worldwide, including three distribution centers in the state of California.

Our interest in this subject primarily relates to our role as a wholesale distributor of pharmaceuticals.

3. *If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to "verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level," including specification of the means and methodology for certification.*

In the absence of further guidance and having not yet participated in or seen the results from successful, supply chain wide, pilots, we have not yet made final determinations on the specific means and methodology we will use to comply with California's ePedigree requirements.

Medline currently uses a purchased software system to pass electronic pedigrees. We anticipate using a similar or upgraded version of this software to comply with California's ePedigree requirements.

4. *If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those*

transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

Because of the cost and unreliability of Radio Frequency Identification (RFID) technologies, we anticipate that the vast majority of manufacturers will serialize using two-dimensional matrix barcodes, which require a line of sight scan. If required to manually unpack each case and pallet and scan each individual unit, the entire pharmaceutical distribution chain will break down—endangering public health and safety by significantly exasperating drug shortages while drastically increasing the cost of pharmaceuticals for California consumers..

Therefore, we anticipate that the majority of our transactions will involve inference. We anticipate that we would utilize inference on approximately 70% of incoming product. We anticipate that we would utilize inference on approximately 15% of outgoing product.

On receipt of a product, we believe that scanning should occur at the level of product purchased (e.g. if Medline purchases a sealed case, we would scan the case and infer the Standardized Numerical Identifier (SNI) for each unit within the case). On sale of product, we believe scanning should occur at the level of product sold (e.g. if Medline sells a sealed case, the case would be scanned and inference would be used to collect the SNI for each unit within the sealed case).

With approximately 500 million prescription dispensed in California each year, we believe the only way the system can possibly function without significantly delaying the delivery of prescription drugs is to allow inference in this way.

Example 1: Medline purchases and then resells an entire pallet of drug X. Medline purchases a pallet of drug X from the manufacturer of drug X or an Authorized Distributor of Record (ADR) of drug X. Upon receipt of the pallet, Medline would use inference to collect the SNI for each individual unit contained within the pallet—leaving the pallet itself sealed. Upon resell of the sealed pallet, inference would again be used to capture the SNI from each outbound unit within the sealed pallet.

Example 2: Medline purchases a pallet of drug X, breaks down the pallet to the case level, and then sells a sealed case. Medline purchases a pallet of drug X from the manufacturer of drug X or an ADR of drug X. Upon receipt of the pallet, Medline would use inference to collect the SNI from each individual unit contained within the pallet—leaving the pallet itself sealed. When the pallet is opened for the sale of a sealed case contained within the pallet, inference would again be used to capture the SNI from each outbound unit within the sealed case.

Example 3: Medline purchases and then resells an entire case of drug X. Medline purchases a case of drug X from the manufacturer of drug X or an ADR of drug X. Upon receipt of the case, Medline would use inference to collect the SNI from each individual unit contained within the

case—leaving the case itself sealed. Upon sale of the sealed case, inference would again be used to capture the SNI from each outbound unit with the sealed case.

Example 4: Medline purchases a case of drug X, breaks down the case to the unit level. Medline purchases a case of drug X from the manufacturer of drug X or an ADR of drug X. Upon receipt of the case, Medline would use inference to collect the SNI from each individual unit contained within the case—leaving the case itself sealed. When the case is opened for the sale of an individual unit(s), individual units will be scanned to capture the SNI.

- 5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.*

Medline supports the use of inference, as described above.

- 6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).*

We believe that inference can be used in the ways described above without increasing the risk of diversion or counterfeiting (or other risks(s) in the supply chain) and may in fact reduce some supply chain risks.

- 7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.*

Our SOPs will be shaped by the statutorily mandated regulations under development by the Board. In the absence of these regulations and without a more complete understanding of how manufacturers will utilize inference and aggregation Medline is unable to craft detailed SOPs.

- 8. A proposal for the allocation of any liability that may be incurred due to use of inference.*

We believe any liability that may be incurred due to the use of inference should be assumed by the aggregator—e.g. the manufacturer or repackager. The aggregator is the one who makes and certifies the aggregation which those further down the supply chain must rely upon. Should there be any issues with that initial aggregation/inference, the manufacturer or repackager who made it should be fully liable.



Merck
556 Morris Avenue
Summit, NJ 07901 USA
www.merck.com

August 31, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

**RE: Opportunity to Submit Information Necessary to Possible Board Rulemaking
On Inference and Certification of Individual Package Units – Drug Pedigree Law**

Dear Ms. Herold:

MERCK & CO., INC. appreciates the opportunity to provide information to the California Board of Pharmacy (the Board) in response to its request for information for a possible Board rulemaking on inference, pursuant to California Business & Professions Code § 4163.3. Merck is fully supportive of appropriate measures to increase supply chain security. The seriousness of pharmaceutical counterfeiting goes well beyond the financial impact that is experienced by other industries. When counterfeit pharmaceuticals are introduced into U.S. commerce, patient safety and confidence in our drug distribution system is compromised and the potential for patient harm, including even death exists. It is for this reason that we continue to believe that a national system should be developed, aligning all states with a system that is both technically viable and will foundationally support further enhancements, if required.

Merck is a global healthcare company working to help the world be well:

- We manufacture and provide innovative medicines, vaccines, biologic therapies and consumer and animal health products to help improve health and well-being;
- We work with customers in 140 countries to deliver broad-based healthcare solutions; and
- We demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships to help people around the world lead healthier lives.

Merck has been actively engaged in standard setting groups such as GS1 and currently co-chairs the National Council for Prescription Drug Programs (NCPDP) work group 17 on product traceability. As a global company, we have also been active in the European Federation of Pharmaceutical Industries and Associations (EFPIA) in the development of the European pharmaceutical authentication system and have successfully deployed serialized product in specific markets based on their requirements.

Merck has performed pilot programs and continues to make significant investments to prepare for the future supply of serialized product to the U.S. market. In fact, some earlier investments, such as in software as an example, may never be utilized since the method to communicate serial numbers has not been fully defined (i.e., DPMS electronic pedigree most aligned with current California law versus EPCIS track and trace aligned with the FDA vision).

Merck is supportive of inference. We believe it is necessary and should be permissible. Today, inference is widely and effectively used throughout the supply chain to ascertain key information (i.e., product, lot number and expiration date) regarding product in sealed, homogenous cases. Another example would be for supply of bulk tablets to off-site packaging operations. In this latter situation, appropriate controls are maintained when Merck fills drums of tablets to assure the identity of the product and the associated lot number are accurate. These sealed drums are then brought to a tablet filler, again through an appropriately controlled environment, allowing inference of the product and lot number in each bottle when packaged.

While we acknowledge the utility of inference, we also recognize its limitations. There are situations in which inference is not accurate enough. For example, the FDA requires that labeling use one-hundred percent electronic verification because using inference would not guarantee that a supply of labels from a supplier is homogeneous and the ramifications of a misbranded lot are serious enough to warrant recalls. Merck performs documented testing to prove the consistent reliability of these systems. This includes operator training, to ensure that each and every alarm is reviewed.

Further, inferring the serial number of each unit associated with each case is different than inference of tablets filled in bottles. First, each packaging line is different. Merck packages prescription drugs in various types of dosage forms, including, blisters, vials, tubes, and bottles - each with its own separate packaging process. Packaging is further complicated by the complexity of equipment, speed of the lines and available space to install new or additional equipment on existing lines, both at Merck facilities and/or at contract facilities. Exceptions in the packaging and distribution processes can have a dramatic impact on case accuracy. For example, if a machine stops, it may cause a change in the normal flow of product on a line impacting case accuracy. In the case of general business processes, the quality unit may sample from a selected case at any time while in our possession. If management of business processes after packaging are not managed correctly, such as the quality sampling example, case accuracy may also be impacted.

In distribution, product is picked into totes that will again have its content inferred. This is currently done for billing purposes and is managed in a similar way that lots are managed. However, transitioning the level of inference from its current use for billing purposes to inferring all serial numbers is a significant leap in technology and business processes for the quantities and varieties of packages required for the State of California.

This is another area that will take substantial efforts to improve if current error rates are not acceptable.

We respectfully submit that the Board considerations, include the level of accuracy required for serial number aggregation and whether that level of accuracy may be achieved through the varying processes within the supply chain. The example often cited by the California Board of Pharmacy is the ability to pick a product on the shelf and establish where it has been. What if this cannot be established because of a glitch in inference? In accordance with 4163.3 (e), what should be the disposition of that product and what supply chain partner should be responsible for the glitch?

Given the concerns regarding accuracy outlined above, Merck is also concerned with how statistical sampling may be applied to the inference process as requested in 4163.3 (d). If one was to use ANSI ASQ Z1.4 2008: Sampling Procedures and Tables for Inspection by Attributes, as an example, there would be a number of variables that all come back to the level of acceptable risk. Developing a sampling plan using this methodology requires understanding confidence limits, acceptable quality levels, lot size and sampling locations. From a manufacturer's perspective, each packaging line would represent a different process having its own unique operating curves. As the Board considers statistical sampling requirements, it should consider what the impact would be if a lot fails statistical evaluation? Would that product be acceptable for sale? Would it put into question other packages within that lot?

With respect to inference upon the effective date, Merck agrees that it:

- **Can** certify that the correct product, lot, and expiration date are aggregated to a sealed, homogeneous case allowing for accurate inference.
- **Can** certify that case and individual unit serial numbers are aggregated to a lot allowing for accurate inference.
- **Can** verify the serial number associated with sealed, homogeneous cases along with its recipient.

However, Merck **Cannot** certify the level of accuracy for individual unit serial numbers being aggregated to a case number. We will require considerable commercial operation, assessment time (not pilot) to fully evaluate every potential cause for variation and to understand the impacts of corrective actions.

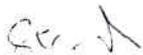
Finally, with respect to responsibility, Merck should not be held responsible for downstream participants who do not verify pedigree information. Manufacturers can only reasonably be expected to certify to the accuracy of the information they generate with each outbound shipment, and to, with appropriate security controls in place, certify to the authenticity of particular standardized numerical identifiers, when requested. Once

a product is outside of a manufacturer's control, it is not reasonable or feasible to hold that manufacturer responsible.

In conclusion, Merck appreciates California's efforts to highlight this important national issue. We are committed to doing our part in enhancing supply chain security in a manner consistent with our capability and Merck will work to continually improve that capability. We believe that inference should be allowed based on both process capability and level of acceptable risk. It is critical that, for this system to meet safety objectives, the rule making process takes in all comments and considerations when establishing achievable expectations.

Merck appreciates the Board's leadership in protecting the public and providing us an opportunity to provide input on this important legislation. Please do not hesitate to contact me should you have any questions.

Sincerely,



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NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



August 29, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, CA 95834

RE: Comments regarding Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Executive Officer Herold:

The California Retailers Association (CRA), the California Pharmacist Association (CPhA) and the National Association of Chain Drug Stores (NACDS) thank the Board of Pharmacy (“Board”) for the opportunity to submit written comments in response to the Board’s request for information regarding supply chain participants’ ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law.

The retail community pharmacy industry is committed to maintaining and enhancing the safety and security of the U.S. drug distribution supply chain through feasible and workable means. We believe that the United States prescription drug distribution system is one of the safest in the world, if not the safest. A number of proactive safety measures in the private sector and a comprehensive set of federal and state laws and regulations contribute to this safety. We are proud of the private sector initiatives that our members have taken along with other industry stakeholders to enhance the security of the U.S. drug supply chain. Retail community pharmacies have made changes in their purchasing practices, such as requiring their wholesale distributors to purchase prescription drug products directly from manufacturers. This policy creates a secure system of distribution known as the “normal distribution channel” -- a direct flow of product from the manufacturer to the wholesale distributor, and to the pharmacy for dispensing.

Contact Information

The contact information for the submitting entities and persons are provided at the conclusion of this letter.

Submitting Parties’ Interest in this Subject

CRA is a statewide trade association representing all segments of the retail industry including chain drug stores. CPhA is the largest statewide pharmacy association in the country, with over 5,000 members practicing in all practice settings. Additionally, CPhA represents nearly 1,000 independent community pharmacies operating throughout California. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. Our members dispense over 2.6

billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. In the state of California, NACDS represents 20 companies operating 3,916 pharmacies.

Reasons Inference is Necessary and Advantageous

While we continue to have concerns about the necessity and effectiveness of extending electronic pedigree requirements to individual community pharmacies, we believe that allowing inference is a significant and necessary component for maintaining supply chain integrity under California's electronic pedigree law. Inference must be available for use by pharmacies and other supply chain participants. Allowing inference at the pallet, case, and tote levels is critical to preserve supply chain security and enhance patient safety by preserving the integrity of the pallet, case, tote or other aggregated distribution unit.

Without inference, it is highly likely that the aggregated product, e.g. pallets, cases, totes, would need to be opened, creating the potential for loss of product, diversion, and risks to the safety and security of the supply chain. We believe that inference has the potential to decrease the risk of diversion and enhance security and safety by maintaining the integrity of the aggregated containers.

Without inference, each pallet, case, or tote would have to be opened and each individual drug package scanned. This would lead to an inefficient, costly, and time consuming process that would cripple the entire drug distribution supply chain. Without inference, the supply chain will likely see insurmountable product delays from having to manually scan millions of products. As a result, pharmacies will have difficulties meeting the medication needs of their patients. Moreover, opening up the boxes or containers for scanning will destroy the security of the sealed containers. Imposing such an inefficient time-consuming system on pharmacies and other healthcare providers makes little sense.

Proposed Standard Operating Procedures

At this time to our knowledge, due to the very limited availability and use of serialized prescription drug product packages, we believe that standard operating procedures are under development. As associations that representing retail community pharmacists and pharmacies, we look forward to the development and review of such procedures as they are made available. We defer our comment until that time.

Liability

In regards to liability, we believe that liability has little usefulness in the area of inference. However, we certainly believe that pharmacies should not be held liable for inaccurate packing by the wholesaler or manufacturer. Rather, we believe that the better approach is to understand the complexities of this as yet untried and untested system, and therefore to allow supply chain stakeholders to exist in a learning environment. This system is not in use in California and is being built from the ground up. As such, we recommend that liability be forestalled as stakeholders learn this new system.

Conclusion

Although our concerns remain about the feasibility and workability of California's electronic pedigree law, we support inference and believe that it is a critical component of the electronic pedigree process. Please do not hesitate to contact Mandy Lee with the CRA at mlee@calretailers.com or 916-425-8481, Brian Warren with CPhA at bwarren@cpha.com or 916.779.4517, or Mary Staples with NACDS at mstaples@nacds.org or 817.442.1155 if we can provide further assistance.

Virginia Herold
Executive Officer, California Board of Pharmacy
August 29, 2012
Page 3 of 3

Sincerely,



Mandy Lee
Director of Government Affairs
California Retailers Association



Mary Staples
Director of Government Affairs
National Association of Chain Drug Stores



Brian Warren
Director of Government & Professional Affairs
California Pharmacists Association



August 27, 2012

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

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Board of Pharmacy:

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,600 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug distributors, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP and its membership are interested in a safe, secure and efficient supply chain for drugs and biological products.

NCPDP Response:

The stated goal of the pedigree regulation is to establish and implement a system to ensure patient safety and improve the security of the drug supply chain against counterfeit, diverted, sub potent, substandard, adulterated, misbranded, or expired drugs. Inference is essential to the practical achievement of this goal.

Inference, as it is currently used within the supply chain, supports both the security of the product being shipped and the efficiency of the supply chain. The manufacturer/repackager, following established security protocols, seals and places the identifier on a case (or higher level shipping container) of medication prior to shipping. So long as that seal is unbroken, the downstream trading partners can trust, i.e. infer, that content received is the content packed by the manufacturer/repackager. If an error is found on opening the container at the point of use, then it can be reported back to the manufacturer/repackager and the product quarantined until the problem is resolved.

To not use inference, that is, to inspect the contents of every case as it moves through the supply chain, would dramatically slow the movement of products, but more importantly, it would substantially increase the opportunity for substitution and diversion. If a problem is found at the point of use, there is no way to pinpoint where it occurred since the integrity of the case was not maintained to the final destination.

Conclusion

Inference allows a reasonable level of security with a lower expenditure of resources and may even protect the supply chain from introduction of adulterated, misbranded or counterfeit product that could otherwise be missed due to the massive number of reviews that would be required. Therefore, the use of inference can provide the necessary protection while allowing the reasonable flow of product through the drug distribution chain.

Enhancing the safety and security of the prescription drug supply chain is of acute interest to NCPDP and its members. For the last four years NCPDP Work Group 17 Pharmaceutical Pedigree and Traceability has explored the many facets of pedigree, track and trace regulations and other potentially inter-related pharmacy technology initiatives. Based on our experience with the successful implementation of networked systems, NCPDP understands the magnitude of developing and implementing a track and trace system.

NCPDP stands ready to assist the CA Board of Pharmacy in achieving consensus and support within the pharmaceutical industry for the development and implementation regulations to enhance the safety and security of the drug supply chain.

Thank you for the opportunity to respond to this request for comments.

For direct inquiries or questions related to this letter, please contact

Sue Ann Thompson
Standards Advisor, NCPDP

Direct:

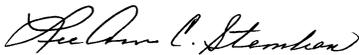
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sthompson@ncpdp.org

Sincerely,



Lee Ann C. Stember

President

National Council for Prescription Drug Programs (NCPDP)

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cc: NCPDP Board of Trustees

The Pharmaceutical Distribution Security Alliance
Response to the California State Board of Pharmacy
Regarding Inference and Certification of Individual Package Units

INTRODUCTION

The Pharmaceutical Distribution Security Alliance (PDSA) appreciates the opportunity to submit these comments in response to the request of the California State Board of Pharmacy (the Board) for information necessary to any Board rulemaking on inference and certification of individual package units – drug pedigree law (Bus. & Prof. Code, §§ 4034, 4163 et seq.).

PDSA's mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution chain for patients, and to articulate a technical migratory pathway to implement such a policy. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, U.S. Food and Drug Administration (FDA)-approved medicine. Membership of PDSA spans the entire spectrum of the U.S. pharmaceutical distribution chain, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. Twenty-nine organizations are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group. Please see the “About Us” document attached for more information about the submitting party, including contact information for PDSA.

While we are fortunate to live in a nation where the pharmaceutical distribution chain is relatively safe, grave threats from sophisticated criminal elements still exist, and are becoming more severe. PDSA appreciates the efforts of the Board to protect California consumers by preventing, assessing, and responding to threats of prescription drug counterfeiting and diversion in the state supply chain. We agree with the Board, FDA and other stakeholders that more must be done to protect U.S. patients from these public health threats.

RESPONSE¹

The ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of prescription drugs is operationally essential to facilitate the efficient movement of prescription drugs in California.

We encourage the Board to carefully consider the technical input from the many diverse participants in the distribution chain, whose abilities and needs may vary depending on the nature and scope of their operations and the California populations they serve. PDSA, with membership representing a broad spectrum of distribution chain participants, fully appreciates the difficulty of crafting policies and rules that will be feasible for all stakeholders – but striking this balance is essential when seeking to craft a comprehensive supply chain security system, as the chain is only as strong as its weakest link. We encourage the Board to remain highly attuned to this challenge as it considers possible rulemaking.

The California statute will require the creation of a substantial interoperable electronic system to connect the thousands of unique participants in the pharmaceutical distribution chain to enable tracking and tracing all individual prescription drug product packages at the smallest saleable unit (“unit”) through use of “electronic pedigrees” (e-pedigree) showing the full distribution history of each

¹ Separate and distinct from these comments, PDSA members may also opt to respond to the Board’s request for information in their individual capacity. Any such response should not be construed to reflect the views of PDSA.

individual unit sold in the state. Creating such a system that consistently and efficiently works for the thousands of small and large entities in the distribution chain – including drug manufacturers, wholesale distributors, third-party logistics providers, and retail, independent, hospital and clinic pharmacies – is a novel, complex, expensive, and highly technical undertaking. Accordingly, PDSA appreciates the Board’s recognition that technical input from distribution chain participants is essential to the development and implementation of a new pharmaceutical distribution system.

While we fully expect that all legitimate companies interested in continuing to do business in California will seek to comply with the e-pedigree law, we recognize the substantial challenges in doing so. As such, it is critical to establish an interoperable electronic system that meets an industry accepted standard that connects all trading partners and allows for the reliable and efficient exchange of e-pedigree data in order for companies to be able to comply with the California law.

A. Compliance with the California Law Requires a Workable Interoperable Electronic System

Functional technology and interoperability is the foundation of the envisioned California e-pedigree system, and is the essential first step for companies seeking to comply with the law. While regulations on inference and certification are important to creating a functional e-pedigree system, without a workable interoperable electronic system as the starting point, even the most consensus driven regulations would be of limited utility.

To enable companies to comply with the California law, the interoperable electronic system must function for every one of the thousands of entities in the pharmaceutical distribution chain operating and doing business in California. Unless all can do it, the ability of only some (or even most) companies and healthcare entities to exchange e-pedigree data will be negate the intended results as the required chain of ownership would be broken in many instances. Simply put, unless the e-pedigree system works for all of us, it works for none of us, and interoperable exchange of e-pedigree data is the keystone to the CA system.

B. Concerns with the Current State of E-Pedigree Technology and Interoperability

The envisioned California e-pedigree system relies on an interoperable electronic system(s) that connects all trading partners and ensures an efficient and secure exchange of e-pedigree information. Though efforts to create such a system are ongoing, no such system currently exists for all participants in the chain, and industry discussion and debate about the most efficient and effective model continues. This creates significant compliance challenges that cannot quickly or easily be overcome:

- The development of standards for information exchange and business process for data management (including protocols regarding master data and exceptions management), and the reliable use of vendor systems takes time and testing. Even if these pieces were in place for manufacturers, all downstream partners must also have an interoperable system including the availability and testing of the necessary standards in place to exchange serial numbers, e-pedigrees, and associated transaction information (i.e. from shipments, receipts, returns, etc).
- Despite many stakeholders’ attempts to build systems to comply with the e-pedigree law, there is very little data to estimate expected failure rates. As an example: for just one company, even a 99% accuracy rate would result in exceptions impacting 550,000 units each year, meaning approximately 2,201 items per day could enter the supply chain and would be inaccurate, thereby compromising the integrity of the system. Moreover, any of the errors that surface could sit in quarantine awaiting resolution. If each company along the supply chain experiences 1% or even higher failure rates, the amount of possibly inaccurate and possibly quarantined

product is further increased. If current pilot projects' accuracy rates do not improve, the distribution of many thousands of products would be inaccurate and could be delayed. Such findings highlight the need for extensive testing of this functionality across all products, all trading partners, and all shipping/receiving points well in advance of the effective date of such a requirement.

- In another company's pilot, the inference concept was tested in small application, using transactions containing roughly 10,000 serialized units. The pilot used 2D and 1D GS1 standards barcodes with aggregation of unit to case, case to pallet relationships. When the data exchanged were 100% accurate to the labels for the product, inference did work. However, when technical exception issues occurred – which many did – it either took tremendous time to correct the problem or it could not be corrected at all. In this pilot, most of transactions required some level of human intervention to correct technical issues; less than 10% went through without error.
- Implementation of an interoperable electronic system is complicated by the fact that many trading partners have varying legacy systems, different solutions providers, and significantly different resources and capabilities to effectively deploy and test such a system.

While it is concerning that liabilities may be imposed on legitimate pharmaceutical distribution chain participants not capable of meeting unproven expectations, technical challenges are not merely issues that impact corporate compliance. Accuracy and interoperability – and in this case the lack thereof – can compromise the integrity of the system and potentially impact patient access to medication and the public health. According to IMS 2010 data, approximately 638,400,000 prescriptions are dispensed to patients in California each year, and these products reach consumers through many more millions of transactions in the pharmaceutical distribution chain. If any part of the complex e-pedigree process fails – even if only for technological reasons – the prescription drug cannot be distributed, resulting in possibly dangerous delays or limited supplies in medications available to patients due to slower distribution schedules and large-scale product returns. We trust that all stakeholders will actively work to avoid such outcomes that endanger the public health while also seeking to comply with the California law.

CONCLUSION

While we agree with the Board's intent to enhance patient safety, PDSA respectfully urges the Board to consider the important prerequisite of proving the functionality and reliability of the interoperable electronic system for all participants in the pharmaceutical distribution chain. Such is the essential first step for companies seeking to comply with the California law and is critical for ensuring system accuracy and integrity so that patients will continue to have timely, efficient access to prescription medications.

Thank you for your consideration.

The Pharmaceutical Distribution Security Alliance

Attachment: PDSA "About Us" Document

Pharmaceutical Distribution Security Alliance (PDSA)

Our Mission

The Pharmaceutical Distribution Security Alliance's (PDSA) mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

About Us

The Pharmaceutical Distribution Security Alliance is a multi-stakeholder and interdisciplinary initiative. Membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. More than 20 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group.

Membership



For more information about the PDSA or this document, please contact:

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Tom McPhillips
Vice President – US Trade Group

Pfizer Inc
235 East 42nd Street, New York, NY 10017
Tel 212 573 3192

August 30, 2012

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

Re: Pfizer Inc.'s Submission Regarding Possible Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (Bus & Prof Code § 4163.3)

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 provide written comments regarding inference and certification of individual package units. (Bus. & Prof. Code, § 4034, 4163 et seq.)

As one of the world's leading pharmaceutical manufacturers, Pfizer remains strongly committed to providing patients with safe and effective medications of the highest quality. We share the Board's concern for the risk to patient health posed by counterfeit drugs, and welcome the opportunity to work with the Board 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.

With this in mind, Pfizer respectfully offers the following comments:

General Comments on Inference

As a general matter, Pfizer believes that a single, federal serialization and traceability law is preferred to the existing patchwork of state pedigree requirements. While Pfizer continues to invest in serialization and works diligently toward compliance with the California pedigree law, we recognize that a phased-implementation approach is necessary. A migration path that begins with implementation of item-level serialization and deployment of the required IT infrastructure is a practical step toward the implementation of an item-level track-and-trace solution. To implement the California requirements, Pfizer strongly supports the need for inference.



The use of inference implies the need for aggregation (associating serialized items to a serialized case, for example) and we believe an item-level track-and-trace solution will require aggregation. Aggregation requires a means to exchange information regarding the aggregated items (the serialized units contained in a serialized case). With respect to the exchange of serialized pedigree information, California's electronic pedigree law requires an interoperable electronic system. As a threshold matter, it must be emphasized that such an interoperable electronic system does not yet exist. As a result, Pfizer recommends the Board work with industry stakeholders, standards bodies, and the U.S. Food and Drug Administration (FDA), to define and enable such an interoperable electronic system on a national basis.

Industry is currently assessing three potential electronic systems or models: centralized, decentralized, and semi-centralized. In this context, "system," is used to mean a network that connects all the necessary stakeholders and provides a means for the secure, reliable, timely and cost-effective exchange of information. The nature of the ultimate "system" design and data requirements will impact the need for inference as well as the associated rules.

Since 2005, Pfizer has been working with industry stakeholders, solution providers and standards bodies to deploy and test our serialization capabilities, including our ability to aggregate individual serialized items to higher levels of logistical units (item to cases and cases to pallets) and to successfully exchange the associated data with our trading partners. We have implemented a drug pedigree messaging standard (DPMS) solution and are currently testing an EPCIS "event-based" pedigree model.

In order to align ourselves with where we believe industry is trending, Pfizer has recently made a decision to utilize 2D bar codes going forward as the primary data carrier for serialization, with linear and/or human readable back-up when possible. Pfizer's decision to use 2D bar codes is globally harmonized with initiatives in the EU and elsewhere; it is also aligned with the direction many other pharmaceutical manufacturers are pursuing in the U.S.

The use of 2D technology and the California requirement for item-level tracking necessarily requires the use of inference, given that it is not practical or advisable for others in the supply chain to open sealed cases from the manufacturer for the sole purpose of the confirming serial numbers. In fact, to require sealed manufacturer's cases be opened to scan serial numbers would destroy tamper evident tape and other features designed to alert supply chain participants to potential issues with the package. Indeed, opening cases that are outside the manufacturers' control, as a normal course of business, would increase supply chain risk by increasing the opportunity for theft, diversion and tampering that would then go unnoticed as opening and resealing cases would become common place.

Pedigree Certification

With respect to pedigree certification, based on our pilot experience, we believe unavoidable aggregation errors will sometimes occur, especially in the early stages of adoption of an item-level track-and-trace system. We also believe that other



mistakes are likely to occur, such as shipping errors and master data management issues. As a result, the Board should allow for reasonable accommodations to be made for these situations.

For example, the Board should recognize that if a rigid certification requirement is mandated, which does not allow for exceptions or unintentional errors, the inability to provide an unrestricted certification will likely impede the flow of goods. The inability to resolve these unavoidable errors and exceptions in a timely manner due to strict certification requirements, may impede the flow of goods and prevent them from reaching patients when needed.

Allocation of Liability

Concerning the allocation of liability that may be incurred due to the use of inference, Pfizer believes that provisions or allowance should be made in the Board's rulemaking process to distinguish between unintentional shipping or technology/data errors and intentional misrepresentations of information for the purpose of introducing counterfeit or diverted product into the legitimate supply chain. More specifically, it would be unreasonable to expect that there will never be inadvertent or unintentional errors with physical shipments, whose errors are then captured in a pedigree. It is our belief that the intent of the California law is not to prosecute individuals or organizations for unintentional shipping errors. Nor, do we believe the unintended consequence of unnecessary delays in the delivery of important medications to patients should be permitted as a result of unintentional shipping errors.

As a result, the requirements for certification relating to pedigrees should reflect this reality and provide that inadvertent and unintentional errors would not render a certification to be considered false. Further, at best, any entity within the supply chain can only certify as to the information that such entity provides. Entities should not be liable for the accuracy of information that the entity cannot itself verify, e.g., information supplied by participants further down the supply chain. This should be clarified through the rulemaking process.

Regarding liability associated with the accuracy of pedigree information using inference, we believe the Board should clarify that provided there are processes and procedures in place to ensure a reasonable degree of accuracy with respect to information contained in a pedigree based on the use of inference, no liability should flow from the reasonable and intended use of inference. To the extent any liability should be associated with the accuracy of pedigree information, it should be determined based on the intentional misrepresentation of information.

Conclusion

Finally, Pfizer supports the use of inference and believes it should be permissible in an item-level track-and-trace system. In fact, given the industry movement toward adoption of 2D bar code technology, we believe the use of inference is a necessity. We are committed to working with the California Board of Pharmacy, the FDA and other industry stakeholders to develop the requirements around its use. However, before the inference rules can be written, additional details about the item-level track-



and-trace system to be utilized are needed. There should be a better understanding of the complete process, including the system architecture and data requirements and how exceptions will be resolved in order to inform decisions around inference rules. For example, whether an item was read or "inferred" upon receipt will impact how an exception is resolved. The entire process is inextricably linked and must be defined before Inference rules can be determined.

Pfizer is committed to working with the Board, GS1, and others to further assess various system architecture models (the GS1 network centric e-pedigree models) and to address exception handling issues. We are actively engaged at this time in the work being done by GS1 Healthcare US to address the resolution of exceptions and in documenting findings from our pilot activities in the GS1 Implementation Guide, "Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes". We look forward to sharing this work with the Board when complete.

Pfizer appreciates the opportunity to provide this input to the Board and looks forward to working with you in the future. Please contact me at (212) 573-3192 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom McPhillips".

Tom McPhillips
Vice President
US Trade Group

RECEIVED BY CALIF.
BOARD OF PHARMACY
2012 AUG 30 PM 12:31



August 28, 2012

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Use of Inference

Dear Ms. Herold:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide information to the California Board of Pharmacy (the Board) in response to its request for information for a possible Board rulemaking on inference, pursuant to California Business & Professions Code § 4163.3. PhRMA represents the country's leading innovative biopharmaceutical companies, who operate globally. PhRMA member companies are committed to researching and developing new medicines to help patients live longer, healthier lives.

While PhRMA recognizes that the Board specifically requested input on inference, the Board's request for information touches on key aspects of an interoperable electronic pedigree system that must first be defined, in order to fully evaluate inference. PhRMA also continues to believe that a national system is preferable to any one state system. Nonetheless, we remain committed to helping California implement its law, and encourage the Board to define the data elements, system architecture, and other infrastructure necessary to achieve an interoperable electronic system.

Since California amended its law in 2008, PhRMA members have engaged in a number of pilot activities and have learned a great deal about data exchange and the elements and steps necessary to achieve an interoperable electronic pedigree system. The pilot work completed to date suggests that an item-level track and trace system as envisioned under California law is not the most effective electronic system to prevent diversion and counterfeiting of finished pharmaceutical products in the finished product distribution chain. The only known way to currently achieve an item level track and trace model is to use the Drug Pedigree Messaging Standard (DPMS). However, the pilots conducted to date suggest that the DPMS model

Pharmaceutical Research and Manufacturers of America

950 F Street, NW, Washington, DC 20004 • Tel: 202-835-3400

introduces unrealistic supply chain risks because it requires a high degree of accuracy that has not been proven in pilot work conducted.

More precisely, in order for any electronic pedigree system to function as intended, the pedigree information must be exchanged electronically between trading partners, and these electronic data exchanges must match the physical flow of the product. Both pieces must work together to allow uninterrupted movement of pharmaceuticals through the distribution chain. However, the pilot experiences with DPMS to date demonstrate that when exceptions or errors in the data exchange occur, the physical flow of the product stops. PhRMA members are greatly concerned about the cumulative impact of this phenomenon on the ability of patients to obtain their medicine. If, when the system envisioned in California is fully operational, exceptions or errors in data exchange halt the further distribution of products, this will have a negative impact on product supply and patient care. And, the cumulative effect of these errors will have a ripple effect throughout the distribution chain.

The pilot work conducted to date has also involved distributed database models. PhRMA members believe that pilots of other database models, to assess both patient access and product protection, are necessary, and we are willing to work with the Board and others to conduct such pilots.

Notwithstanding this fact, PhRMA members remain committed to helping the state implement its law. As such, PhRMA members are beginning to serialize products at the item level, and to create databases containing information about those products at the item level that will allow for downstream supply chain participants to authenticate or verify those item numbers. These activities will facilitate the exchange of item level information in the supply chain, but they do not lead to the creation of an interoperable electronic system required under California law. Thus, this is where the Board must exercise its leadership to develop such an interoperable system.

Given that it's unclear what type of interoperable pedigree system will be developed nationwide or in California, developing regulations on inference at this time could be premature. Manufacturers need to know what type of interoperable system will be established to enable supply chain participants to meet the state's interoperable pedigree requirements. Will California establish a centralized system, a semi-centralized system, or a de-centralized system? As stated above, pilot work completed to date have only tested the distributed or de-centralized model.

Moreover, under California law, the exchange of pedigree information throughout the distribution chain is not complete until 2017. As downstream supply chain participants begin to receive and exchange pedigree information, a host of unanticipated outcomes that can't be predicted today should be expected. A "detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy," is not possible today. Moreover, hardware and software specifications, processes, means and methodologies cannot be known today as they likely haven't been built, and once designed, built, and tested, will be modified and adopted over time.

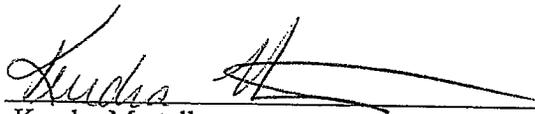
No matter what interoperable electronic system is ultimately adopted, PhRMA members believe inference is necessary and should be permissible. To manufacturers, "inference" consists of one or more steps that allow a person to infer the contents of a collection of containers as it moves through the supply chain, without having to separately verify each unit or item within the individual collection. As the Board considers these issues, a GS1 document from May 2010 entitled, "The Practice of Inference in the Pharmaceutical Supply Chain," could be helpful to the Board. As product flows through the supply chain, homogenous cases from a manufacturer are broken down and further distributed into secondary packages and containers. In fact, manufacturers believe that very few of their original packaging configurations remain intact throughout the supply chain to a dispensing location. The Board will need to understand the impact of these activities on the use of inference and on product supply and patient access to medicines. Additionally, standard operating procedures (SOPs) to accomplish inference do not presently exist within many manufacturers.

Finally, with respect to liability, manufacturers should not be liable for downstream participants who do not verify pedigree information. Further, the California law requires a certification that the information contained in a pedigree is true and accurate. As the Board considers issues around certification and liability, it should consider the appropriateness of requiring such certifications in each instance. For example, how can an entity certify to the accuracy of a pedigree once legal title to the product has transferred to another entity? This is especially true in the case of returns, which must be documented on the same pedigree as the original transaction. Manufacturers can only reasonably be expected to certify to the accuracy of the information they generate with each outbound shipment, and to, with appropriate security controls in place, certify to the authenticity of a particular standardized numerical identifier when requested. Manufacturers generally understand that achieving a zero defect system may not be expected for the purposes of certification, and that business rules may be used to manage exceptions.

Virginia Herold
California State Board of Pharmacy
August 28, 2012
Page 4

Thank you again for the opportunity to provide input into the Board's request for information on inference. Should you have any questions or comments regarding the issues raised in this letter, please feel free to contact me at 202-835-3549.

Sincerely,

A handwritten signature in black ink, appearing to read "Kendra", followed by a long, sweeping horizontal line that extends to the right.

Kendra Martello
Assistant General Counsel

RECEIVED BY CALIF
BOARD OF PHARMACY

2012 NOV 26 PM 3: 34

November 20th, 2012
California State Board of Pharmacy
1625 N Market Blvd.
Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Board of Pharmacy:

Thank you for the opportunity to comment on the proposed rulemaking regarding inference and certification of individual drug package units. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 450 independent owned community pharmacies in the State of California. These pharmacies in many cases are the most accessible health care providers in their local communities. Importantly, IPC is also one of the largest member-owned wholesale drug distributors in the nation.

The Case for Inference

The California drug pedigree law requires recipients of drugs to certify that they received specific drug items at a unit level based on unique serial numbers. However, to be able to certify that you have received a given set of serialized units one would have to open, scan the units and reseal every case. This requirement would be very labor intensive, costly and inefficient. Currently, the Independent Pharmacy Cooperative brings cost effective drug wholesale solutions to independent owned pharmacies that allows them to better compete with large chain pharmacies. The significant costs associated with a strict unit level certification, which we estimate to be in excess of 1.15 million dollars per year for our operation, would jeopardize our ability to continue this business model.

Today, when a drug wholesaler receives a full case of drugs they normally do not open the container, instead they confirm that it contains exactly what the case label says; including, NDC, quantity and lot number. This type of inference is standard operating procedure across the entire supply chain. If case inference is not allowed, it would dramatically slow the movement of products, but more importantly, it would substantially increase the opportunity for substitution and diversion possibly resulting in adulterated, misbranded or counterfeit product entering the distribution channel.

Solution

The above mentioned security concerns are one of the drivers behind the practice of inference, under which companies use other evidence, rather than opening outer containers and scanning each individual item, in order to verify the integrity of a shipment. This aligns with the Agency's description: "inbound inference" that upon receipt of sealed cases from a known and demonstrably reliable manufacturer

trading partner, that are homogenous both in product/SKU and lot number, it be allowed to "infer" that the case identifier is accurately linked to the individual package serial numbers, so that it can receive and certify receipt of the individual items based on that relationship without opening the sealed case.

Proposed Standard Operating Procedures

At this time there is very limited availability and use of serialized prescription drug product packages. It is our understanding that FDA is working on a standard Serialized Numerical Identifier (SNI). Standard Operating Procedures will be tailored to the SNI when made available.

Conclusion

Inference allows a reasonable level of security with a lower expenditure of resources and may even protect the supply chain from the introduction of adulterated, misbranded or counterfeit product that could gain entry due to the massive number of open container events that would be required.

Therefore, the use of inference can provide the necessary protection while allowing for the efficient flow of drug product through the drug distribution supply chain.

For direct inquiries or questions related to this letter, please contact

Mark Kinney R.Ph
Vice President of Government Affairs
Independent Pharmacy Cooperative
15550 Columbus Street
Sun Prairie, WI 53590

California Business & Professions Code
Chapter 9, Division 2
Article 11. Wholesalers and Manufacturers

4163.1. (a) For purposes of Sections 4034 and **4163**, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.