

## Letters List

1. **Actavis**
2. **Allergan**
3. **B A Systems**
4. **Biogen Idec Inc.**
5. **BIO Technology**
6. **Boehringer Ingelheim**
7. **California Hospital Association**
8. **Catalent**
9. **Centrex Pharmaceutical Inc.**
10. **C H I (California Healthcare Institute)**
11. **Creekwood Pharmaceutical Inc.**
12. **EMD Serono**
13. **Ferndale**
14. **Gilead**
15. **GphA (Generic Pharmaceutical Association)**
16. **GPSG (Global Pharmaceutical Supply Group)**
17. **Grifols**
18. **HDMA (Healthcare Distribution Management Association)**
19. **Hogan & Hartson**
20. **Lilly**
21. **McKesson Corporation**
22. **MedImmune**

- 23. MGI Pharma**
- 24. Mylan**
- 25. NACDS (National Association of Chain Drug Stores)**
- 26. NCPA (National Community Pharmacists Association)**
- 27. Novartis**
- 28. Pfizer Inc.**
- 29. PhRMA**
- 30. PPTA (Plasma Protein Therapeutics Association)**
- 31. Safeway**
- 32. Takeda**
- 33. Talecris**
- 34. Tercica**
- 35. Teva**
- 36. University of California**
- 37. Wal-Mart**
- 38. Watson**





2008 JAN -9 PM 4: 20

January 8, 2008

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

Via FAX: 916-574-8618

To Whom It May Concern:

Re: Actavis strategy for compliance to California ePedigree law.

This is to inform the Board of Pharmacy that Actavis has determined that it will be unable to be in full compliance with the regulations set forth in the California ePedigree law by the January 1, 2009 date. However, Actavis plans to be in full compliance by January 1, 2011 and we therefore respectfully request a two-year extension of the compliance date until January 1, 2011.

The format of this correspondence conforms to your published "Template for Submissions Regarding Implementation Date of California ePedigree Laws (Business and Professional Code 4163.5)." We have developed an implementation strategy and have a team working to implement that strategy. We expect that this effort will continue and intensify until we reach the milestones necessary for full compliance to the California law.

By way of background, founded in 1956, Actavis is the fifth-largest manufacturer of generic pharmaceuticals, manufacturing over 600 different products. With over 11,000 worldwide employees, Actavis continues to grow at a rapid pace. Within the US, we manufacture in Elizabeth, NJ, Lincolnton, NC, Baltimore, MD and Totowa, NJ. In a few cases, like other generic manufacturers, we use third party contract manufacturing. From the supply chain standpoint, Actavis has an ongoing logistics management relationship (3PL) with UPS.

We believe that providing prescription drugs to California consumers at a lower price than similar branded drugs is vital to overall patient safety as more people in lower economic strata have access to our products. However, other dynamics of our business that we share with other generic manufacturers such as lower margins and higher unit volumes make the expenses and technological uncertainty risky to integrate quickly.

Our involvement with pedigrees started some years ago with the passing of the state laws not only in California, but in Florida as well as other states.

We have formulated a going-forward strategy around our ePedigree compliance for California. This has involved the formulation of an ePedigree team inside our company consisting of members representing:

- Corporate Management
- Supply Chain Management
- Plant Management
- Customer Service
- Information Technology

In addition, we have secured the efforts of outside consultants and built relationships with several ePedigree vendors, other pharmaceutical companies – both branded and generic – as well as our supply chain partners, as well as the trade associations where we have memberships. All told, we have hundreds of “person-days” involved in ePedigree activities from our employees and retained consultants. This number does not include vendors, other companies or trading partners. We are dedicated to compliance with ePedigree laws in all states using best of breed technologies and business practices. Our efforts have resulted in:

- Implemented lot-level EDI Advance Ship Notifications (RxASN) as well as ASN shipment labels to comply with Florida Pedigree legislation (July 2006)
- An internally published preliminary analysis of ePedigree study, completed during 2007.
- Ongoing efforts with industry sources (i.e., vendors, colleagues at other pharma companies, supply chain partners and others).
- Formulation and management of the ePedigree project team for California compliance.
- Agreed-to implementation strategy which is referenced and excerpted in this document.
- Understanding of the milestones and benchmarks to be achieved within stated timeframes to comply with California ePedigree laws as we understand them.
- Establishment of a phased-in, risk-based serialization strategy designed to maximize patient safety.

The attached ePedigree project management document (Appendix A) illustrates the milestones with accompanying timeframes, we believe are integral to achieving full compliance by January 1, 2011. For the “phased-in” approach we have planned for our compliance strategy, we will have ePedigree (lot level only) on all Actavis dangerous drugs by the end of 2008. We will have pilot programs where we will identify and serialize our most dangerous drugs in the first phase. In this way, we believe that we will be in full compliance on the drugs with the most profound effect on patient safety first, with the rest of our product line to follow in a phased, risk-based approach. We have enclosed our model to identify risk criteria to classify those drugs as Appendix B.

Actavis believes that full compliance to California’s ePedigree law represents a major resource commitment to the consumers of California. The total cost of compliance for January 1, 2011 as outlined in this document and attachments represents 30% of our 2006 (last year for which information is available as of this writing) EBIT. This investment takes into account not only the cost of unit-level serialization, but also of the ePedigree systems and the networks necessary to integrate this new data with our legacy systems and those of our trading partners. The effect of ePedigree and the capital re-allocation necessary to comply has significant ramifications on our business processes, infrastructure as well as those of our supply chain partners. As a generic manufacturer, our margins are significantly smaller than “branded” pharmaceutical companies; however our unit volumes relevant to our size are higher due to the lower prices, therefore making our serialization costs a higher commitment than branded companies. Our ability and that of other generic manufacturers, to provide lower cost medications to the consumers of California is dependent on our ability to carefully manage our capital and cost structure. We believe that a two-year extension would alleviate some financial and safety risk as the technology matures and production applications become more reliable than our analysis shows they are today.

Actavis’ perspective on the effect of the extension on patient safety is:

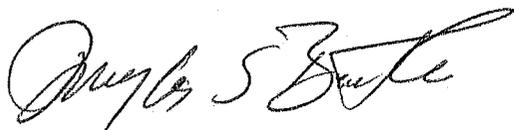
- We believe that a phased-in approach, where more dangerous drugs are serialized on a priority basis enables a more cost effective and safer deployment of serialization and ePedigree. We believe premature deployment of promising, but currently unreliable serialization technologies will lead to production delays, supply issues and increased prices to consumers in California. The increased prices and decreased supply of generic drugs may curtail availability to portions of the population or result in consumers buying dangerous drugs through the Internet or from out-of-state sources, thereby decreasing patient safety and distribution control.

- Technology refinements most likely will make serialization more effective and reliable by the 2011 proposed deadline than the 2009 deadline. This, in turn, will make ePedigree data flow through the supply chain more accurately and help to curtail drug counterfeiting thereby increasing patient safety through the two-year extension.
- We believe that the entire supply chain should be able to fully comply with the tenants of the law by January 1, 2011, where very few, if any, would be able to fully comply by January 1, 2009. A situation where most companies in the industry do not comply by January 1, 2009, results in increased complexity of supply chain management and decreased supply chain integrity and therefore, patient safety.
- The current Federal law mandates a technology recommendation which would lend itself to industry standardization on serialization technology, thereby increasing reliability and furthering the California ePedigree initiative. The technology recommendation is scheduled within the period of the proposed two-year extension.
- Actavis does not believe that an extension of the deadline for ePedigree would mean that work towards compliance would slow down or stop. Rather it means that the industry understands the complexity involved as well as the ramifications on all of our systems and business processes to do this right to achieve the desired result – increased safety of all patients. We suggest that, should the Board grant the two-year extension we propose ongoing measures to monitor the progress of the industry to comply with the law by the January 1, 2011 extended deadline, be implemented as a condition of the extension.

We believe that this request for extension meets the requirements set forth in your Template and hope that our request will be granted. Actavis shares the California Board of Pharmacies dedication to improving patient safety and we are making a very significant commitment of financial and human resources to achieve this goal. We ask for the Board's cooperation on this deadline extension request to allow us the time necessary to successfully implement a project of this large scale.

Thank you very much for the opportunity for Actavis Inc. to provide to the Board a detailed response, our implementation strategy and timelines as part of this request for extension. Please do not hesitate to contact me directly at [dboothe@actavis.com](mailto:dboothe@actavis.com) or 973-889-6633 if you have any follow-up requests for clarification or additional information.

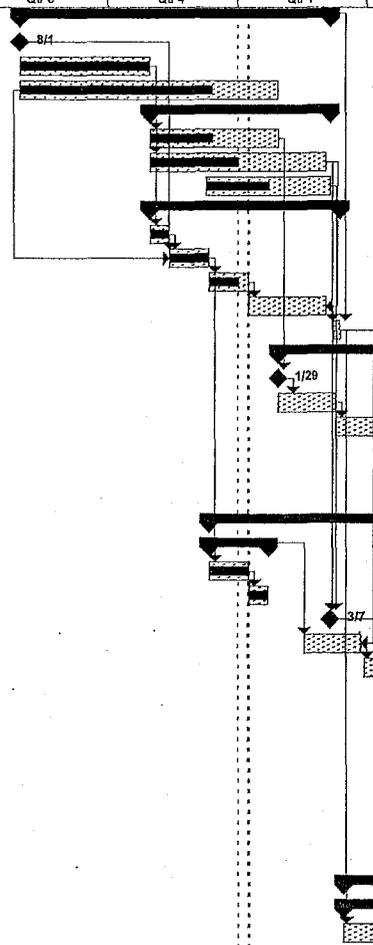
Respectfully yours,



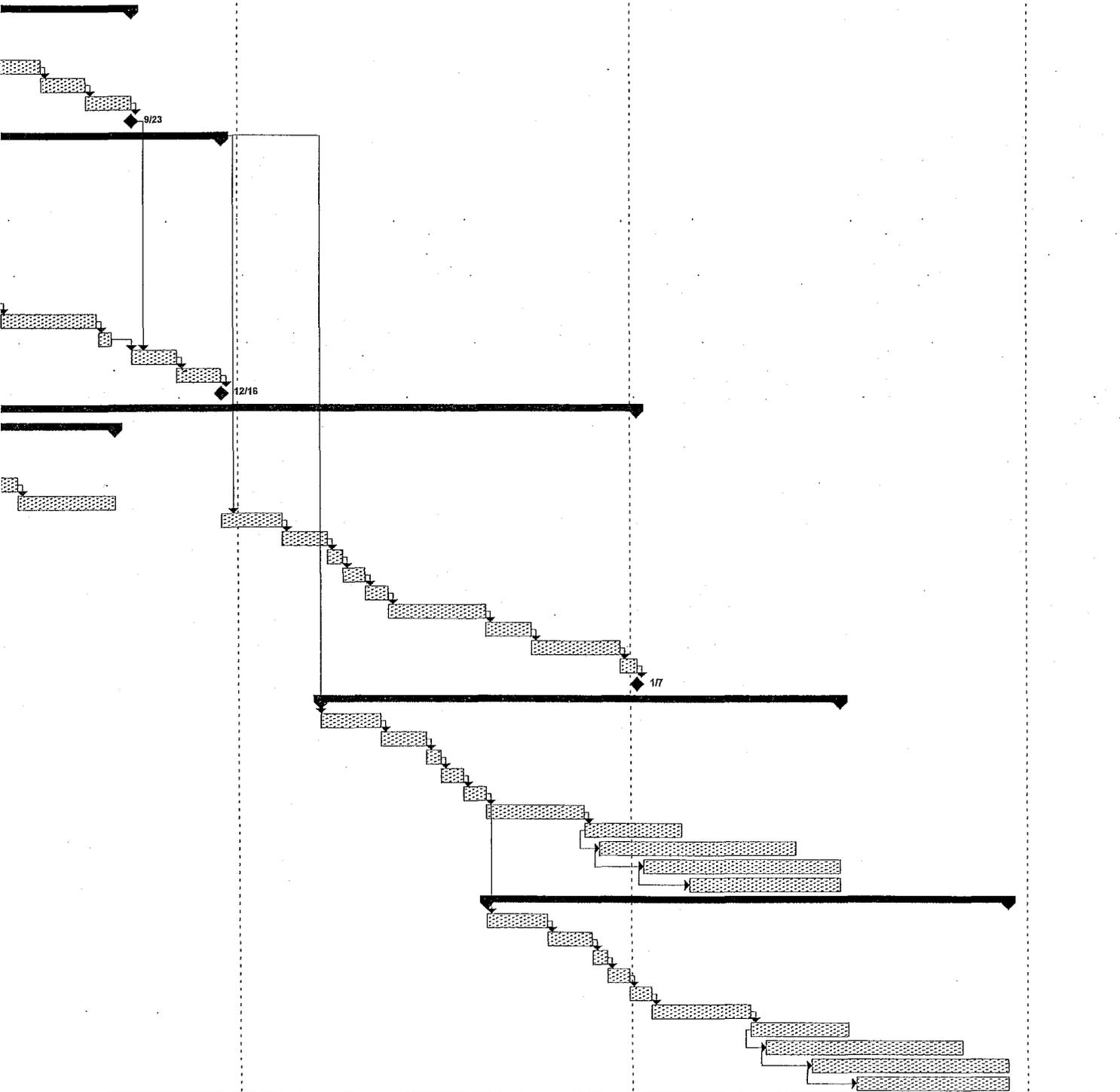
**Douglas Boothe**  
Executive Vice President  
Actavis Inc.

# Appendix A Project Timeline

| ID | Task Name  | Duration | Start        | Finish       | Predecessors    | 2007  |       |       |       |
|----|--|----------|--------------|--------------|-----------------|-------|-------|-------|-------|
|    |  |          |              |              |                 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 1 |
| 1  | Analysis Phase   | 168 days | Wed 8/1/07   | Fri 3/7/08   |                 |       |       |       |       |
| 2  | Establish Project Team                                       | 0 days   | Wed 8/1/07   | Wed 8/1/07   |                 |       |       |       |       |
| 3  | Analysis of Current & Pending Legislation                    | 13 wks   | Wed 8/1/07   | Tue 10/30/07 |                 |       |       |       |       |
| 4  | Analysis of Industry Activity                                | 26 wks   | Wed 8/1/07   | Tue 1/29/08  |                 |       |       |       |       |
| 5  | Analysis of Vendors  | 93 days  | Wed 10/31/07 | Fri 3/7/08   |                 |       |       |       |       |
| 6  | Research ePedigree Vendors / RFQ                             | 13 wks   | Wed 10/31/07 | Tue 1/29/08  | 3               |       |       |       |       |
| 7  | Research Serialization Media (1D, 2D, RFID)                  | 18 wks   | Wed 10/31/07 | Tue 3/4/08   | 3               |       |       |       |       |
| 8  | Research Serialization Vendors / Informal RFQ                | 13 wks   | Mon 12/10/07 | Fri 3/7/08   |                 |       |       |       |       |
| 9  | Strategy Development Phase                                   | 98 days  | Wed 10/31/07 | Fri 3/14/08  |                 |       |       |       |       |
| 10 | Develop Functional Requirements / Use Cases                  | 2 wks    | Wed 10/31/07 | Tue 11/13/07 | 3               |       |       |       |       |
| 11 | Formulate Preliminary Strategy                               | 4 wks    | Wed 11/14/07 | Tue 12/11/07 | 4SS+13 wks,2,10 |       |       |       |       |
| 12 | Develop Consensus with 3PL (UPS)                             | 4 wks    | Wed 12/12/07 | Tue 1/8/08   |                 |       |       |       |       |
| 13 | Develop Consensus with Downstream Trading Partners           | 8 wks    | Wed 1/9/08   | Tue 3/4/08   | 7FF,12          |       |       |       |       |
| 14 | Finalize Top Level Strategy                                  | 1 wk     | Mon 3/10/08  | Fri 3/14/08  | 1,13            |       |       |       |       |
| 15 | E-Pedigree Implementation Phase                              | 170 days | Tue 1/29/08  | Tue 9/23/08  |                 |       |       |       |       |
| 16 | Select Vendor  | 0 days   | Tue 1/29/08  | Tue 1/29/08  | 6               |       |       |       |       |
| 17 | Formalize Requirements / Specifications                      | 6 wks    | Wed 1/30/08  | Tue 3/11/08  | 16              |       |       |       |       |
| 18 | Design / Build   | 16 wks   | Wed 3/12/08  | Tue 7/1/08   | 17              |       |       |       |       |
| 19 | Installation / Commissioning                                 | 6 wks    | Wed 7/2/08   | Tue 8/12/08  | 18              |       |       |       |       |
| 20 | Validation   | 6 wks    | Wed 8/13/08  | Tue 9/23/08  | 19              |       |       |       |       |
| 21 | Live   | 0 days   | Tue 9/23/08  | Tue 9/23/08  | 20              |       |       |       |       |
| 22 | Serialization Implementation Phase I - Pilot Line(s)         | 265 days | Wed 12/12/07 | Tue 12/16/08 |                 |       |       |       |       |
| 23 | Risk Profile   | 30 days  | Wed 12/12/07 | Tue 1/22/08  |                 |       |       |       |       |
| 24 | Develop Selection Criteria                                   | 4 wks    | Wed 12/12/07 | Tue 1/8/08   | 11              |       |       |       |       |
| 25 | Develop Product Risk Profile                                 | 2 wks    | Wed 1/9/08   | Tue 1/22/08  | 24              |       |       |       |       |
| 26 | Select Vendor  | 0 days   | Fri 3/7/08   | Fri 3/7/08   | 7,8             |       |       |       |       |
| 27 | Develop Requirements (includes line mods and labeling mods)  | 6 wks    | Mon 2/18/08  | Fri 3/28/08  | 14FF+2 wks,23   |       |       |       |       |
| 28 | Formal RFQ   | 4 wks    | Mon 3/31/08  | Fri 4/25/08  | 27              |       |       |       |       |
| 29 | Develop Capex  | 1 wk     | Mon 4/28/08  | Fri 5/2/08   | 28              |       |       |       |       |
| 30 | Approve Capex  | 2 wks    | Mon 5/5/08   | Fri 5/16/08  | 29              |       |       |       |       |
| 31 | Place Orders   | 1 wk     | Mon 5/19/08  | Fri 5/23/08  | 30,26           |       |       |       |       |
| 32 | Design / Build   | 13 wks   | Mon 5/26/08  | Fri 8/22/08  | 31              |       |       |       |       |
| 33 | FAT  | 2 wks    | Mon 8/25/08  | Fri 9/5/08   | 32              |       |       |       |       |
| 34 | Installation   | 6 wks    | Wed 9/24/08  | Tue 11/4/08  | 33,21           |       |       |       |       |
| 35 | Validation / Commissioning                                   | 6 wks    | Wed 11/5/08  | Tue 12/16/08 | 34              |       |       |       |       |
| 36 | Live   | 0 days   | Tue 12/16/08 | Tue 12/16/08 | 35              |       |       |       |       |
| 37 | Serialization Implementation Phase II - Balance of High Risk | 474 days | Mon 3/17/08  | Thu 1/7/10   |                 |       |       |       |       |
| 38 | 3rd Party Strategy   | 126 days | Mon 3/17/08  | Mon 9/8/08   |                 |       |       |       |       |
| 39 | Develop Questionnaire  | 4 wks    | Mon 3/17/08  | Fri 4/11/08  | 14              |       |       |       |       |
| 40 | Issue Questionnaire  | 1 day    | Mon 4/14/08  | Mon 4/14/08  | 39              |       |       |       |       |
| 41 | Receive Responses  | 6 wks    | Tue 4/29/08  | Mon 6/9/08   | 40FS+2 wks      |       |       |       |       |
| 42 | Develop Preliminary Project Plans for each 3rd Party Entity  | 13 wks   | Tue 6/10/08  | Mon 9/8/08   | 41              |       |       |       |       |
| 43 | Develop Requirements (includes line mods and labeling mods)  | 8 wks    | Wed 12/17/08 | Tue 2/10/09  | 22              |       |       |       |       |
| 44 | Formal RFQ   | 6 wks    | Wed 2/11/09  | Tue 3/24/09  | 43              |       |       |       |       |
| 45 | Develop Capex  | 2 wks    | Wed 3/25/09  | Tue 4/7/09   | 44              |       |       |       |       |
| 46 | Approve Capex  | 3 wks    | Wed 4/8/09   | Tue 4/28/09  | 45              |       |       |       |       |
| 47 | Place Orders   | 3 wks    | Wed 4/29/09  | Tue 5/19/09  | 46              |       |       |       |       |
| 48 | Design / Build   | 13 wks   | Wed 5/20/09  | Tue 8/18/09  | 47              |       |       |       |       |
| 49 | FAT  | 6 wks    | Wed 8/19/09  | Tue 9/29/09  | 48              |       |       |       |       |
| 50 | Installation   | 12 wks   | Wed 9/30/09  | Tue 12/22/09 | 49              |       |       |       |       |
| 51 | Validation / Commissioning                                   | 12 days  | Wed 12/23/09 | Thu 1/7/10   | 50              |       |       |       |       |
| 52 | Live   | 0 days   | Thu 1/7/10   | Thu 1/7/10   | 51              |       |       |       |       |
| 53 | Serialization Implementation Phase III - Medium Risk         | 345 days | Wed 3/18/09  | Tue 7/13/10  |                 |       |       |       |       |
| 54 | Develop Requirements (includes line mods and labeling mods)  | 8 wks    | Wed 3/18/09  | Tue 5/12/09  | 22FS+13 wks     |       |       |       |       |
| 55 | Formal RFQ   | 6 wks    | Wed 5/13/09  | Tue 6/23/09  | 54              |       |       |       |       |
| 56 | Develop Capex  | 2 wks    | Wed 6/24/09  | Tue 7/7/09   | 55              |       |       |       |       |
| 57 | Approve Capex  | 3 wks    | Wed 7/8/09   | Tue 7/28/09  | 56              |       |       |       |       |
| 58 | Place Orders   | 3 wks    | Wed 7/29/09  | Tue 8/18/09  | 57              |       |       |       |       |
| 59 | Design / Build   | 13 wks   | Wed 8/19/09  | Tue 11/17/09 | 58              |       |       |       |       |
| 60 | FAT  | 13 wks   | Wed 11/18/09 | Tue 2/16/10  | 59              |       |       |       |       |
| 61 | Installation   | 26 wks   | Wed 12/2/09  | Tue 6/1/10   | 60SS+2 wks      |       |       |       |       |
| 62 | Validation / Commissioning                                   | 26 wks   | Wed 1/13/10  | Tue 7/13/10  | 61SS+6 wks      |       |       |       |       |
| 63 | Live   | 20 wks   | Wed 2/24/10  | Tue 7/13/10  | 62SS+6 wks      |       |       |       |       |
| 64 | Serialization Implementation Phase IV - Low Risk             | 345 days | Wed 8/19/09  | Tue 12/14/10 |                 |       |       |       |       |
| 65 | Develop Requirements (includes line mods and labeling mods)  | 8 wks    | Wed 8/19/09  | Tue 10/13/09 | 58              |       |       |       |       |
| 66 | Formal RFQ   | 6 wks    | Wed 10/14/09 | Tue 11/24/09 | 65              |       |       |       |       |
| 67 | Develop Capex  | 2 wks    | Wed 11/25/09 | Tue 12/8/09  | 66              |       |       |       |       |
| 68 | Approve Capex  | 3 wks    | Wed 12/9/09  | Tue 12/29/09 | 67              |       |       |       |       |
| 69 | Place Orders   | 3 wks    | Wed 12/30/09 | Tue 1/19/10  | 68              |       |       |       |       |
| 70 | Design / Build   | 13 wks   | Wed 1/20/10  | Tue 4/20/10  | 69              |       |       |       |       |
| 71 | FAT  | 13 wks   | Wed 4/21/10  | Tue 7/20/10  | 70              |       |       |       |       |
| 72 | Installation   | 26 wks   | Wed 5/5/10   | Tue 11/2/10  | 71SS+2 wks      |       |       |       |       |
| 73 | Validation / Commissioning                                   | 26 wks   | Wed 6/16/10  | Tue 12/14/10 | 72SS+6 wks      |       |       |       |       |
| 74 | Live   | 20 wks   | Wed 7/28/10  | Tue 12/14/10 | 73SS+6 wks      |       |       |       |       |



|       |       |       |       |       |       |       |       |       |       |       |
|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 2008  |       | 2009  |       |       |       | 2010  |       |       |       |       |
| Qtr 3 | Qtr 4 | Qtr 1 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 1 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 1 |



## Appendix B Risk Profile

| Factor                 | Weight | Value  | Max Value |
|------------------------|--------|--|-----------|
| Narcotic Schedule      | 35%    | CI = 5<br>CII = 4<br>CIII - CV = 3<br>non-Narcotic = 0   | 1.75      |
| Value                  | 35%    | Split products into quintiles by selling price.<br>Top Quintile = 5<br>Second Quintile = 4<br>Third Quintile = 3<br>Fourth Quintile = 2<br>Bottom Quintile = 1 | 1.75      |
| Manufacturing Location | 15%    | External = 5<br>Internal = 2.5   | 0.75      |
| Sales Volume           | 10%    | Split products into quintiles by unit sales.<br>Top Quintile = 5<br>Second Quintile = 4<br>Third Quintile = 3<br>Fourth Quintile = 2<br>Bottom Quintile = 1    | 0.50      |
| Case Size              | 5%     | > 96 units per case = 5<br>37 - 96 units per case = 4<br>24 - 36 units per case = 3<br>9 - 23 units per case = 2<br>< 9 units per case = 1                     | 0.25      |

Appendix B  
Risk Profile

| <b>Risk Category</b> | <b>Product Count</b> |
|----------------------|----------------------|
| High                 | 15                   |
| Medium               | 91                   |
| Low                  | 317                  |
| Total                | 423                  |



**ALLERGAN**

2555 Duane Drive, P.O. Box 19934, Irvine, California, USA 92619-9934 Telephone: 949.246.4600 Fax: 949.246.4601 [www.allergan.com](http://www.allergan.com)



January 8, 2008

California State Board of Pharmacy  
Sacramento, California

**Re: Allergan, Inc. Submission**

This submission to the California State Board of Pharmacy relates to the current electronic pedigree compliance implementation date and is in response to the Board's request for feedback from industry regarding progress and plans pertaining to the implementation of an electronic pedigree system.

Allergan is committed to ensuring the safe distribution of our products through the effective use of an electronic pedigree system. Currently, we have plans to implement an electronic pedigree system on a limited basis during 2008 but due to the complexity of the project there is simply no possibility that Allergan can become compliant with all of our products by January 1, 2009 and respectfully request a delay in the compliance date until January 1, 2011.

Sincerely,

A handwritten signature in black ink, appearing to read 'Douglas Ingram', written over a horizontal line.

Douglas Ingram  
Executive Vice President,  
Chief Administrative Officer and General Counsel





2501 Lemontree Lane  
Upper Marlboro, Maryland 20774  
<http://www.basystemsllc.com>  
[baservices@basystemsllc.com](mailto:baservices@basystemsllc.com)

2008 JAN -7 PM 2:15

January 1, 2008

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

Dear Sir or Madam:

I respectfully request the opportunity to place comments before the California Board of Pharmacy in regard to pending E-Pedigree regulations being debated by the California Legislature.

Specifically, our comments target remarks made by Mr. Wilcox stating that an RFID solution that can read all serialized identification formats required by E-Pedigree does not exist. Over the course of 2007 we have heeded the calls from the pharmaceutical industry and partnered with Motorola Corporation to build an economical and flexible RFID system. Our Flexible ID System can simultaneously read UHF and HF RFID tags as well as capturing barcode labels without the need for specialized computer hardware.

We worked with Motorola to insure that our RFID solution meets all existing standards and integrates with existing computer software systems with little to no changes. We have met and consulted with many pharmaceutical companies, many of which service California's drug system, to build a solution that is cost effective and easily integrates with existing software.

We have publicly announced our system and it is commercially available. We are prepared to scale up to full production provided that there is a market need.

Our company would like to share with the California Board of Pharmacy our findings from the major pharmaceuticals. We would like to demonstrate our solution to the committee as it is ready for deployment, and has been well received by many of the California drug system's distributors.

I am attaching a press release, a product description, and data sheets as provided to the pharmaceutical partners we have engaged.

I thank you for your time.

Regards,

A handwritten signature in black ink, appearing to read 'William Lee Mapp, III', with a long horizontal line extending to the right.

William Lee Mapp, III  
President, BA Systems, LLC

## BA Delivers First Commercially Available Single Device E-Pedigree Solution

**Upper Marlboro, MD – January 4, 2008** – Today, BA Systems, LLC releases the FlexID Reader, a single device, RFID platform used for reading UHF, HF, and barcode labeled serialized IDs. The solution was developed for the pharmaceutical distribution and verification markets by BA's RFID Practice, leveraging market research conducted in tandem with the RFID division of Motorola's Enterprise Mobility business.

"In conjunction with Motorola, we gathered requirements and listened to the needs of some of the pharmaceutical industry's biggest players, enabling BA to build an elegant solution that can be used by drug distributors and pharmacies with little effort," said BA Systems President, William Mapp. The FlexID Reader is an exclusive combination, harnessing the power and reliability of Motorola's XR series of RFID readers and patent pending RF Interweaving technology produced by BA Systems. The FlexID Reader is the world's only single device RFID solution providing the capability of reading UHF and HF RFID tags while interrogating barcode labels using a single antenna.

California's E-Pedigree Drug Safety regulations require drug distributors and pharmacies to verify the chain of custody and ownership of prescription drugs and controlled substances in California's drug system. The regulations require that a drug's chain-of-custody, or its pedigree, is verified on an item level using UHF or HF RFID tags and 1D, 2D, or Data Matrix barcode labels. The goal of E-Pedigree is to make the prescription drug system safer by lowering the incidence rate of patients receiving tainted or recalled drugs by tracing a product back to its source of manufacture.



Until now, pharmaceutical companies have had to develop custom software and use multiple RFID readers to simultaneously interrogate multiple RFID tag frequencies and capture barcode data. BA's solution doesn't require specialized software to interrogate the various serialized ID data sources. Additionally, the solution only needs one antenna to read both HF and UHF RFID tags, and is one of the few RFID devices capable of reading the recently ratified EPC HF standard of RFID tags.

The pharmaceutical industry has been desperately seeking a single device solution that can be easily installed and maintained for massive e-pedigree deployments. Current systems using multiple RFID readers and computers are expensive to deploy and service while being prone to configuration problems in the field. BA Systems responded to calls from industry and has produced an affordable solution that helps drug distributors and pharmacies maintain productivity while abiding by new e-pedigree rules.

The AP210 integrates easily with existing middleware and custom software systems by using the same data communications protocol as a standard Motorola XR series RFID reader. "Systems integrators building E-Pedigree solutions don't have to change their code to use FlexID," said Mapp. "If a system knows how to talk to an XR, that system knows how to talk to the FlexID Reader."

The solution also provides the capability for future expansion by supplying USB ports for add-on hardware and remote sensing capabilities. Although, originally designed for the pharmaceutical industry, BA is working with its partners to position FlexID for self-service kiosk, verification, and point-of-sale applications. The solution is currently available in limited quantities and is slated for wide delivery via channel sales partners in the Q2 2008 timeframe.

## **About BA Systems**

BA Systems is a leading innovator of RFID solutions and technology. We helps companies that are afraid of losing business and profitability because of production inefficiencies and lack of inventory controls. Our RFID Practice helps our customers gain and maintain a competitive advantage by automating their most critical operations using RFID technology. We foster a culture of innovation and creativity. Using the best in techniques and technology, BA has demonstrated industry excellence by bringing many firsts to the RFID industry. For more information, visit <http://www.basystemsllc.com>.

## **Media Contact**

Ayisat Herbert

[ayisat@basystemsllc.com](mailto:ayisat@basystemsllc.com)

Office: [1]301.390.0171

Mobile: [1]301.928.4922

**Written Comments of William Mapp on behalf  
of BA Systems LLC  
January 4, 2008**

## **I. Introduction**

Members of the Enforcement Committee, I thank you for an opportunity to present comments to the California Board of Pharmacy in regard to E-pedigree issues.

BA Systems is a Maryland technology company specializing in wireless and mobile systems. We are in partnership with Motorola Corporation and have designed RFID systems and solutions for several industries.

In collaboration with Motorola we have design the FlexID Reader System, an RFID and barcode data capture platform that can read UHF and HF RFID tags as well as 1D, 2D, and RSS barcode label formats. We implemented this system specifically for the pharmaceutical industries need to meet E-pedigree guidelines instituted by the State of California.

## **II. A Device for Interrogating E-Pedigree Mandated Drugs Exists and is Ready**

We support the need for safe and verifiable drugs in the prescription drug system. To that aim, Motorola and BA Systems have been working to specifically develop a system that can read all RFID tag frequencies and capture barcode data without needing specialized computer software and hardware. Our development teams have traveled to several pharmaceutical distributors that must abide by California's rules to continue operations.

The distributors consulted with us and gave us insight into their operations and the requirements they must implement in order to be in compliance of E-pedigree regulations. We used their inputs as requirements to build a system that can readily be deployed and requires minimal effort to maintain. From these numerous visits with the pharmaceutical distributors we compiled a list of requirements that will be used to build a device. The list below is a subset of the major device requirements:

- Easy to deploy and maintain
- Scan all UHF and HF RFID frequencies simultaneously
- Scan all required barcode formats while scanning RFID frequencies simultaneously
- Require little to no changes to existing software systems
- Capture all ID formats fast, less than 1 second response time
- Economically obtainable for large deployment

Using the requirements as a baseline, we designed a system that utilizes a standard platform for interrogating all serialized ID types. The Motorola XR series RFID reader is certified by EPCglobal and is widely supported by numerous software platforms. This RFID reader serves as the foundation for our solution in which we can build in the remaining functionality without requiring a pharmaceutical distributor's software to change. This was extremely important because the distributors were adamant in not having to change their software because they have already committed a sizeable investment in their RFID infrastructure.

## **A. Our solution addresses interoperability issues**

Building our device around a standard platform benefits both distributors and pharmacies. There are companies building E-pedigree software for the pharmacies that do not want to change their software implementations as well. Since our system is built around an industry standard RFID reader, we meet their needs by giving them a way to communicate with our device that is supported by a wide variety of software systems.

The next step in building the device involved reading all of the available HF RFID frequencies that are available to the drug manufacturers. We developed a technique called RF Interweaving that gives our solution the capability of quickly interrogating RFID frequencies quickly. Our solution reads all of the available HF frequencies including the recently ratified EPC HF standard.

Once the UHF and HF reading capability was completed, we incorporated barcode datacapture technology in cooperation with Motorola. The use of their barcode scanners gives our system complete barcode data capture capabilities that can read 1D, 2D, DataMatrix, and RSS barcode formats.

## **III. Our Solution is Well Received by Pharmaceutical Distributors**

After completing implementation we visited the pharmaceutical companies with our finished product. In every demonstration, the distributors were impressed with the rate in which all data formats were read, and the accuracy of each RFID interrogation. Additionally, each company was very pleased knowing that they would not have to make many changes to their existing IT infrastructure in support of our product.

These companies are interested in acquiring our product to use in their verification labs for their E-pedigree solution.

We demonstrated our product to the major pharmaceutical companies as well as a nationwide retailer that offer pharmacy service at its store locations.

## **IV. We are Sensitive to the Deployment Costs for Meeting E-Pedigree Regulations**

One of our major requirements for designing this system was that it had to be cost effective to deploy the solution over a wide area. Our customers operate multiple distribution centers and pharmacy counters and require high product visibility to maximize productivity.

We implemented our solution to be cost effective and require little to no maintenance over the course of its life. Our system uses best-of-breed technologies and techniques that help extend its life span and reduce its cost. We can offer the product in single unit quantities for less than \$10,000. Prices will be further reduced in large quantities.

## **V. We Understand the Pharmacy Community's Hesitation**

There are always many challenges when companies implement systems for meeting regulatory compliance. We have seen this recently when companies began installing controls to be in compliance for Sarbanes-Oxley legislation.

From our experiences, many pharmaceutical companies have not begun to seriously consider the required changes to their environments. We have responded to their needs by building a platform that reads everything required by E-pedigree while maintaining a small footprint. We understand the logistical and deployment challenges facing retail and community pharmacies.

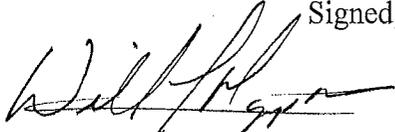
Instead of delaying the deployment of E-pedigree for another 3 years, we recommend extending the E-pedigree requirements for pharmacies to the start of 2010 instead of the start of 2009. This would give the pharmacies enough time to evaluate the products being built by industry as well as observing how the pharmaceutical distributors are implementing E-pedigree.

Although we recommend that pharmacies begin compliance in 2010, we do believe that it would prudent for the Board of Pharmacy to institute a test period in which the pharmacies must deploy the systems to make their operations E-pedigree compliant. This test period would give the pharmacies time to evaluate the software and hardware systems they have deployed before compliance is mandatory. Additionally, it would avoid another delay in implementing E-pedigree legislation as many companies have not begun addressing the regulations up to this point.

Additionally, the extra time will give the industry an opportunity to work out any kinks in their business processes before bringing a multitude of pharmacies online. We believe our recommendation poses a benefit to both distributors and pharmacies while giving the population a safer prescription drug system.

## **VI. Conclusion**

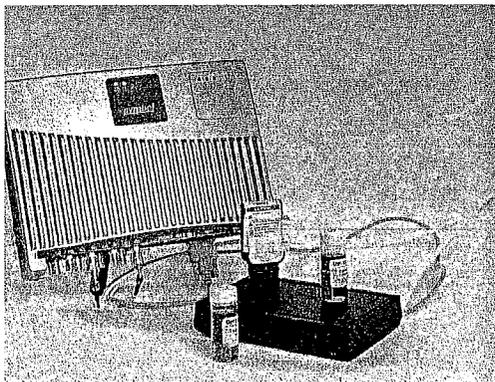
We appreciate the opportunity to submit comments to the California Board of Pharmacy in regard to E-pedigree issues. We believe that extending the implementation date for pharmacies is a good step in the E-pedigree process. Because we have helped solve the problem with inoperability issues we think that extending the pharmacies implementation of E-pedigree regulations to a responsible date is prudent.

Signed,  


William Lee Mapp, III  
President, BA Systems, LLC  
mapp@basystemslc.com  
Office: [1]301.390.0171  
Mobile: [1]240.535.0049

hf + hf + 2d = e-pedigree

- ◆ Get high performance dual-frequency and multi-protocol capability for challenging reader environments
- ◆ Expand Auto-ID capture capabilities by adding other Symbol imagers, scanners, and additional UHF antennas
- ◆ Simultaneously read UHF and HF tags as well as barcodes using a single antenna, a single command, and a single API



## AP210 Multi-Protocol RFID Platform – Exclusive Combination of Motorola XR Series Readers + BA Systems Dual-Frequency Antenna technology.

*As the deadline for meeting e-pedigree regulations approaches, BA Systems recognizes the need to support pending requirements cost effectively. The AP210 RFID Platform provides best-of-breed ID capture with minimal impact to integration costs.*

Building on the proven performance of the Symbol XR440 reader, the AP210 delivers the flexibility and performance of Gen2 while providing the stability and regulatory compliance of HF.

The AP210 is the world's first table-top RFID platform with the capability of reading and writing both HF and UHF RFID tags. The reader platform features an enclosed antenna pad that also provides a seamless interface for 2-D barcode scanners.

The AP210 provides a service-oriented architecture that seamlessly integrates with your existing IT infrastructure and maximizes application flexibility. The leading development tools including .NET 2.0 and Java 3 APIs help you build scalable customized applications.

The AP210 offers the performance, features, and manageability needed in enterprise RFID deployments. The superior read performance and scalability of the XR440 is matched with the flexibility and power to read both UHF and HF tags. The AP210 is the only reader platform that can interrogate both tag frequencies and 2-D barcode readers using a single API command infrastructure.

Previous dual frequency solutions required 2 readers and 2 antennas. If utilized, a barcode device required you to manage a third interface. The AP210 integrates all 3 functions into one easy to manage device.

### High Performance and Reliability

- Robust platform for industrial class UHF and HF RFID Implementations
- Enterprise Connectivity
- Open Architecture
- Expandable
- Single Point of Interrogation

# System Specifications

## Physical Characteristics

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**Dimensions:** 5 in. L x 5 in W x 1.25 in H  
**Visual Status Indicators:** LEDs for Power (green) and Activity (yellow)

## Connectivity

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10/100 Base T Ethernet – RJ45  
Control I/O DB15  
RS232  
USB Host Interface

## Environmental

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IEC 600-2-1/2/14  
**Operational:** 32 deg to +141 deg F (0 deg to +55 deg C)  
**Storage:** -4 deg to +158 deg F (-20 deg to +70 deg C)

## System

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**Memory:** 64MB Flash (DRAM)  
**OS:** Windows CE Version 5.0  
**Management:** SNMP and Airbeam Level 2 Support  
**Frequency:** UHF (902-928 mHz [US]), HF (13.56)  
**Method:** Frequency Hopping Spread Spectrum  
**Power Output:** > 30 dBm  
**Air Link Protocols:** EPC Class 1 Gen2  
HF 13.56  
EPC  
ISO 15693  
Genplus Folio  
PicoTag  
Omron V720  
I-CODE  
MCRF 355/360  
Tag-IT

**Synchronization:** NTP  
**IP Addressing:** DHCP/Static IP  
**Host Interface Protocols:** HTTP/Byte Stream/Arphidium intelligent Reading





biogen idec

CALIFORNIA STATE BOARD OF PHARMACY

2008 JAN 15 AM 8:25

January 7, 2008

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

Dear Sir or Madam:

This letter is in reference to your intent to place on the agenda for your January 23-24, 2008 meeting in San Diego an item regarding the readiness for the January 1, 2009 implementation/compliance date for electronic pedigree. At this time, Biogen Idec is requesting additional time to implement electronic technologies to track the distribution of our products within the state of California. We are currently in the planning phase of our project with an expected implementation date of mid-2009. We have worked diligently to meet the current deadline, yet have experienced several challenges while pursuing the best technological solution to allow us to successfully integrate with our supply chain partners downstream. In order to manufacture and distribute product which meets the legal specifications of the state of California, Biogen Idec must implement a solution which impacts our entire supply operation. To this end, we have already accomplished the following tasks;

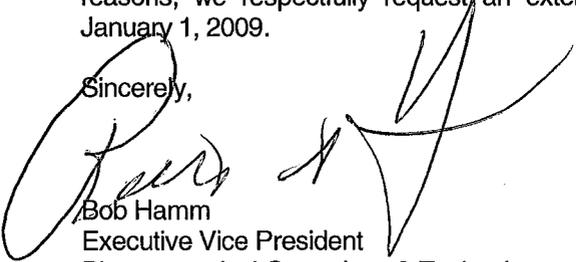
|   |         |
|---|---------|
| Diligence on legal requirements & available technologies  | H2 2005 |
| Business requirements gathering                           | H1 2006 |
| Vendor/Partner presentations                              | H2 2006 |
| Diligence on partner integration & available technologies | H1 2007 |
| Equipment selection & packaging line modification design  | H2 2007 |
| System solution design & vendor selection                 | H2 2007 |
| Vendor Contract negotiations                              | H2 2007 |

The remaining tasks are scheduled and are estimated to be completed in the following timeframes;

|  |         |
|--|---------|
| ePedigree generation configuration & test            | Q1 2008 |
| Serialization system configuration & test            | Q2 2008 |
| Serialized, tagged distribution configuration & test | Q3 2008 |
| Process validation & approval                        | Q4 2008 |
| ePedigree testing with downstream partners           | H1 2009 |

Going forward with the current deadline of January 1, 2009 would mean, at a minimum, California patients currently utilizing Biogen Idec's commercial products, namely AVONEX® (interferon beta-1a) and TYSABRI® (natalizumab) for multiple sclerosis, would experience an interruption in the supply of their medications supporting their treatment regimens. Furthermore, physicians would be limited in designing effective regimens for newly diagnosed patients suffering from this same disease. For these reasons, we respectfully request, an extension to the current implementation/compliance date of January 1, 2009.

Sincerely,

  
Bob Hamm

Executive Vice President  
Pharmaceutical Operations & Technology  
Biogen Idec Inc.

Biogen Idec Inc. 14 Cambridge Center, Cambridge, MA 02142 www.biogenidec.com

2008 JAN -9 AM 11:18

January 9, 2008

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

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

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment in response to the Board of Pharmacy's (Board's) request for information from stakeholders regarding industry readiness for the January 1, 2009 implementation/compliance date for the ePedigree laws. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. In particular, many of our members are involved in the research and development of life-saving therapies and play a critical role in delivering treatments that both prolong life and reduce the burden of disease for patients worldwide.

#### Counterfeit Pharmaceuticals Pose a Threat to the Public Health

BIO commends the Board for its commitment to securing California's drug supply against counterfeit drugs and biologics. Protection of the public is a priority for BIO and all of the pharmaceutical and biologic manufacturers we represent. The American drug distribution system is the most secure in the world. Indeed, several of our member companies that experienced counterfeit attacks in 2001 and 2002, have reported that they have not detected any counterfeits of their products in the U.S. pharmaceutical supply chain since then. However, it is noteworthy that there has been an increase in counterfeiting activity outside of the U.S. Due to the efforts of the U.S. Food and Drug Administration (FDA), drug manufacturers, distributors, and patients have high confidence that the drugs they are prescribed are safe and effective.

Nevertheless, the presence of any amount of fake, adulterated, sub-potent, or super-potent drugs in the U.S. pharmaceutical distribution system poses a threat to the public health. These dangers can be even greater with counterfeit or adulterated biologic drugs, which must be injected or infused directly into a patient's bloodstream. Our industry has been proactive in combating counterfeiters, and the industry has taken productive steps to secure drug and biologic products with holograms, color shifting dyes, and numerous



other anti-counterfeiting technologies. In addition to these product-based security features, many companies have put in place integrated programs to protect their medicines. These processes often include:

- Full-time, dedicated staff to ensure company-wide vigilance in the fight against counterfeiting.
- Contractual requirements for distributors to buy directly and only from the manufacturer, and to report any evidence of product diversion or counterfeiting.
- The use of secure distribution practices to prevent a drug shipment from being stolen, tampered with, or otherwise interfered with in transit.
- Investigation of all complaints received from patients, health care providers, and others in the chain of distribution and use.

However, there is an opportunity for industry to do more to address the problems and secure the drug supply to ensure continued patient safety.

### Implementation of ePedigree Technologies

BIO recognizes that there are vulnerabilities within certain parts of the supply chain that could be remedied through the use of ePedigree technology. Implementation of electronic track-and-trace technology would help create transparency, disclosing the origin and distribution history of drug and biologic products. BIO supports its use within the drug distribution system in a responsible manner. BIO believes that fully implemented electronic tracking from the manufacturer to the pharmacist will reduce any gaps in the supply chain which could lead to opportunities for counterfeit medicines entering the distribution system. If products carry serialized machine-readable tags, their authenticity can be verified through the electronic pedigree at every level of distribution. Indeed, such serialized machine-readable tags could also be used effectively to authenticate the drugs being dispensed at the pharmacy or clinic, thereby protecting patients with a single-system, negating the need to create a complex interoperability matrix.

### Current Industry Efforts to Comply with the 2009 Implementation Date

In November 2007, BIO and the California Healthcare Institute (CHI), conducted a joint survey of our collective members to ascertain timelines and milestones toward compliance with the ePedigree laws<sup>1</sup>. Overall the results revealed that the manufacturers we represent are working diligently toward implementing the changes in business practice that will be required to bring them into compliance with the ePedigree mandate. It should be noted that the creation and implementation of new electronic technologies to track the distribution of drug and biologic products is a tremendous undertaking for large pharmaceutical companies and small biotech companies alike. These changes in business practice will have profound consequences for the highly complex operations of manufacturing facilities, packaging lines, distribution centers, and the operations of third-party partners and logistics providers. With so many business components directly

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<sup>1</sup> The results of this survey were presented to the California Board of Pharmacy Enforcement Committee on December 5, 2007.

affected by the adoption of an electronic track-and-trace system, great care and deliberation must be employed to ensure that a safe, appropriate, and cohesive structure is put in place.

Our survey results show that the manufacturers we represent are actively engaged in the process of working toward the development of an interoperable track-and-trace system that will benefit the industry, the supply chain, and all California consumers of drug and biologic products. There is no quick or simple solution to addressing this problem. Companies responding to our survey indicated diverse levels of readiness. Most of our surveyed companies have indicated that they are currently in the planning phase, testing various technology applications internally. Only a small percentage of our responding companies indicated that they are currently implementing track-and-trace technology for all or a limited number of product lines. There are many technological and production hurdles for manufacturers to overcome before any system can be implemented. Companies continue to develop, deploy, and adopt standards that will serve as the basis for a new supply chain that will ensure safe, secure, and reliable pharmaceutical distribution.

#### Barriers to 2009 Implementation of ePedigree Requirements

As manufacturers work toward the January 1, 2009 compliance date, numerous implementation barriers have come to light. Specifically, companies continue to struggle with technological obstacles, a lack of clear standards, and business process limitations. At the forefront of concern for most manufacturers, and other members of the supply chain, is the fact that to date there is no uniform, agreed upon standard for track-and-trace technology. Additionally, companies are working to overcome the substantial business process system changes, validation issues, interoperability issues, and hardware issues. There are also outstanding challenges related to packaging and labeling. Modifications will be needed for packaging lines and these projects require validation per FDA Good Manufacturing Practice (GMP) requirements. Packaging line modifications pose a significant concern due to the inherent risk that the validation will not prove successful and may result in lost manufacturing capacity that could lead to supply disruption.

There are also specific concerns related to biologic products. A particularly difficult issue facing manufacturers of biologic products relates to the extent that biologics will have to be reworked/re-labeled to comply with the ePedigree laws. Biologic manufacturers face major cold chain issues and impediments. BIO is also concerned that biological stability will be impacted. Most biotechnology products are complex, protein-based biologics that are produced by living systems and are particularly vulnerable to changes in their environment. Biologic manufacturers must ensure their products are safe from chemical impurities following the application of the apparatus to be used to track-and-trace the product. With this goal in mind, manufacturers are deliberately and methodically working toward implementing the safest and most appropriate system possible. BIO member companies do not want to make premature decisions or adopt incomplete or inadequate track-and-trace technologies that may be detrimental to the pharmaceutical supply chain and California consumers of prescription drugs.

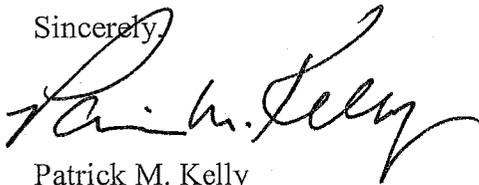
Industry Members are Unable to Meet the January 1, 2009 Compliance Date

The biotechnology industry has developed more than 200 drugs and vaccines that have helped millions of people worldwide. Improving the lives and well-being of patients is our first priority. The adoption of electronic track-and-trace technology should support patient safety and public health. The vast majority of our member companies are working to implement the necessary technologies to meet the compliance date. However, it has become clear that it will not be possible to create an interoperable system that can ensure effective delivery of medicine to patients by January 1, 2009. In order to accomplish this goal and not deprive California patients of needed medicines, additional time is needed. **BIO, on behalf of our membership, requests that the Board exercise its authority to extend the date for compliance to a new date of January 1, 2011.** The biotechnology industry will continue to work with all segments of the supply chain to implement the law, ensuring that the standards, distribution processes and technologies employed will further protect the California public.

Conclusion

We thank the Board for the opportunity to provide our comments and look forward to continuing to work with the Board and all members of the supply chain to fight counterfeit drugs. If we may be of further assistance on any of the topics addressed above, please do not hesitate to contact us.

Sincerely,



Patrick M. Kelly  
Vice President  
State Government Relations  
Biotechnology Industry Organization (BIO)





**Boehringer  
Ingelheim**

January 8, 2008

BOARD OF PHARMACY

2008 JAN -9 AM 11:19

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

J. Martin Carroll  
President and Chief Executive Officer

Dear Ms. Herold,

The California State Board of Pharmacy has directed companies who desire re-scheduling of the operative effective date of California's drug pedigree / item-level serialization legislation to do so formally, in writing. Boehringer Ingelheim recognizes the serious threat that counterfeit drug products pose to the health and well-being of our society and economy. This threat is an urgent "call to action" for supply chain participants: manufacturers, wholesalers, distributors, retail chain and independent pharmacies.

An inter-operable solution, as required by law, demands unprecedented collaboration and cooperation amongst industry trading partners in a regulatory environment that remains fragmented with various state and federal requirements enacted and/or pending. Designing and implementing a solution is fraught with complexities and faces enormous challenges from technological and regulatory perspectives. Also, the role and importance of pharmacies at the critical point of dispensing drug products must be clearly defined. Change of this magnitude must be managed carefully and methodically to avoid disruption in the product supply chain.

Various industry work groups have collected information and gained valuable insight to the current status of "track & trace" technologies (e.g. RFID) and related standards which are at relatively early stages of emergence for this type of regulatory application. From this, we realize that premature implementation of systems and technologies introduce significant risks in maintaining continuity and integrity of the supply chain. Complexity of international supply chains also present further challenges for many companies.

In light of the aforementioned, we believe that patient safety will be best served by re-scheduling the operative effective date of the California statute on drug pedigree and item-level serialization. Boehringer Ingelheim hereby requests the California State Board of Pharmacy exercise its authority to grant an extension to 01/01/2011.

Granting of this extension provides the time needed for:

- resolution of incongruent approaches existent amongst trading partners
- systems and technologies to be firmly established and aligned across the supply chain
- reconciliation of disparate requirements between state and federal legislation

Boehringer Ingelheim has a comprehensive Product Safety and Security Strategy to ensure patient safety and preserve brand integrity. We are actively evaluating vendor solutions to enable electronic pedigree, product serialization, and authentication. We are also building collaborative working relationships and seeking the support of our trading partners in the design and integration of identified solutions.

In closing, we take this opportunity to commend the California State Board of Pharmacy for its efforts to promote the security of the pharmaceutical supply chain and safety of the citizens of California. We hope you understand our concerns and need for a re-scheduling in order to better assure that these shared goals are achieved in a manner that best serves patients in California and the rest of the United States.

**Boehringer Ingelheim  
USA Corporation**

900 Ridgebury Rd./P.O. Box 368  
Ridgefield, CT 06877-0368  
Telephone (203) 798-5100  
Telefax (203) 791-6260

  
J. Martin Carroll



2008 JAN -9 AM 11:57



**CALIFORNIA  
HOSPITAL  
ASSOCIATION**

*Providing Leadership in  
Health Policy and Advocacy*

January 9, 2008

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

California State Board of Pharmacy:

The California Hospital Association is intimately involved in providing pharmaceutical products to millions of the state's citizens on a daily basis. We take very seriously our responsibility to provide Californians the drugs they need to prevent and treat diseases and illnesses. We share your belief that protecting the integrity of the pharmaceutical supply chain is essential. Accordingly, hospitals have implemented and are regularly updating policies and procedures to achieve that goal.

We are committed to protecting our patients. However, it will not be possible for all hospitals to implement electronic technologies to receive the pharmaceutical products, as described, at the serialized individual unit level by January 1, 2009. Hospital pharmacies cannot begin to plan, much less implement, a process until the tracking system, beginning at the manufacturers and through the chain, can be described in detail. Once this process is established, it will take several months for hospitals to create their own system to receive the products. Accordingly, we respectfully request the Board of Pharmacy exercise its authority pursuant to Section 4163.5 of the Business and Professions Code to extend the date for compliance with the electronic pedigree requirements.

It is apparent progress is being made. However, failure to extend the deadline would place patient safety at risk by jeopardizing access to medicines for millions of Californians who depend on prescription drugs to enhance quality and length of life. The risk of denying these patients access to their medicines far outweighs any risks that may exist in the current system.

Thank you for your consideration. We are closely monitoring your work and will encourage hospitals to prepare once the requirements are known.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dorel Harms".

Dorel Harms  
Senior Vice President, Clinical Services  
California Hospital Association

DH:lw







Catalent Pharma Solutions  
14 Schoolhouse Road  
Somerset, NJ 08873  
T (732) 537 6200  
F (732) 537 6480  
www.catalent.com

STATE BOARD OF PHARMACY  
2008 JAN -9 AM 11:14

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

**From:** Renard Jackson, Executive Vice President and General Manager  
Catalent Pharma Solutions, Packaging Services.

**Date:** January 8, 2008

**Subject:** Support for California ePedigree Legislation and readiness assessment of US pharmaceutical contract packagers ability to comply with Jan 1, 2009 implementation deadline

**Submitted by:**  
Akan Oton, Global Marketing Director, Catalent Pharma Solutions, Packaging Services  
(on behalf of Renard Jackson)

**Background:**  
Manufacturers of Branded and Generic Pharmaceutical companies frequently utilize contract packaging organizations to supplement their internal manufacturing capability or as a permanent outsource solution. According to third party market research<sup>1</sup>, contract packaging accounts for approximately 8% of the drug sales in the United States. The contract packaging industry is also highly concentrated, with three contract packaging organizations (Catalent Pharma Solutions, Amerisource Bergen, Sharp Container Corporation) accounting for over 60% of production. With steady growth, in excess of 6% annually, this vital segment of the pharmaceutical supply chain and its technical readiness is critical to the successful implementation of ePedigree.

**Catalent's Position:**  
As the largest contract packager of pharmaceutical drugs in the United States, on a sales basis, Catalent Pharma Solutions is confident that there is sufficient maturity in the underlying technologies (track & trace) to enable ePedigree, as well as sufficient resources to assist pharmaceutical manufacturers in their drive for compliance by January 2009.

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<sup>1</sup> Freedonia Research Group: March 2004 US Pharmaceutical Packaging Market Report, 2006 World Pharmaceutical Packaging Market Report

It is Catalent's belief that although implementation will not be seamless and there is the potential risk of supply disruptions, shifting the implementation deadline to January 2011 will not materially eliminate the risk, but merely postpone it.

**Challenges to Compliance:**

In order to comply with the legislation by January 1, 2009, the following factors must exist:

1. A robust track and trace solution that supports product serialization and e-pedigree.
2. The ability to upgrade and validate new equipment on packaging lines in a timely manner.
3. Commitment from pharmaceutical manufacturers and outsource partners to make the necessary investments.

**Statement on Track & Trace Solution Robustness:**

Catalent Pharma Solutions (formerly Cardinal Health Packaging Services), working with several technology vendors, participated in the first end-to-end track & trace pilot in the pharmaceutical industry. This pilot assessed RFID in production environments at normal packaging line speeds. Catalent then conducted a similar pilot focused on the production environment with a strategic vendor (Secure Symbology, Inc.) utilizing a complementary track and trace technology, Serialized Barcodes.

It is our position, that

- a) Serialized Barcodes are a *cost-effective* and *immediately* implementable solution to enable ePedigree compliance. Serialized Barcode solutions are complementary to RFID and can be supported by the majority of existing equipment in the retail pharmacy environment.
- b) The costs and reliability of RFID, which we expect to be the eventual technology standard, will *sufficiently improve* over the next few years driven by scale and the demands of pharmaceutical manufacturers on vendors to improve.
- c) A shift in the ePedigree compliance deadline will only act to ensure that entry costs into RFID remain high.

**Statement on Timeline to Upgrade and Validate Equipment:**

Based on the experience that Catalent garnered during our end-to-end pilot and our subsequent work with our strategic vendors (Secure Symbology, Inc. and Alien Technology, Inc), we believe that the required time to upgrade a single packaging line is 3 to 4 months. This includes equipment builds, equipment installation and validation, and network integration.

As such, we believe that there is sufficient time for experienced outsourced providers, such as Catalent, to begin the equipment upgrade process in order to support the January 1, 2009 deadline.

## **Statement on Catalent's Commitment to ePedigree and the Role of Contract Packagers:**

Catalent Pharma Solutions believes that securing the pharmaceutical supply chain is a critical and necessary step to ensuring patient safety. We are committed to aiding pharmaceutical manufacturers in their efforts to comply with California's ePedigree legislation.

We also recognize that many pharmaceutical manufacturers have not yet made the technology investments necessary for compliance. As such, we believe that contract packagers will play a prominent role in helping pharmaceutical manufacturers "bridge" their supply chains during this transition period. Additionally, we believe that for drugs manufactured outside of the United States, domestic contract packagers will provide a cost-effective option to facilitate compliance.

### **Recommendations for ePedigree Implementation:**

If the Board of Pharmacy deems that there is sufficient reason to delay implementation of ePedigree beyond the January 1, 2009 date, Catalent recommends that a phased approach be considered.

This approach would attempt to balance the need to protect consumers from drugs that would pose the greatest risk to patient safety if adulterated, with a desire for a relatively easier path for manufacturers and distributors.

#### In Phase 1:

Manufacturers of lifesaving drugs and all New Drug Approvals post January 2009 would need to comply. As sterile/biotechnology drugs are typically lower volume and would undoubtedly employ the more reliable Serialized Barcode technology, starting implementation here would be less complex and allow for the downstream infrastructure to be established.

#### In Phase 2:

Manufacturers of acute and chronic therapies would need to comply. This would involve the highest volume products in the pharmaceutical supply chain, and allow for the costs and reliability of RFID solutions to come in line with the market need.

#### In phase 3:

Manufacturers of so called lifestyle drugs or drugs of convenience would need to comply.

A chart outlining this approach is presented below in figure 1.

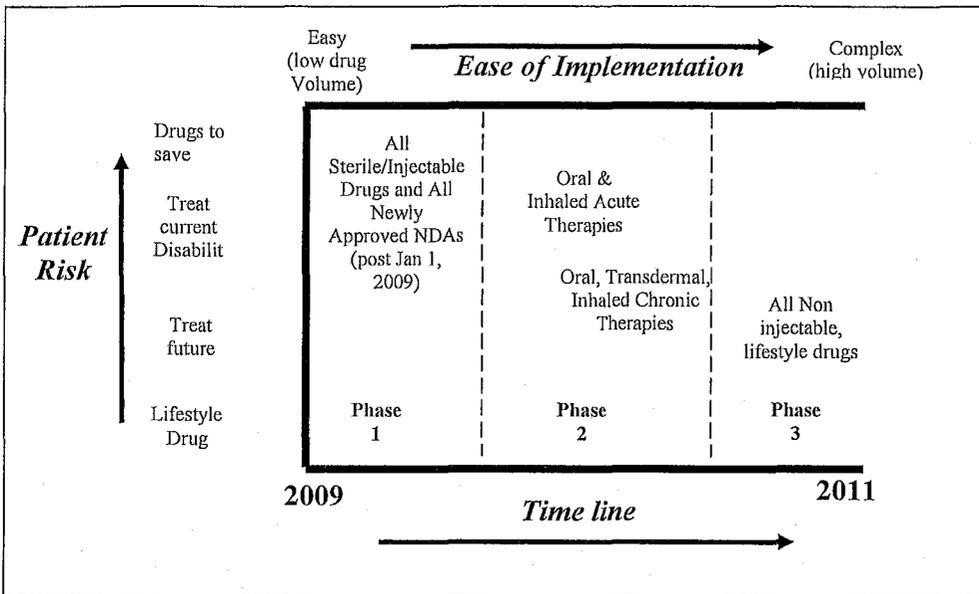


Figure 1: Phased ePedigree Implementation Recommendation

It is Catalent's belief that this approach would achieve the objective of patient safety while allowing technology to evolve and the appropriate investments to be made.

 1/8/08

**Signed (on behalf of Renard Jackson)**

Akan Oton  
Catalent Pharma Solutions

**Contact Information**

Renard Jackson  
Executive Vice-President and General Manager, Packaging Services  
Catalent Pharma Solutions  
3001 Red Lion Road  
Philadelphia, PA 19114  
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Akan Oton  
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January 4, 2008

**Via Overnight Delivery**

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

Re: Comment to Extend the Implementation Date of California ePedigree  
Laws (Bus. & Prof. Code § 4163.5)

Dear Board of Pharmacy:

Centrix Pharmaceuticals, Inc. ("Centrix") urges the California Board of Pharmacy ("Board") to exercise its statutory authority and extend the implementation date of the California ePedigree Laws until January 1, 2011. As explained below, a January 1, 2011 implementation date is necessary to ensure that Centrix has sufficient time to implement and verify electronic technologies required to track the distribution of dangerous drugs within California.

Centrix is a privately held developer and marketer of prescription and non-prescription pharmaceutical products. Centrix plans to market several prescription drugs within California, and will be required to comply with the ePedigree laws when the laws become effective.

At this time, Centrix is not able to meet the January 1, 2009 implementation date, but is confident it will be able to comply with a January 1, 2011 implementation date. Centrix requires the additional two years to develop, test, and ensure that the required electronic technologies are uniform and effective. In accordance with the Board's direction on the submission of comments on the ePedigree laws' implementation date, Centrix provides the Board with the following information the ePedigree requirements.

Without complimentary and uniform ePedigree technologies, Centrix will not be able to comply with the ePedigree requirements. Pursuant to California law, a drug must be tracked from its manufacturer to "its final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug." Ca. Bus. & Prof. Code § 4034(a). In its position as a developer and marketer of prescription drugs, Centrix must ensure that technologies implemented to comply with the ePedigree laws by manufacturers and distributors complement one another.

Therefore, Centrix has contacted its wholesalers and manufacturers to determine the steps they are taking to comply with the ePedigree laws. Centrix has also been working closely with its logistics provider to establish a process for recording, tracking, and certifying product that complies with the ePedigree requirements.

Despite Centrix's efforts, it faces significant barriers to achieve compliance with the ePedigree requirements by January 1, 2009. Centrix believes that technology which provides a truly unique serial number for individual units is required to meet the California ePedigree requirements. However, a technology that allows for the accurate tracking of an individual unit back to the case and pallet does not exist at the present time.

The technology that is closest to meeting the ePedigree requirements is radio frequency identification (RFID). Currently, RFID can be placed on drug labels. However, the accuracy of an RFID label varies from 60% to 95%, making the reliance on such technology problematic. Thus far, industry has deemed RFID to be too unreliable to use.

Another method of tracking that has shown promise is the use of two-dimensional ("2D") barcoding. However, 2D barcoding does not permit individual units of sale to be read during scans of pallets and/or cases. The industry is moving towards using statistical sampling to verify that the products packed in pallets/cases comply with a parent-child 2D label relationship between larger packages and individual units. However, industry has not agreed upon a standard statistical sampling method or the implementation of 2D barcoding for prescription products.

As outlined above, a reliable technology to comply with the ePedigree requirements does not exist. Further, once such a reliable technology is developed, the technology must be standardized to ensure that all participants in a distribution chain are using complimentary technology. Given the significant time and expense required to standardize a reliable electronic pedigree system, complying with a January 1, 2009 compliance date is not feasible.

A compliance date of January 1, 2011 will allow Centrix, its manufacturing partners, and logistics providers to evaluate the methods needed to truly comply with the requirements. The additional two years will allow the industry to either improve the accuracy of RFID labels or develop a feasible alternative that will allow for pallet, case, and individual unit tracking. The additional two years will also allow Centrix, and companies in similar positions, the ability to spread the costs of the implementation over several years rather than just a few months, lessening the required cost burden that would ultimately be passed on to the patient.

Centrix urges the Board to extend the compliance date for California's ePedigree requirements until January 1, 2011 to ensure that the electronic tracking of drug products is reliable. California has determined that the existence of a reliable and comprehensive drug pedigree system is crucial to ensure that dangerous drugs are safe and effective. When the ePedigree requirements become effective, the tracking of prescription drug products within California will solely be based on electronic tracking methods. Because drug distributors and pharmacists will continue to rely on drug pedigree to ensure that a drug is pure and not counterfeit, mistakes in the pedigree system have the potential to compromise the safety of the patients taking such drugs. Before entrusting the public health to such a system, the Board has a duty to ensure that reliable technology exists to implement the ePedigree system.

Based on the foregoing, Centrix urges the Board to exercise its statutory authority and extend the compliance date for California's ePedigree requirements until January 1, 2011. If you have any questions, please do not hesitate to contact me at 205.991.9870 or booth.bob@cenrx.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bob Booth', with a long horizontal flourish extending to the right.

Bob Booth, R.Ph.  
President and CEO



RECEIVED  
STATE BOARD OF PHARMACY  
2009 JAN -9 PM 4:00



January 09, 2008

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

RE: CHI Request for Extension of Implementation Date of California ePedigree Laws  
(Business & Professions Code Section 4163.5)

Dear Sir or Madam:

The California Healthcare Institute (CHI) welcomes this opportunity to submit comments to the California Board of Pharmacy (Board) regarding the implementation of the state's electronic pedigree requirements scheduled to go into effect on January 1, 2009. Business and Professions Code section 4163.5 vest the Board with the authority to extend the date for compliance with these requirements to a new date of January 1, 2011, if the Board "determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state." Based on a survey of our member organizations, it is clear that while some entities may be able to meet the individual requirements needed for implementation, the supply chain as a whole will not be prepared to implement an interoperable system sufficient to safely and efficiently provide patients in California access to the medicines they need by January 1, 2009. Accordingly, CHI respectfully requests that the Board exercise its authority under the law to delay implementation.

California is the worldwide headquarters for biomedical research and development. As the leading biomedical public policy association in California, CHI represents over 260 of the state's premier biotechnology, pharmaceutical, medical device and diagnostics companies, as well as the leading academic and non-profit research institutions. Our membership represents the broad spectrum of the industry through all stages of the product development pipeline. Forty-two percent of CHI's member companies currently have products on the market, ranging from inhaled and infused biologics, injectables, vaccines, implantable medical devices, diagnostic testing equipment, and traditional prescription drugs.

CHI's mission is to advocate policies that promote medical innovation, access to the best medicines and therapies, and promote the health and well being of patients. CHI strongly supports the Board's goal of protecting the citizens of California from the threat of counterfeit drugs. Our members are committed to providing patients access to safe and effective therapies and have implemented and continue to update policies and procedures to achieve that goal. We are, however, concerned that premature implementation of an electronic pedigree system may disrupt the supply chain, jeopardizing patients' access to the medicines they need. This risk far outweighs any risks that exist in the current system. We remain committed to working with the

**WWW.CHI.ORG**

**HEADQUARTERS** 1020 Prospect Street, Suite 310 • La Jolla, CA 92037 • 858.551.6677 • Fax 858.551.6688

**SACRAMENTO** 1215 K Street, Suite 970 • Sacramento, CA 95814 • 916.233.3497 Fax 916.233.3498

**WASHINGTON, D.C.** 1608 Rhode Island Avenue, NW • Washington, D.C. 20036 • 202.974.6313 Fax 202.974.6330

Board and other stakeholders to address current challenges to meet the goal of a safe and efficient supply chain.

The changes that manufacturers must put into practice to comply with the requirements of the law are extensive. Creating and implementing a system to track all individual units of products moving through the supply chain is an enormous undertaking for companies of all sizes. Changes to current business practices will affect manufacturing facilities, packaging lines, and distribution centers, as well as operations of third-party partners and logistic providers. With so many business components directly affected by electronic pedigree requirements, great care and deliberation must be taken in order to ensure that a secure and effective system is put in place – a system that functions smoothly, with minimum disruption.

In preparation for the most recent Board Enforcement Committee meeting on December 5, 2007, CHI in conjunction with the Biotechnology Industry Organization (BIO) conducted a survey of our memberships to address the Board's request for more information from industry on current activities and the challenges to meeting the requirements of the law. The results of this survey were presented to the Enforcement Committee on December 5 and have been submitted into the public record. From the results of the survey it is clear that CHI's members are working diligently towards implementation. A small percentage of respondents have or are currently running track-and-trace pilots with outside parties on all or a limited number of product lines, but the majority today remain in the planning phases. They are working internally and with service providers, testing various technology applications on their product lines to gain a better understanding of what suits their particular businesses and products. Two-thirds of those surveyed expect to begin outside pilots with other members of the supply chain within the next year. Survey respondents voiced specific reasons for delaying pilot tracking systems.

### **Technology Concerns**

The major issue to be resolved prior to widespread adoption is industry consensus on an appropriate interoperable technology platform. At present, there are no agreed upon standards for electronic pedigree. Companies are testing a variety of technologies, including RFID (high and ultra-high frequency), 2-D barcodes and others. Absent agreement on standards that will provide interoperability, there is no way to ensure a safe and effective drug supply chain. By placing tags or barcodes on products, an individual company may be technically compliant under the law. But this serves little purpose if downstream partners are unable to read them.

Lack of a uniform technology standard has the potential to cause significant disruption to the supply chain. If required to meet the January 1, 2009 implementation deadline, a company has limited options. In order to sell their product in the state a company will have to choose and then implement a specific technology. With no agreed upon standard there will be a variety of platforms put forth in the beginning. Over time one technology standard is sure to rise above the others. This puts companies in a very difficult situation. Some companies will be fortunate enough to be able to overcome the lost investment of millions of dollars, however, there is the very real possibility that companies working on slimmer margins will be forced out of business. As a last resort, companies may have to make a business decision to pull their products from the California market until they have a clearer idea of which technology to invest in. Either way, pushing forward without an agreed upon standard is sure to hurt California's patients by limiting their access to the medicines they require.

### **Reliance on Third Parties**

Solution Providers – With the January 1, 2009 deadline looming there is no feasible way for technology suppliers, even if a technology standard is developed, to provide all members of the supply chain with the hardware, software, and support necessary to implement an effective system. Smaller companies are concerned that, under time pressure, suppliers would overlook them in favor of larger customers.

Business Partners – In addition to activities and processes performed in-house, the majority of our members rely on third party manufacturers, packagers, labelers and carton suppliers to move products into distribution. In our survey results there was significant concern regarding these third parties' ability to comply and move product into the marketplace. Even if these business partners can become compliant, there was significant concern on the part of smaller companies about their needs being met.

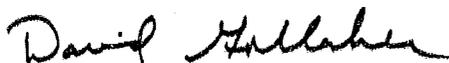
### **Production Issues**

The manufacturing and production of medicines is a complex and carefully monitored process. Implementation of the law will effectively require all manufacturers to redesign and reconfigure current manufacturing and packaging lines. These processes are regulated by the Food and Drug Administration (FDA) and will require validation under the agency's Good Manufacturing Practices (GMP) requirements. Any change in manufacturing processes may invalidate a company's GMP certification. The result of this would be a disruption of manufacturing that would reduce or eliminate the supplies of medicines for patients. In addition, there is a lack of surplus packaging capacity required to ensure a continuous supply of product while the packaging lines are being reconfigured. This will be even more prevalent as all entities in the state attempt to meet a single deadline.

The biomedical industry in California is committed to improving lives and protecting patients by providing access to safe and effective therapies. The passage of the state's electronic pedigree law will build upon current safeguards established by the FDA and upheld by manufacturers and distributors that provide patients with the confidence that their supply chain is the safest in the world. While we fully support the Board's goal of protecting the integrity of the supply chain, we strongly believe that moving forward with the January 1, 2009 implementation date will jeopardize access to medicines for millions of Californians. In consequence, CHI respectfully requests that the Board exercise its authority to extend the date for compliance.

Thank you for the consideration of this request and we look forward to continuing our work with you to protect the citizens of California. Please do not hesitate to contact us if we may be of any assistance to you.

Sincerely,



David L. Gollaher, Ph.D.  
President & CEO  
California Healthcare Institute





STATE BOARD OF PHARMACY

2000 JAN -8 AM 11:56

January 7, 2008

**Via Overnight Delivery**

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

Re: Comment to Extend the Implementation Date of California ePedigree  
Laws (Bus. & Prof. Code § 4163.5)

Dear Board of Pharmacy:

Creekwood Pharmaceutical, Inc. ("Creekwood") urges the California Board of Pharmacy ("Board") to exercise its statutory authority and extend the implementation date of the California ePedigree Laws until January 1, 2011. As explained below, a January 1, 2011 implementation date is necessary to ensure that Creekwood has sufficient time to implement and verify electronic technologies required to track the distribution of dangerous drugs within California.

Creekwood is a privately held developer and marketer of prescription and non-prescription pharmaceutical products. Creekwood plans to market several prescription drugs within California, and will be required to comply with the ePedigree laws when the laws become effective.

At this time, Creekwood is not able to meet the January 1, 2009 implementation date, but is confident it will be able to comply with a January 1, 2011 implementation date. Creekwood requires the additional two years to develop, test, and ensure that the required electronic technologies are uniform and effective. In accordance with the Board's direction on the submission of comments on the ePedigree laws' implementation date, Creekwood provides the Board with the following information the ePedigree requirements.

Without complimentary and uniform ePedigree technologies, Creekwood will not be able to comply with the ePedigree requirements. Pursuant to California law, a drug must be tracked from its manufacturer to "its final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug." Ca. Bus. & Prof. Code § 4034(a). In its position as a developer and marketer of prescription drugs, Creekwood must ensure that technologies implemented to comply with the ePedigree laws by manufacturers and distributors complement one another.

Therefore, Creekwood has contacted its wholesalers and manufacturers to determine the steps they are taking to comply with the ePedigree laws.

Creekwood has also been working closely with its logistics provider to establish a process for recording, tracking, and certifying product that complies with the ePedigree requirements.

Despite Creekwood's efforts, it faces significant barriers to achieve compliance with the ePedigree requirements by January 1, 2009. Creekwood believes that technology which provides a truly unique serial number for individual units is required to meet the California ePedigree requirements. However, a technology that allows for the accurate tracking of an individual unit back to the case and pallet does not exist at the present time.

The technology that is closest to meeting the ePedigree requirements is radio frequency identification (RFID). Currently, RFID can be placed on drug labels. However, the accuracy of an RFID label varies from 60% to 95%, making the reliance on such technology problematic. Thus far, industry has deemed RFID to be too unreliable to use.

Another method of tracking that has shown promise is the use of two-dimensional ("2D") barcoding. However, 2D barcoding does not permit individual units of sale to be read during scans of pallets and/or cases. The industry is moving towards using statistical sampling to verify that the products packed in pallets/cases comply with a parent-child 2D label relationship between larger packages and individual units. However, industry has not agreed upon a standard statistical sampling method or the implementation of 2D barcoding for prescription products.

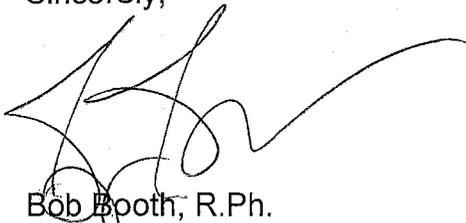
As outlined above, a reliable technology to comply with the ePedigree requirements does not exist. Further, once such a reliable technology is developed, the technology must be standardized to ensure that all participants in a distribution chain are using complimentary technology. Given the significant time and expense required to standardize a reliable electronic pedigree system, complying with a January 1, 2009 compliance date is not feasible.

A compliance date of January 1, 2011 will allow Creekwood, its manufacturing partners, and logistics providers to evaluate the methods needed to truly comply with the requirements. The additional two years will allow the industry to either improve the accuracy of RFID labels or develop a feasible alternative that will allow for pallet, case, and individual unit tracking. The additional two years will also allow Creekwood, and companies in similar positions, the ability to spread the costs of the implementation over several years rather than just a few months, lessening the required cost burden that would ultimately be passed on to the patient.

Creekwood urges the Board to extend the compliance date for California's ePedigree requirements until January 1, 2011 to ensure that the electronic tracking of drug products is reliable. California has determined that the existence of a reliable and comprehensive drug pedigree system is crucial to ensure that dangerous drugs are safe and effective. When the ePedigree requirements become effective, the tracking of prescription drug products within California will solely be based on electronic tracking methods. Because drug distributors and pharmacists will continue to rely on drug pedigree to ensure that a drug is pure and not counterfeit, mistakes in the pedigree system have the potential to compromise the safety of the patients taking such drugs. Before entrusting the public health to such a system, the Board has a duty to ensure that reliable technology exists to implement the ePedigree system.

Based on the foregoing, Creekwood urges the Board to exercise its statutory authority and extend the compliance date for California's ePedigree requirements until January 1, 2011. If you have any questions, please do not hesitate to contact me at 205.995.7390 or [bbooth@creekwoodpharma.com](mailto:bbooth@creekwoodpharma.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'Bob Booth', with a long, sweeping horizontal line extending to the right.

Bob Booth, R.Ph.  
President and CEO





January 11, 2008

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

Re: Implementation Submission

Issue/Topic

E-Pedigree and Serialization

Submitted by

EMD Serono, Inc.

Background

EMD Serono is taking an active role in ensuring the safety and integrity of our products. Our primary focus is to protect our patients from unauthentic products.

In 2002, EMD Serono implemented a secured distribution model including a track and trace program for Serostim<sup>®</sup>, a recombinant human growth hormone indicated for the treatment of HIV associated wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Shipments of Serostim<sup>®</sup> 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<sup>®</sup> tracking program is an effective solution.

Since the CA Board of Pharmacy proposed the ePedigree and serialization legislation in 2004, EMD Serono has been actively working with all parties necessary to implement an effective solution to comply with the law effective January 1, 2009. A global project team includes the following: Supply Chain, IT, Packaging, Manufacturing, Quality Assurance, Regulatory Affairs, Government Affairs, Legal and Procurement. The team has been very productive in providing solutions and decision-making, and implementing a clear plan with action dates to ensure compliance with the law. The goal is to have unit level serialized product available by January 1,

EMD Serono, Inc.  
One Technology Place  
Rockland, MA 02370

Phone 800-283-8088  
Fax 781-681-2923  
www.emdserono.com



2009. EMD Serono has also been actively working with third party vendors to develop, design, and implement an effective ePedigree solution in 2008.

EMD Serono applauds the efforts by the FDA 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 medicines will reach patients for whom they are intended. To assure our products remain safe and effective throughout the supply chain, EMD Serono remains committed to assessing, testing and incorporating potential new technological advances in product tracking and distribution as they become available and are practical.

#### Challenges

EMD Serono has clear timelines and is moving forward aggressively to meet these timelines. The major challenge is having a sound, widely adopted system and a standard in place to track the serial number events. To that end, we have had contact with our key customers to understand and incorporate their needs into our planning process.

Our goal is to begin shipping serialized product in 2009. However, our warehouse and customers may still have non-serialized product on hand and non-serialized product will need to be distributed and dispensed to ensure adequate supply of product. As a result, EMD Serono will face the challenge of managing this "grandfathered inventory" to ensure compliance with California law.

#### Cost of Implementation

EMD Serono's estimated cost analysis is as follows:

Packaging/ IT Solution for Serial number Tracking/ ePedigree Solution

Initial cost – \$2,200,000

Ongoing cost - TBD



Desired solution

We are requesting guidance from the Board on the following items:

- Flexibility on "grandfathered inventory" and sufficient time to deplete non-serialized product in the pipeline.
- Additional time to complete serialization at the item level for low volume products with high inventory levels.

Contact Information and Date

Richard Feldman  
Vice President, Trade and Strategic Projects  
781-681-2838

January 11, 2008





RECEIVED BY CALIF.  
BOARD OF PHARMACY

2008 JAN -9 PM 4:19

VIA COURIER

January 8, 2008

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

**Re: Request for Delay of Implementation Date of California e-Pedigree Laws**

Ladies and Gentlemen:

Ferndale Laboratories, Inc. ("Ferndale") submits this request for a delay in the January 1, 2009 effective date of California's electronic pedigree requirements based on our determination that we cannot possibly meet this date.

Ferndale is a small pharmaceutical manufacturer of prescription and non-prescription semi-solids and qualifies as a "small business" as that term is defined by the U.S. Small Business Administration. Our core products (creams, ointments, lotions and gels) are produced in batch operations. The filling of primary containers (tubes, bottles) is performed separately from secondary packaging (carton) and distribution packaging (shipper) activities. This batch production method does not facilitate the tracking of individual primary units (tubes) in sequence from beginning to end of our process. Therefore, the secondary/distribution packaging components are not capable of receiving a serial number matching that of the primary container. The parent-child relationships cannot be established. This prevents data visibility at the different levels of packaging which also prevents data use for members of the distribution chain.

To obtain such capability would require change to a continuous method of manufacture. Because much of our current operations are semi-automatic or manual activities, replacement of our tube filling, cartoning, and labeling equipment is required. Modification and integration of our current equipment could cost more than the current value of the equipment itself. However, there is a concern with making such large capital investments prior to the establishment of standards and commitment to widespread adoption of technology that has yet to prove reliability in the global market place.

Despite the pilot trials that have occurred with RFID, the literature reviewed indicates some short-comings with performance around metals and liquids. Many of our products are semi-solids packaged in metal collapsible tubes. Extensive testing for each of our product/tube combinations, under multiple circumstances, would be required to determine RFID viability for our products. This is a costly resource-consuming activity for a company of our size.

2D Matrix codes are subject to the limitations associated with line-of-sight scanning. If efforts are to be invested in 2D Matrix capability, we must know the specific data to be

put into the code. Will this be only the NDC number and a serial number? Or, is it to be the company name, address, license number, NDC number, GTIN number, product name, dosage form, strength, container size, lot number, expiration date, serial number etc? Much of this information may be useful for multiple business reasons. Is the established "Interoperable Electronic System" capable of handling all of this information, for all companies, for all products, for all units? That is a world of information to share, store, and secure.

In 2005, Ferndale initiated a project to obtain continuous production capacity. This investment is nearly two million dollars and requires the resources from every part of the company. However, the benefits of this investment will serve only a portion of our business. It involves the following activities:

- Identification of needs
- Specification of requirements
- Survey and investigation of available equipment and technological capabilities
- Selection and design of appropriate equipment
- Capital planning, appropriations, and expenditures
- Construction, delivery, installation, training, validation, and implementation of equipment
- Revision of operational methods and procedures
- Associated documentation

The primary equipment manufacturer for this project is a large, well-known, reputable, global company. Ferndale is their first customer to inquire about serialization capability on their collapsible tube fillers. Therefore, the equipment manufacturer must initiate design work to determine the method of achieving reliable serialization capability. This one capability will significantly increase costs and delay the delivery of the equipment. The earliest this equipment may be operational is the fourth quarter of 2008, and again, it will only serve a portion of our business.

The manufacturer of our existing distribution label printing equipment is a global leader. They offer print and apply equipment with RFID capability. However, this vendor does not currently offer equipment that can acquire, process, and print serial numbers for parent-child relationships without significant manual intervention. This would slow our production rates down to that of a manual activity and increase costs. Identification of appropriate labeling equipment involves the steps listed above.

While the technology exists to apply a serial number to an individual product unit, it cannot do so reliably, efficiently and cost-effectively in a rigorously controlled pharmaceutical manufacturing environment at this time. Accordingly, we urge you to delay imple-

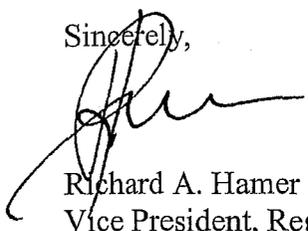
California State Board of Pharmacy

January 8, 2009

Page Three

mentation of the e-pedigree requirement until such time as a consensus emerges on a national standard and the technology necessary to implement it becomes more widely available. In the interim, the California public may be adequately protected by means of paper pedigrees and similar controls used in other states, particularly in the case of semi-solid products such as Ferndale's which present a very low potential for counterfeiting or diversion.

Sincerely,



Richard A. Hamer  
Vice President, Regulatory/Clinical Affairs  
and Quality Assurance





# GILEAD

Advancing Therapeutics.  
Improving Lives.

REGISTRATION UNIT  
BOARD OF PHARMACY

2008 JAN 10 PM 1:12

January 9, 2008

Virginia Herold  
Executive Officer  
California State Board of Pharmacy  
1625 N. Market Blvd., Suite N-219  
Sacramento CA 95834-1924

Dear Ms. Herold:

On behalf of Gilead Sciences, Inc. (Gilead), please accept this submission requesting that the Board of Pharmacy (Board) extend the implementation date of California's electronic pedigree requirements from January 1, 2009 to January 1, 2011, consistent with the authority granted under Business and Professions Code Section 4163.5.

**Gilead shares the Board's commitment to consumer protection and ensuring the safety and integrity of the supply chain and intends to fully comply with the California law. However, for reasons that we will articulate further in this letter, we believe that an extension of the implementation date is justified to implement necessary electronic technologies and that this delay would enhance, and not detract from, the safety and protection of the California public.**

#### **Gilead Overview**

Founded in 1987, Gilead Sciences, Inc. is a California-based, biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need with the goal of improving the care of patients suffering from life-threatening illness. Headquartered in Foster City, we employ over 3000 people and have operations on three continents. Our primary areas of focus include antivirals, such as HIV/AIDS and chronic hepatitis, cardiovascular conditions, such as pulmonary arterial hypertension and resistant hypertension, and respiratory disease, such as influenza and cystic fibrosis. Gilead has 11 marketed products which include a number of category firsts and market leaders such as Atripla® - the first single tablet regimen for HIV infection approved by the U.S. Food and Drug Administration in 2006. Gilead continues to focus its resources on research and development of new life-saving therapies while also undertaking a number of initiatives to further expand access to our medicines.

#### **Gilead's Implementation Efforts**

The Board has requested information about what steps Gilead has taken to date in order to implement the California electronic pedigree law. The primary focus of our efforts has been to identify all of the business practices within Gilead that will be impacted, and thus need to be modified, in order to establish an electronic pedigree at the unit level. To ensure that our analysis is comprehensive, we have established a multi-disciplinary team that meets regularly to develop our internal implementation plan. This team includes representatives from the manufacturing, quality control, materials management, customer service, logistics, and information technology divisions.

Additionally, we retained outside legal counsel with expertise in California's pedigree law to provide us with advice to ensure that we are fully compliant with the provisions of the law.



# GILEAD

Advancing Therapeutics.  
Improving Lives.

Virginia Herold  
California State Board of Pharmacy  
Page 2

We have actively engaged in discussions with our industry partners (including wholesalers and manufacturing partners) to identify both opportunities to work collaboratively and identify those implementation areas that represent challenges. In addition, we have met with four different technology vendors to explore the options available to us and the steps required to implement the technologies in order to comply with the law. Further, Gilead staff has attended meetings of the Board's Enforcement Committee as well as the conference hosted by HDMA, all with the goal of ensuring a complete understanding of the law and working towards compliance. We continue to reach out to our contract manufacturers, both to ensure that they are aware of the law's requirements and to discuss ways to collaboratively implement those requirements.

We are in the process of selecting a technology vendor who will be able to ensure that our technology is interoperable within the supply chain and our downstream partners. Our current plan is to implement the pedigree using a 2-D barcode, relying heavily upon inference as a means of efficient and secure compliance.

While we believe that we can meet the 2009 implementation date our efforts may be far less than optimal. To comply by January 1, 2009 will force Gilead to very quickly make choices for systems that may not be compatible with our downstream partners and could put these partners at risk. It is also important to note that while we intend to comply by January 1, 2009, it is unlikely we will be in compliance prior to such date. As such, there will be little or no time for our downstream partners to integrate newly acquired Gilead products into their systems or use up existing non-pedigreed inventory. **By affording us with the additional time for implementation, it is our sincere belief that our electronic pedigree will be better tested and more "user friendly" to our partners, which as a result, will better serve to protect the California public.**

## **Obstacles to Compliance by 2009**

### Inference:

We understand that the Board will be clarifying the definition and parameters surrounding the use of inference either via a rulemaking procedure or legislation. This issue is of paramount importance to us as it will impact our ability to successfully pedigree our products. As such, we look forward to engaging the Board in a dialogue on this topic.

### Grandfathering:

Within the universe of products that Gilead manufactures, some of our products have high utilization, and thus are manufactured frequently and in relatively high volume. Because of the frequency of manufacturing, we are able to apply a pedigree to those products in advance of the deadline. However, given that our products are for those suffering from life-threatening illness, in order to ensure continuity of distribution to the public, we carry high levels of inventory for these products, typically 3 – 4 months worth, contributing to the difficulty of introducing pedigreed product prior to the deadline. We also manufacture products that have much lower utilization and are manufactured as infrequently as once a year. We are struggling the development of our internal implementation plan for these low utilization products. Without any flexibility in the law about how we might be able to grandfather in our existing stock of products,



# GILEAD

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California State Board of Pharmacy  
Page 3

we fear that we will be faced with a host of unfavorable scenarios and approaches from which we will have to choose.

It is important to note that this is not something we see as an ongoing issue. Once we have dealt with all of our outstanding stock and have implemented our electronic technologies, a pedigree will be included on every product that is manufactured. Thus, to protect the integrity of the law, we encourage you to consider a temporary model under which we would be able to certify to the Board the specific amount of these products that we have in stock and move those through the supply chain without pedigree until that supply is exhausted. We believe that it is important to create a mechanism for non-pedigreed products to be grandfathered into the distribution chain but that a delicate balance must be struck to ensure that this mechanism does not unintentionally create a means for some to avoid the pedigree requirement altogether. It is our understanding that the Board has been considering this issue and will be pursuing some clarification, either via a rulemaking procedure or legislation, similar to the approach you will be taking on the issue of inference. This is a key clarification for us and again we look forward to engaging with you as you commence this process.

#### Systems Redundancy:

Within Gilead, manufacturing occurs at more than one physical location. It is our standard practice to have systems redundancy in place across these locations, both for purposes of business continuity and disaster preparedness. As part of our implementation plan, we are working to ensure that we have the capacity to apply a pedigree at each of these locations. Should a disaster occur that forces us to shut down one of our manufacturing locations without the capacity at other locations to perform the pedigree function, our distribution would be severely disrupted placing the California consumers who rely upon our products at risk. However, [given the time required to implement the necessary electronic technologies,], we have determined that only one manufacturing site would be able to deliver pedigreed product by January 1, 2009. While we will work diligently to bring other sites online as quickly as possible, it will take at least another year to complete this upgrade. Until there is at least one more site online there will be significant risk to our distribution channel which could adversely affect the public who rely on our products as noted above. This is an obstacle that we think can be remedied by the Board granting an extension.

#### Specialty Pharmacies:

Because of the nature of certain of our products, we have contracted with a variety of specialty pharmacies to provide exclusive distribution of such products. We anticipate that these contracting relationships will become even more prevalent with the approval of a number of new products that are currently being reviewed by the FDA. We are assessing the capabilities of our specialty pharmacy partners to comply with the pedigree law and to better understand how our contracting relationships fit within the structure contemplated by the existing law. At this time, we are not sure what issues will emerge in this arena but anticipate that resolving any issues will be critical to our ability to successfully implement the pedigree requirement. We are happy to share the outcome of these discussions with the Board staff as more information becomes available.



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California State Board of Pharmacy  
Page 4

## Consumer Protection

Gilead is best known for its innovation in HIV/AIDS therapies. Based upon years of research and development, we now manufacture best in class products which have dramatically improved the quality of life for persons living with HIV/AIDS. These products include:

- Atripla®, the first and only once-daily single tablet regimen for the treatment of HIV infection in adults.
- Truvada®, a fixed-dose once-daily combination pill containing Viread® and Emtriva®, which is used in combination with other antiretroviral agents for the treatment of HIV infection in adults.
- Viread® is an oral formulation of a nucleotide analogue reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in adults.
- Emtriva® is an oral formulation of a nucleoside analogue reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in adults.

The development of drug resistance is the leading cause of HIV treatment failure. The success of these therapies is dependent upon strict adherence to the treatment regimen. Disruption in the treatment regimen can literally be life-threatening. Thus, from Gilead's perspective, it is absolutely critical that distribution of these products be completely secure and flawless. With the additional two years to implement the pedigree, we will have had the opportunity to fully integrate our pedigree implementation into our manufacturing and distribution systems, reducing the risk of supply disruption to consumers. Gilead believes that the Board's obligation to protect the public is best served by extending the implementation date to January 1, 2011. We support the goal of securing the supply chain. However, we believe that to implement these requirements before all of the interoperable systems are in place puts consumers at great risk of not being able to access products that they depend upon.

## Conclusion

Our ability to successfully deliver our products to consumers is contingent upon many diverse relationships with our downstream trading partners. The ability of a consumer to take one of our life-saving products every day depends upon our ability to manufacture that product, to distribute it to a wholesaler, to work in concert with a contract manufacturer in some instances, and for a pharmacist or other authorized dispenser to counsel and dispense the product to that consumer. Consumers depend upon us to ensure that all of these relationships work seamlessly. We believe that the additional time will enable us to ensure that these relationships continue to function in the patient's interest, even with the introduction of the extensive measures needed to implement an electronic pedigree serialized at the unit level.

We believe that should the Board exercise its authority to extend the implementation date from 2009 to 2011, it will enable us to ensure that our systems are comprehensive, efficient, secure and interoperable with our business partners. We will have incorporated the application of a pedigree into our high speed manufacturing processes at all of our manufacturing plants. These additional two years will also provide an opportunity for a more cogent application of the forthcoming clarification on the use of inference and grandfathering of product into our



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California State Board of Pharmacy  
Page 5

implementation process. Further, an extension will allow us more time to collaborate with our business partners to make sure that the supply stream is not disrupted by the challenges our partners may face in implementation, even if Gilead is ready to initiate the pedigree at the point of manufacture. Accordingly, we respectfully request the Board to exercise its authority to extend the January 1, 2009 implementation date to January 1, 2011.

Notwithstanding Gilead's ability to comply with California's electronic pedigree law, we do not want to diminish the challenges that are faced by other members of the supply chain. We do not intend to speak for the industry as a whole or to assume their challenges can be addressed on the same time line.

Thank you for the opportunity to share our implementation efforts and challenges with you. Should you have any questions about our position, please contact Kacy Hutchison at (650) 522-1831.

Sincerely,

Tony Caracciolo  
Senior Vice President, Manufacturing and Operations  
Gilead Sciences Inc.

cc: Carrie Lopez, Director, Department of Consumer Affairs  
Scott Reid, Chief Deputy Director, Department of Consumer Affairs





GENERIC PHARMACEUTICAL ASSOCIATION

January 9, 2008

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

To the California State Board of Pharmacy:

The Generic Pharmaceutical Association (GPhA) applauds the California Board of Pharmacy's dedication to its mission to protect public health. GPhA deeply shares the Board's concern that the dispensing of counterfeit medicine poses a serious threat to the safety of patients and consumers. Protecting patient safety is always paramount for GPhA and its members. Thus, GPhA has joined efforts at the state, federal and international level to address and help solve the problem of counterfeit and substandard medicine. GPhA hopes that through supporting anti-counterfeiting initiatives the incidence of counterfeit medicines in the supply chain, domestically and world-wide, will be eliminated or dramatically reduced.

To this end, GPhA strongly supports the underlying intent of California's drug pedigree legislation to maintain patient safety. In harmony with that goal, GPhA's members have been working to find a feasible method of making serialized pedigree an operational reality. In an overall effort to reduce counterfeiting, GPhA's members have already committed and continue to dedicate a great deal of resources to evaluate anti-counterfeiting measures for their actual benefit to patients, and the corresponding costs. To date, GPhA's members have conducted numerous individual analyses and pilot studies to determine how the requirements in California's statute will be implemented on a practical level. Studies that are ongoing and those initiated recently include a focus on interoperability among the various trading partners within the supply chain. By these efforts, the generic industry and its trading partners have gained significant knowledge and made progress toward a fuller understanding of what it will take to accomplish the specific California initiative. Yet, significant obstacles remain that will need resolution before all stakeholders in the supply chain can coalesce around one solution.

### **Section I: Formal Request for Extension**

GPhA previously stated in its December 5, 2007, presentation that meeting the drug pedigree and serialization requirements by January 1, 2009, is extremely problematic for the vast majority of the generic pharmaceutical industry. Establishing an industry-wide interoperable system to electronically track and trace billions of uniquely serialized individual packages within a production system as sensitive and pervasively regulated by the federal government as



GENERIC PHARMACEUTICAL ASSOCIATION

pharmaceutical manufacturing requires a great deal more time and resources than contemplated by the January 1, 2009, compliance date. Accordingly, on behalf of the generic pharmaceutical industry, GPhA respectfully reiterates its request for an extension of the deadline for implementation of California's drug pedigree requirements.

The discussion set forth below responds to the "Implementation Readiness" template provided on the California Board of Pharmacy's website and briefly explains existing sector and industry challenges.

## **Section II: Response to California Board of Pharmacy Template**

*"a. A specific demonstration of all efforts expended thus far by the requesting party or parties, including timelines or specifications showing date(s) on which such efforts began and progress thus far, methods employed, costs and employee hours expended, and similar data, as well as a detailed demonstration of specific barriers or obstacles to compliance by January 1, 2009, including timeline(s) and specification of efforts between date of submission and January 1, 2009, any partial compliance to be achieved, etc."*

### **Efforts To Meet Requirements:**

In response to the Board's request for very specific data illustrating industry's efforts to comply with California's pedigree requirements by January, 2009, GPhA is working diligently to complete a survey of its members to secure that data and develop it into a form that can be shared with the Board. In an extremely competitive environment such as the generic pharmaceutical industry, proprietary information collected from pilot studies is very sensitive and generic manufacturers are concerned with how such information may be used, potentially by competitors, to gain an advantage. Thus, with regard to providing specific information on the pilots, methods employed, costs and employee hours expended and other details, GPhA is currently working with independent consultants through a confidentiality arrangement in order to acquire, anonymize, and aggregate such data from member companies. While individual companies are free to provide the Board with their specific information, GPhA fully intends to share industry aggregate information with the Board of Pharmacy regularly as the data analysis develops. GPhA anticipates that data acquired from these efforts will be ready within 30 days.

GPhA can confirm now, based on data collection efforts thus far, that many of its members have completed or are currently conducting drug pedigree and/or serialization pilots. Pilots have varied widely in design, size, scope, duration and result. However, according to an analysis of data submitted in confidence to GPhA's consultant, the results gathered from these pilots uniformly demonstrate that serialization of individual packages and the capability to electronically track and trace each change in ownership of a product throughout the entire supply



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chain will require years, not months, to achieve. For the interests of all stakeholders in the supply chain—from manufacturer to patient—it is important for anti-counterfeiting technology to be widely available, reasonably priced, specifically adapted by vendors to meet anti-counterfeiting guidelines and compatible with pharmaceutical packaging materials and designs. Moreover, given the unique role of the generic industry in providing access to affordable medicine, it is particularly important to the public that adoption of anti-counterfeiting measures be well-tested, interoperable, efficient and not needlessly raise the cost of medicine without a proven corresponding benefit to patient safety.

Generic manufacturers have exerted considerable effort thus far in gaining understanding of how an interoperable electronic serialized pedigree system could work effectively. Over the past few years, generic manufacturers have been selecting and implementing solutions for e-pedigrees. A number of GPhA members have supplied Wal-Mart with package-level serialized products for a subset of SKUs, and companies have developed pilots with contract manufacturers, distributors, and large retailers. Further, companies have conducted studies to determine the best RFID tags available for specific applications and other studies to determine optimal placement for RFID tags. Many companies have solicited proposals for implementing packaging line and other hardware modifications, middleware, and internal or external data centers. In addition companies are working with vendors to convert existing serialization systems and data structures from lot-level to item-level serialization and are working with consultants to determine the best approaches to supplying serialized products.

The challenge of implementing large-scale unit serialization of all products in an interoperable system across the supply chain is an enormous and complex task; and as such, will require further study. Making certain that this task is accomplished without causing disruptions to the public's access to a reliable supply of affordable medicine requires further investigation and complete and comprehensive assessments—assessments that are underway, but need more time to ensure they are carried out in the thorough manner that protecting the public's health demands. Granting additional time for pilot studies to progress and surveys to be completed will provide the industry needed time to ensure that standards are adequate and will allow the smoothest possible implementation of a safe, efficient and practical system to be developed and will provide the industry time to ensure that standards are adequate. Indeed, a delay will help to minimize the impact of costs to consumers and the healthcare system as companies are able to invest in systems with greater certainty of interoperability. In short, the collective data from newer pilot studies combined with data from existing pilots will provide critical knowledge on how such a system can best be implemented. Without a full assessment of this data GPhA's members cannot guarantee compliance even by January 1, 2011.



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**Timeline and Obstacles to Compliance:**

*“b. As an extension of or part of the same timeline(s), a specific demonstration of steps/efforts necessary between January 1, 2009 and January 1, 2011 that make it possible to comply by 2011 where it would not be possible to do so by 2009, i.e., evidence that this additional time is required for implementation, including costs to be expended, specific milestones to be accomplished by which dates, etc.”*

The greatest obstacle to compliance is the lack of agreement among supply chain stakeholders on one technological standard that will support interoperability. As you know, the statute requires a drug pedigree to be “created and maintained in an interoperable electronic system ensuring compatibility throughout all stages of distribution.” Currently, no industry-wide guidance for implementation of a track and trace system exists, and no industry-wide agreement on EPCIS usage or standards for serialization has emerged. Efforts to reach compliance by 2011 must start by addressing this issue.

Even if agreement on an interoperable system were to be achieved already, GPhA members are concerned that software and tag vendors themselves may not be able to meet the volume demand for tags or have adequate time to implement software by January 1, 2009. Once an interoperable approach is established, manufacturers would need time to validate databases necessary to manage the information. The very purpose of California’s pedigree and serialization law—to ensure safe medicine for consumers—may be undermined by the requirements taking effect while the feasibility of such a system remains in question. In the meantime, the Food and Drug Administration Amendments Act (FDAAA) requires the FDA to “develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit . . . drugs” as well as to develop a “standardized numerical identifier.” The development of these standards by a federal agency represents another necessary step in creating a nationally acceptable system that will be necessary for securing the interstate flow of prescription medicines from the entry of counterfeit medicines. Finally, while working together to create a collective solution, stakeholders in the supply chain have faced and will continue to confront potential antitrust concerns. As FDA develops standards as required by FDAAA, supply chain stakeholders can continue working cooperatively towards a single, nationally acceptable system with the benefit of regulatory guidance.

In order for the generic pharmaceutical industry to provide an accurate estimate of the time it would take to implement a system that would satisfy California’s statute, numerous uncertainties must be resolved. Projections based on internal cost analyses by many companies indicate that implementation and operational costs for creating and maintaining a serialized electronic pedigree system will be extremely high—even insurmountable for some manufacturers. Thus far, GPhA’s conservative start up cost estimate simply for the equipment is in excess of \$500



GENERIC PHARMACEUTICAL ASSOCIATION

million. Data management costs alone will exceed this amount, and GPhA estimates that yearly operating costs will exceed \$300 million for RFID enabled labels alone. At this time, the ability of the industry in its entirety to adopt an interoperable serialized electronic pedigree system is uncertain.

**Protecting Public Health:**

*“c. In order to show that any delay in implementation would be consistent with a first priority of the Board to protect the California public, a specific articulation or demonstration of how public protection would be served by delay, including any evidence that January 1, 2009 compliance would be detrimental to this interest or that a January 1, 2011 compliance date would better serve this interest, any anticipated developments between 2009 and 2011 that would better serve the Board’s first priority to protect the public, and any additional interim measures which a requesting party is committed to taking between 2009 and 2011 to further drug distribution security pending compliance on January 1, 2011.”*

Delaying the pedigree and serialization requirements would serve public health by ensuring that the consistent flow of the drug supply is not disrupted needlessly for protracted time periods due to the shutting down of packaging lines for retooling, validation, and software implementation. Additional time would allow generic manufacturers to determine the most cost effective approach to implementing an electronic track and trace system, enabling the industry to remain competitive and keep access to medicine affordable and available. Without a delay, the immediate cost of implementing a system—one that may or may not achieve interoperability—could reduce or eliminate competition in California both from those companies that cannot comply, and from low cost/low margin products that may become too costly to manufacture. Further, the delay will allow knowledge gained from pilot studies on various technologies to be extrapolated into larger scale models of electronic track and trace systems, ultimately leading to a more refined and efficient system for securing the supply chain.

\* \* \*

GPhA intends to present regular updates to the California Board of Pharmacy regarding industry aggregate data and progress on pedigree and serialization pilots as the association’s independent analysis incorporates new results and becomes more refined.

GPhA®

GENERIC PHARMACEUTICAL ASSOCIATION

GPhA appreciates the opportunity to present the industry's position on this issue. Thank you for your consideration and we look forward to continuing to work with the Board to keep the drug supply safe and free of counterfeits.

Sincerely,



Kathleen Jaeger  
President & CEO

Generic Pharmaceutical Association



biogen idec

STATE OF CALIFORNIA  
BOARD OF PHARMACY

2008 JAN 15 AM 8:25

January 7, 2008

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

Dear Sir or Madam:

This letter is in reference to your intent to place on the agenda for your January 23-24, 2008 meeting in San Diego an item regarding the readiness for the January 1, 2009 implementation/compliance date for electronic pedigree. At this time, Biogen Idec is requesting additional time to implement electronic technologies to track the distribution of our products within the state of California. We are currently in the planning phase of our project with an expected implementation date of mid-2009. We have worked diligently to meet the current deadline, yet have experienced several challenges while pursuing the best technological solution to allow us to successfully integrate with our supply chain partners downstream. In order to manufacture and distribute product which meets the legal specifications of the state of California, Biogen Idec must implement a solution which impacts our entire supply operation. To this end, we have already accomplished the following tasks;

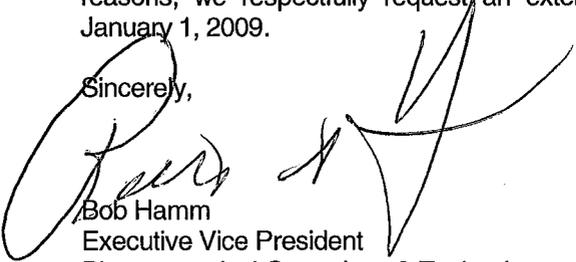
|   |         |
|---|---------|
| Diligence on legal requirements & available technologies  | H2 2005 |
| Business requirements gathering                           | H1 2006 |
| Vendor/Partner presentations                              | H2 2006 |
| Diligence on partner integration & available technologies | H1 2007 |
| Equipment selection & packaging line modification design  | H2 2007 |
| System solution design & vendor selection                 | H2 2007 |
| Vendor Contract negotiations                              | H2 2007 |

The remaining tasks are scheduled and are estimated to be completed in the following timeframes;

|  |         |
|--|---------|
| ePedigree generation configuration & test            | Q1 2008 |
| Serialization system configuration & test            | Q2 2008 |
| Serialized, tagged distribution configuration & test | Q3 2008 |
| Process validation & approval                        | Q4 2008 |
| ePedigree testing with downstream partners           | H1 2009 |

Going forward with the current deadline of January 1, 2009 would mean, at a minimum, California patients currently utilizing Biogen Idec's commercial products, namely AVONEX® (interferon beta-1a) and TYSABRI® (natalizumab) for multiple sclerosis, would experience an interruption in the supply of their medications supporting their treatment regimens. Furthermore, physicians would be limited in designing effective regimens for newly diagnosed patients suffering from this same disease. For these reasons, we respectfully request, an extension to the current implementation/compliance date of January 1, 2009.

Sincerely,

  
Bob Hamm

Executive Vice President  
Pharmaceutical Operations & Technology  
Biogen Idec Inc.

Biogen Idec Inc. 14 Cambridge Center, Cambridge, MA 02142 www.biogenidec.com



**GPSG**

Global Pharmaceutical Supply Group

2008 JAN 11 AM 10:48

January 9, 2008

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

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

Dear Sir/Madam:

Johnson & Johnson shares the Board of Pharmacy's commitment to protect California's drug supply from counterfeit prescription pharmaceutical and biological products. Ensuring that patients and healthcare professionals receive genuine products that are 100% pure to original form is based in the Johnson & Johnson Credo. We have provided the Board of Pharmacy Enforcement Committee with regular updates on our progress and milestones and will continue to do so.

Our dedication to safeguarding our products and protecting patients who use has always been a fundamental value for our company, before and since the Tylenol tampering incidents in the 1980's. Some of the steps Johnson & Johnson has taken over the years to secure our supply chain and our products include:

- Eliminated our wholesalers' practice of purchasing from secondary sources via our distribution purchasing agreements
- Conducted an awareness campaign that encourages healthcare providers to buy products from approved sources
- Established a worldwide brand protection organization focused on market monitoring, enforcement, anti-counterfeiting measures and educational programs
- Invested in various product authentication technologies and developed strategies to apply them on select products and packages.

Johnson & Johnson has been investigating, piloting and implementing various auto-identification and track and trace technologies. Adoption of these technologies will have an extensive impact upon our internal operations including information technology systems, quality assurance, production planning, distribution, etc.

Since we are a global manufacturer to comply with the California law, we must:

- Significantly redesign and validate *all* of our packaging, distribution operations, and their supporting IT systems
- Apply and verify unique identifiers on *every* individual package
- Track these unique numbers to *every* order that we ship to *all* of our customers.

In order for us to be fully compliant with the California e-pedigree/serialization law, Johnson & Johnson's master plan has a significant and geographically diverse scope that spans:

- More than 100 million units sold annually
- More than 200 products, across nine packaging types
- Twenty manufacturing facilities based in four continents
- Dozens of packaging lines
- Multiple products manufactured or packaged by external manufacturers.

Our plan must ensure that all of our external third party manufacturers are in regulatory compliance with California law.

All pharmaceutical and biological manufacturers must conform to FDA regulated Good Manufacturing Practices (GMPs). Compliance with FDA GMPs requires manufacturers to completely revalidate a packaging line whenever a modification to the line occurs. Validation of a single packaging line typically requires several months to complete.

Additionally, we must accomplish all of the above while continuing to ensure that there is no interruption in the availability of medicines to our customers and allow for the introduction of important new therapies that address unmet clinical needs.

Since 2002, Johnson & Johnson has completed five major anti-counterfeiting projects each with several supporting work streams, evaluated more than two dozen technology suppliers and expended substantially more than \$10 million to understand the application of these technologies and their business impact. Several of our projects have included interaction with our supply chain partners. Our latest estimates indicate that Johnson & Johnson's e-pedigree/serialization master plan will cost more than \$100 million. (Due to the proprietary nature of the work completed to date, we prefer to discuss the details of these projects upon request in an appropriate setting.)

It is the collective obligation of all supply chain parties to ensure that patients receive genuine products that have not been altered or tampered. This collective obligation requires an industry-wide, standardized interoperable system with enabling business practices. Such a system does not exist today. Any shared system will have to be designed, tested, scaled-up and implemented to ensure that drug supply is not interrupted. This cannot be accomplished without the active joint participation now of all parties in the pharmaceutical supply chain. Joint activities must include development and completion of standards that will provide consistent utilization throughout the supply chain, and development and deployment of an interoperable industry-wide system. The

goal must be to ensure seamless delivery of accurate pedigree information throughout the supply chain. Full adoption by those who distribute or dispense our products, such as hospitals, wholesalers, pharmacies, etc. is essential. Without this shared infrastructure, disconnected "solutions" will emerge, leading to compliance gaps and supply interruptions. If these required interoperable systems and standards are designed, developed and implemented in a cooperative and timely manner, Johnson & Johnson can continue to work toward compliance to the California law.

We are committed to protecting those whom we serve. For the aforementioned reasons, it is not possible to implement all of the electronic technologies and business practices to track and trace at the serialized individual unit level by January 1, 2009. Accordingly, we respectfully request the Board of Pharmacy to exercise its authority to extend the date for compliance.

We thank the Board for its ongoing outreach and for the opportunity to provide our comments. Johnson & Johnson looks forward to continuing to work with the Board and all the members of the supply chain to combat counterfeit drugs.

Please contact us if you have questions or would like additional information.

Sincerely,

A handwritten signature in cursive script that reads "Ron Guido".

Ronald Guido  
Vice President, Global Brand Protection  
Global Pharmaceutical Supply Group  
Unit of Ortho-McNeil-Janssen Pharmaceuticals, Inc.



# GRIFOLS

**Grifols, Inc.**  
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January 9, 2008

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

**Re: Request to Delay Date of Compliance for E-Pedigree Requirements**

Dear Board Members,

Thank you for the opportunity to provide comments regarding the January 1, 2009 compliance implementation date for the e-pedigree requirements under California Business and Professional Code §4034 and §4163. While Grifols Inc., (Grifols) supports the transition to e-pedigree, we believe that public health considerations weigh in favor of delayed implementation with respect to plasma therapies. Consequently, Grifols is requesting that the California State Board of Pharmacy delay the compliance date for e-pedigree requirements under California Business and Professional Code §4163.5 until January 1, 2011.

Grifols is one of the world's leading producers of plasma therapies and one of only five companies that supply plasma therapies to the United States with manufacturing facilities in Barcelona, Spain and Los Angeles, California. Plasma therapies are biologic products derived from donations of human blood plasma that are used to treat a variety of rare, chronic and life threatening diseases such as hemophilia and other bleeding disorders, congenital and acquired immune deficiencies, as well as shock trauma and other life threatening conditions. Uninterrupted access to these life-saving medicines is critical to the patients who rely on them.

Because of the unique nature of plasma therapies and the conditions they treat, the potential for adverse public health consequences arising from a January 1, 2009 e-pedigree implementation date is very real. More specifically, Grifols is concerned a January 1, 2009 compliance implementation date for e-pedigree will result in:

- Adverse impacts on product stability (and patient health) resulting from product track and trace instrumentation such as radio frequency tags and other coding technologies, and
- Disruptions in patient access to life-saving plasma therapies resulting from a lack of uniform track and trace technologies across the industry.

Given the life saving nature of plasma therapies and the fragile patient populations they serve, public health concerns weigh in favor of delaying the compliance date for e-pedigree implementation until January 1, 2011.

## Background

Plasma therapies are dramatically different from traditional, small molecule pharmaceutical products. They are delicate biologic products derived from donations of human plasma that are used to treat rare diseases and fragile patient populations. Because of their human source and the inherent potential for disease transmission, plasma therapies are subjected to an unsurpassed level of regulatory control and oversight from the US Food and Drug Administration (FDA). Unique elements of this oversight include:

- licensure of both the product starting material (human source plasma) and the finished therapies (e.g., intravenous immune globulin (IVIG)),
- traceability from every final product vial to each plasma donation and donor who contributed to that product, and
- increasing safety and quality requirements for the collection of human plasma and the production of FDA-licensed plasma therapies.

This level of oversight and regulation, while appropriate, points to the unique level of scrutiny given to the safety and integrity of plasma therapies.

In addition to FDA oversight and regulation, plasma therapy producers have established a unique Patient Notification System (PNS) to provide timely, direct notification of product recalls or withdrawals to registered users. This one-of-a-kind system was pioneered through collaborative efforts of plasma therapy user patient/consumer groups and manufacturers in the late 1990's. See [www.patientnotificationsystem.org](http://www.patientnotificationsystem.org) for more information about the PNS. The PNS has served healthcare providers and patients by providing an unprecedented level of confidence in the integrity of the products they administer and receive that does not exist for other healthcare products.

The distribution of plasma therapies to the marketplace also differs significantly from traditional pharmaceutical products. Plasma therapies are not dispensed through retail pharmacies and plasma therapy producers, including Grifols, typically do not rely on product wholesalers. Instead, the vast majority of plasma therapies are distributed by relatively few specialty biologic product distributors who have the requisite resources and experience to properly warehouse, store, transport and distribute these fragile medicines. As a result, plasma therapies change hands very few times in their lifecycle: from manufacturer to distributor and from distributor to healthcare provider. This means that there are significantly fewer opportunities for diversion of plasma therapies as compared to traditional pharmaceutical products.

### **Basis of Request to Delay E-Pedigree Implementation Until January 1, 2011**

As noted above, Grifols strongly supports the implementation of track and trace technology as a means of demonstrating product integrity. While significant gains have been made in track and trace technologies for pharmaceutical products over the past few years, significant questions remain with respect to the impact of these technologies on volatile biologic products, including plasma therapies. Furthermore, because the plasma therapies market is a small sector within the much larger pharmaceutical marketplace, differences in implementation of track and trace technologies of even one or two manufacturers or distributors could significantly disrupt patient access to these therapies.

Consequently, the risks to public health in terms of patient health and well-being are too great to move forward while questions of product impact and technological uniformity remain open. This is especially true when considered against the backdrop of the fragile patient populations served by plasma therapies, the unique level of FDA oversight of the plasma industry, and the voluntary measures the plasma industry has put in place to help assure product integrity.

#### **Product Stability Concerns**

Grifols is concerned that there is not yet enough known about the potential product impact from exposure to the leading track and trace technologies such as radio-frequency identification (RFID) to move forward with a January 1, 2009 implementation date for the California e-pedigree. Plasma therapies are delicate biologic products that are administered to patients via intravenous infusion. From the time a human plasma donation is made to the time a single dose of a plasma therapy is ready for infusion typically takes from seven to nine months. During this time, plasma donations are pooled and processed through an elaborate matrix of manufacturing steps that are designed to preserve the therapeutic benefit of the delicate proteins contained in the plasma. Even small temperature excursions, deviations in pH or alcohol concentration, among other things, can render an entire production lot impotent and useless.

Similarly, environmental conditions post-production can also impact the stability and potency of plasma therapies. Some plasma therapies are lyophilized (freeze-dried) and must be reconstituted before infusion, while others are liquid and can be infused directly to the patient. In either case, product stability is a primary concern for manufacturers, healthcare providers and patients, alike. As a result, many traditional pharmaceutical distribution channels are not engaged in the acquisition and distribution of plasma therapies. Rather, small specialty biologic product distributors who are uniquely qualified to meet the stringent requirements needed to preserve the therapeutic integrity and stability of the products typically distribute plasma therapies.

The FDA has acknowledged that more needs to be known about the potential impact of RFID on product stability. In 2006 the FDA Center for Devices and Radiological Health

(CDRH) announced plans to study the effects of RFID on biological product stability, liquid temperatures and storage conditions. Similarly, in late 2006 the FDA Center for Biologics Evaluation and Research (CBER) indicated that it would undertake specific studies of the impact of RFID exposure to the stability of plasma therapies. No formal results from either study have been published. Furthermore, in informal discussions, CBER officials have said that additional studies are needed before any definitive conclusion can be made about the impact of RFID on plasma therapies.

In light of these ongoing FDA studies and an indication that further studies may be warranted, it is too early to move ahead with a January 1, 2009 implementation date for e-pedigree in California. The delicate nature of plasma therapies and the fragile nature of the patient populations they treat are too significant to risk product integrity and patient health in the interest of achieving e-pedigree implementation. Delaying implementation until 2011 will provide the FDA and manufacturers with adequate time to fully understand the potential impact of technologies such as RFID on plasma therapy stability.

### **Potential for Patient Access Problems**

The vulnerability of patients who rely on life-saving plasma therapies is too great to risk disrupting access to plasma therapies through a well-intentioned effort to achieve e-pedigree implementation by January 1, 2009. As noted, plasma therapies are used to treat rare and chronic diseases such as hemophilia and primary immune deficiencies, among others. Patient populations that rely on plasma therapies require regular infusions of their therapy in order to maintain their health and well-being. For example, individuals with hemophilia who use plasma therapies may require infusions as often as twice a week in order to prevent damaging internal bleeding episodes. Persons suffering with a primary immune deficiency typically require infusions every three weeks to avoid potentially life-threatening illness or infection.

Disruptions in access to their needed plasma therapies could have devastating effects for the patients who rely on them. In fact, disruptions in patient access to plasma therapies within the last three years (IVIg, in particular) has been the subject of countless media reports, US Congressional inquiries, and government studies by the HHS Office of the Inspector General (OIG) as well as the Assistant Secretary for Planning and Evaluation (ASPE). Last year Federal legislation was introduced in the US House of Representatives specifically to address patient access problems with IVIG. See H.R. 2941 (110<sup>th</sup> Congress, First Session).

In order to avoid potential disruptions to patient access to plasma therapies, the need for standardized track and trace technologies is paramount. Without absolute assurance of uniform technology and interoperability, products could be held-up at a warehouse or other distribution point while large numbers of patients forego treatment. This is particularly true because of the relatively small size of the plasma therapies market, as compared to traditional pharmaceuticals. While a larger marketplace may be able to accommodate differing technologies and operating systems without significant supply

disruptions, the small number of plasma therapy manufacturers and distributors means that if even one system lacks inter-operability, a large percentage of patients could be at risk for reduced access to their therapy.

### **Grifols' Efforts to Assure Product Integrity**

Over the past decade Grifols has expended millions of dollars and thousands of man-hours developing systems and technologies to advance the integrity and authenticity of its products. Two of Grifols' more significant achievements have been the laser etching of all product vials with a lot number and the development of its proprietary Pedi-Gri® system. In addition, Grifols is in dialogue with its industry trade association, customers, vendors and other stakeholders about the technologies and systems necessary for implementation of e-pedigree. These measures underscore Grifols' commitment to assuring product authenticity and integrity.

#### **Lot Number Laser Etched Vials**

Each vial of Grifols plasma therapy is laser inscribed with its unique lot number. Grifols is the only plasma therapy producer to take this important step in providing robust product authentication. Distributors, healthcare providers and patients are advised that they can check each vial for the laser inscribed lot number and to compare it with both the lot number on the vial label and outer carton. By matching these numbers, consumers of Grifols products can have the utmost confidence in the authenticity of the therapies they administer and receive. In addition, Grifols invites its customers to call its customer service hotline to authenticate the product and verify the lot number etched on the product vial or to raise any other questions or concerns.

#### **Grifols Pedi-Gri®**

Over the past decade Grifols has developed a one-of-a-kind on-line product quality and authentication system. The Grifols Pedi-Gri® system is available for registered users of Grifols products and registration is free. By logging onto a secure Grifols website and entering a product lot number, users of the Grifols Pedi-Gri® system can authenticate the lot number of the product they are using and can access detailed product quality and safety information. Although the Grifols Pedi-Gri® does not maintain a log of consignees who take possession of the product, it provides users with unparalleled level of product authentication and quality confirmation.

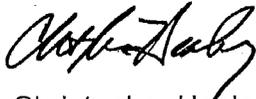
Through the Pedi-Gri® system, healthcare providers can view the specific product characteristics for the product lot number they input. System users can also view detailed information about the plasma that was used to produce the product in question, including: a list of all plasma centers contributing to the product lot, a list of every donor/donation identifier contributing to the product lot, and the results of all serological safety testing performed to assure product safety. No other plasma producer or pharmaceutical producer offers this level of detailed information about product quality and safety.

Currently the Pedi-Gri® system is available for Grifols products marketed in Europe. It is anticipated that the Pedi-Gri® on-line system will be available for all Grifols products by the end of 2008, including those marketed in the US.

**Conclusion**

Thank you for the opportunity to comment on the proposed compliance implementation date for the California e-pedigree. In light of the unique nature of life-saving plasma therapies and the fragile, chronically ill patients they serve, the interests of public health will best be served by delaying implementation of the e-pedigree compliance date until January 1, 2011. Notwithstanding this, Grifols is committed to all appropriate measures to assure the authenticity and integrity of the products it produces. Grifols development of the Pedi-Gri® system and implementation of laser etching lot numbers are a testament to this commitment.

Respectfully Submitted,



Christopher Healey  
Vice President for Government and Public Affairs





January 9, 2008

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

Dear Ms. Herold:

The Healthcare Distribution Management Association (HDMA) respectfully submits the following information and request for an extension of the pedigree implementation date as permitted under Section 4163.5 of California's Business and Professions Code.

HDMA is America's leading association representing the nation's primary, full-service healthcare distributors. Our membership includes large national companies as well as regional and small, family-owned businesses. Combined, HDMA members operate 166 distribution centers, serving every state in the nation. The primary responsibility of HDMA member companies is to help ensure the safe, efficient and reliable management and delivery of life-saving medicines and services to nearly 144,000 pharmacy settings across the United States each day. In fact, 80 percent of all medicines go through an HDMA member distribution facility on the way from the manufacturer to the healthcare provider.

HDMA commends the California Board of Pharmacy for its continued efforts to work with the pharmaceutical supply chain to facilitate progress toward implementation of California's pedigree law, as enacted in 2006 (SB 1476). The Association and our primary distributor members are committed to working with the Board and supply chain trading partners in order to make as much progress as possible toward implementation of this unique and far-reaching state requirement.

However, based on what we know today, we are concerned that the supply chain will not be able to safely and effectively implement pedigree on January 1, 2009, as required under California law. HDMA shares the Board's concern for public safety and believes an extension of that date will be necessary to ensure patient safety and access to necessary medicines in the State in 2009 and beyond. Specifically, HDMA urges the Board to consider the information submitted by us and other industry groups and to recognize that the pharmaceutical supply chain "requires additional time to implement electronic technologies to track the distribution of dangerous drugs within the state." (Bus. & Prof. Code § 4163.5).

HDMA supports the goals and the spirit of California's approach to pedigree. We have stated in past meetings before the Board's Enforcement Committee that the California model offers the best framework for tracking the path of prescription drugs, with certainty, from the point of manufacturer through to the end of

the supply chain. Further, we believe that when it does come to fruition, this type of track-and- trace system will go far to preserve the integrity of the entire supply chain, protect Californians and enable supply chain efficiencies to continue.

### ***Distribution Industry Progress***

To date, much progress has been made. Beyond the legislative environment, track-and-trace technology standards have evolved this year with new e-pedigree and document management standards approved by EPCglobal. Technology providers are producing better and more cost-effective hardware and software products and services. We understand more today about what the technologies can and cannot do, and in studying multi-year pilot findings, we know more about what is required for companies to move toward track-and-trace implementation. Even more importantly, supply chain partners have been working diligently, openly discussing obstacles, opportunities, challenges and varied technologies that must be considered prior to track-and-trace implementation.

Nevertheless, our work still remains in its nascent stages, and greater levels of participation from supply chain partners are needed in order to reach the goal of implementation. A typical HDMA member distribution facility receives product from approximately 1,154 manufacturers and serves approximately 1,700 pharmacy settings.<sup>1</sup> We need to understand more about how the decisions made by each individual company will affect trading partners both up *and* downstream. This will become critical in the coming months, particularly as we continue work to achieve a true track-and-trace system in California.

HDMA's primary distributor members have taken a lead in this area and have engaged in numerous activities in order to explore technologies, build relationships with other segments of the healthcare supply chain and work in good faith toward meeting the requirements of the California pedigree law. HDMA members have invested millions of dollars, hours of labor and additional resources to explore technology solutions, design systems, and initiate track-and-trace pilot projects with their trading partners to prepare for compliance with California's pedigree requirements.

Our distributor members have also participated in EPCglobal and the standards development process. They have helped to educate manufacturers and pharmacies about the challenges the industry faces in meeting the California requirement and continue to work with supply chain partners to develop compliance solutions.

### ***Challenges to Implementation***

In working toward compliance, distributors have faced a number of challenges, which we believe can be overcome with additional time, resources and exploration. For example:

- Only very few products exist today that are uniquely serialized at the unit level. This causes concern, not only because distributors are dependent on their suppliers to help facilitate implementation, but because we do not yet have enough data to build solutions for our pharmacy customers to test.

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<sup>1</sup> Center for Healthcare Supply Chain Research. 2007-2008 HDMA Fact book. (2007).

- At present, there are no products available that use two-dimensional (2D) data matrix bar codes as a primary means of serialization; as a result, the industry has no real experience reading them and collecting their associated data in a high-volume distribution facility setting.
- Today, the solutions we are building have not been built out to scale. With a limited number of products, and in limited transaction sets, technology development is progressing; however, there is no way to know what technical difficulties may arise when we reach a more realistic scale of product to work with. Average distribution facilities process about 1,387 orders and deliver over 67,600 products on any given day.<sup>2</sup>
- Thus far, programs have focused on tagging product at the manufacturer, and reading product at the distributor level. We are just beginning to test systems for the actual collection, storage and transmission of pedigree data.
- Guidance is needed for unique or variant business cases, such as how to handle returns, drop shipments, third party logistics providers, inference and grandfathering of non-serialized products.
- Finally, distributors' position at the center of the supply chain makes compliance with the California law impossible unless our upstream trading partners can meet the serialization and data exchange requirements, and our downstream customers are able to receive and store pedigree data.

There are, however, three *primary* areas where we believe critical development must occur in order to meet the requirements of California's pedigree law: Standards development, technology issues and availability, and further awareness/readiness of other sectors of the supply chain.

### Standards Development

The California pedigree law requires that any pedigree be created and maintained in an "interoperable electronic system." (Bus. & Prof. Code § 4034 (a)). Further, an "interoperable electronic system" is defined by statute as "... an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug." (Id. at 4034 (i)).

In making a determination that industry participants require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state, the Board should consider, in concert with evidence that the industry is unable to implement such technologies by January 1, 2009, whether the industry will have in place an interoperable electronic system meeting the statutory definition. HDMA contends that such a system will not be ready in time to meet that deadline.

A major reason why such a system will not be ready and available for use across the supply chain is due to a lack of standards development for serialization – or unique identification of products. While standards for unique identification with the use of RFID technologies have been under way, it appears that very few

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<sup>2</sup> Id.

manufacturers are preparing for use of RFID track-and-trace methods. Rather, they are focusing product identification efforts on the use of 2D bar codes.

The use of 2D bar codes as part of an electronic track-and-trace pedigree system is in this early stage of development. Pharmaceutical manufacturers are employing both RFID and 2D, depending on company preferences. However, there is a significant issue of conflicting product identification data encoded in 2D bar code label versus the data encoded in an RFID tag on the same product. This will cause a conflict when trying to identify the product and match it to the appropriate data in the electronic track-and-trace system. The healthcare associations are working with GS1 to resolve the issue.

Further, though there is an approved pedigree document standard from EPCglobal, there is no clear guideline for the industry to use in the implementation of the standard across the supply chain and the standards for track-and-trace are still in the development process. Decommission standards are still under development as well. We continue to aggressively work on guidelines and standards; however, it is not foreseeable that these issues will be resolved in time to meet California's requirements across the supply chain by January 1, 2009.

#### Technology Issues and Availability

In addition to the development of standards, technology development and the availability of technology solutions are necessary to facilitate implementation. There also are a variety of RFID frequencies and protocols that could be used. It is very difficult to prepare the systems and infrastructure when standards are still under development and there are variations in data carriers that could be used to uniquely identify products at item level. As mentioned above, 2D bar codes are being used by many manufacturers and are assumed to be an acceptable means of meeting the California requirements for unique identification of dangerous drugs. According to HDMA members, however, there is no, a currently available technology solution to accommodate the use of 2D in a high-volume distribution facility.

While solutions may exist that can accommodate a lower volume of product movement, such as in small distribution facilities or pharmacies, the nature of 2D data matrix technology is such that it would make even case-level identification and scanning an incredibly difficult process in a high-volume facility. 2D bar codes use an "image" technology that requires specific positioning of the bar code at the point of reading or scanning the product or case because the scanner must, in essence, take a snap shot of the 2D image. Since there is no standardized way to place or format 2D bar codes on unit- and case-level packaging, there is no way to automate the intake process. In addition, 2D data carriers cannot be read with existing linear barcode reader technology; 2D bar codes are not scanned like their linear counterparts - they must use an "image" capture technology. Compared to linear technology, HDMA members have indicated that it takes 2 to 3 times longer to decode 2D technology. The use of inference may help in recording unit-level products in unopened homogenous cases, however, it will not solve the problems that exist at the case level, and this will cause major through-put issues for the supply chain. Without the use of inference, industry partners would be forced to increase the amount of product in inventory, thereby presenting potential risks to efficiency and security.

In addition to the lack of standards development and technology solutions for the use of 2D barcodes as a unique product identifier, healthcare distributors have not had enough products made available to them for

development and testing of internal systems. This situation adds several additional complications to implementation. First, while HDMA members have begun to test the exchange of pedigree data with trading partners, there is a lack of solutions that can work with 2D barcodes, and there is no uniformity among formats put forth by trading partners. Second, with respect to those products that employ RFID tags, there is no current HF (high frequency) standard for RFID. Even after such a standard is developed and approved, there will be considerable lag time necessary to adopt and implement it across the industry. We do not believe that six months or less will be an adequate time frame in which to accomplish this.

Finally, due to the lack of serialized product available, mixed use of technologies and availability of technology solutions, HDMA members have not been able to adequately build and/or assist their downstream trading partners in building systems at the pharmacy level.

#### Awareness/Readiness of Other Industry Segments

Distributors' have faced obstacles in helping prepare pharmacy customers for receipt of product and pedigrees via an interoperable electronic system. HDMA members note that there is variable level engagement and/or development of processes among many segments of their customer base. In many cases this is due to customer resources issues, lack of guidance, or focus on other business concerns such as reimbursement or patient care. This is not intended to be a criticism of those entities, but rather a statement of the realities of the market.

While it is true that many pharmacies – such as smaller independents – are relying on their distributors to help them develop processes and technologies in order to comply with the California pedigree law, there are also other pharmacy entities that could be more engaged in the process (i.e., hospitals, health systems, clinics, etc.) As a result, there are very few trading partners downstream with which to explore solutions and test systems. It is our sense that while we can speculate what solutions may work in the pharmacy setting, it is impossible for distributors to ensure that they will work and be fully operational only one year from now.

#### *Conclusion*

HDMA points out these issues and findings in order to show the Board what we have learned so far, what we have accomplished, and that we are committed to working toward compliance with the requirements of the California pedigree statute. We believe that the California model is the correct approach for tracking and tracing prescription drugs and we emphasize that we do not want to see any fundamental changes to the spirit or goals of the law; however, the supply chain needs additional time to meet those goals. We encourage you to consider an extension in order to reinforce the Board's commitment to the California pedigree model, and to give the supply chain adequate time to implement successful solutions.

Unless the issues we have raised are addressed appropriately and all supply chain partners are decidedly ready and able to implement pedigree systems using an interoperable electronic system, we fear that patient access to life saving medicines will be compromised. Quite frankly, on January 1, 2009, based on the anticipated state of the supply chain, our members would not be able to supply their pharmacy customers with many medications without violating the California pedigree law.

HDMA Request for Extension  
January 9, 2008

We continue to try to work though the obstacles, as manufacturers, distributors and pharmacies, by definition, all have different business models. We have different customers. We have different business incentives, IT capabilities, core competencies and legal obligations. We have to consider all of that as companies work toward individual solutions. But make no mistake; this is a monumental, unprecedented undertaking, involving thousands of supply chain partners and billions of product transactions every day.

As we move forward and begin developing solutions that apply to a broader array of products, we must work together with our supply chain partners to resolve some very real, very controversial issues. I believe these discussions will be highly engaging, and ultimately will be necessary to maintain forward momentum and create a sustainable future for the healthcare system in California and the patients we serve.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth A. Gallenagh". The signature is fluid and cursive, with a large initial "E" and "G".

Elizabeth A. Gallenagh, Esq.  
Senior Director, State Government Affairs



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January 9, 2008

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

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

To the Members of the California State Board of Pharmacy:

Hogan & Hartson, LLP submits this letter in response to the California Board of Pharmacy's (the Board's) request for comments regarding the pharmaceutical industry's readiness to implement steps to timely comply with California's electronic track and trace and unit-serialization requirements for prescription drug products sold in California. Hogan & Hartson is a law firm that represents pharmaceutical and biotechnology companies that develop, manufacture, and provide to the residents of California important prescription drugs that address critical medical needs.

I appreciate the opportunity to respond to the Board's invitation for comments by describing a client's efforts to comply with California's requirements, the difficulties of fully implementing electronic track and trace and unit serialization, and the feasibility of meeting the deadline on January 1, 2009. I refer to the client as "the company" below for ease of reference and hope that the Board finds these comments helpful and considers them in deciding whether to extend the deadline to January 1, 2011.

*Background Information.* The company markets one product, an injectable drug product used to treat often life-threatening illnesses, to hospitals and out-patient centers, and uses a third party logistics (3PL) provider to implement a drop-shipment program. Rather than using the traditional drug distribution model, the company's finished drug product is not stocked by wholesalers but is warehoused by the 3PL that exclusively manages the company's inventory program and distributes the finished product to customers. There are two segments to the drop-shipment program. First, a pharmacy or

other person administering or dispensing the drug product will place an order through the 3PL, which processes the order and ships the product directly to the end user (*i.e.*, a hospital or out-patient center), but title to the product remains with the company until delivery to the end user. Second, orders may be placed through a wholesaler and then passed on to the 3PL, which processes, fulfills, and ships the product directly to the end user and bills the wholesaler. Under the second type of arrangement, title to the product (but not possession) transfers from the company to the wholesalers. Among other reasons, the company instituted this drop-shipment business model to closely monitor inventory levels, assure efficient distribution, and, importantly, recognize any unusual purchasing patterns that may suggest abuse or diversion.

*Demonstration of Efforts to Meet Deadline.* In anticipation of the upcoming implementation date of the e-pedigree requirements in California, the company has explored several "e-pedigree" options. In doing so, the company has taken into consideration the unique properties of its injectable drug product, the drop-shipment distribution model, and prior experience with electronic tagging and distribution line management. With the information it has currently, the company believes that a file transfer of information through a two-dimensional bar code matrix encoded with the required information may represent its best option. However, it is still too early to know what will work best for the company to allow compliance with the statute, while continuing to deliver this important medicine to California patients.

The company considered but ultimately rejected the use of radio-frequency identification (RFID) chips for several reasons. There is a lack of definitive data as to how RFID technology may affect heat-sensitive products. The company's injectable product, for instance, must be continuously refrigerated within a narrow temperature range approved by the Food and Drug Administration to maintain the product's stability. The RFID option, therefore, may adversely affect the drug product's efficacy, potency, safety, or stability to the detriment of patients. Another concern is that RFID technology may not be sufficiently accurate. Currently, the company utilizes RFID chips to track the inventory of certain drug components, but experiences on average a 2% error rate in reading information encoded in the RFID chips. It appears that this error occurs because of the wide scanning range of RFID chips, whereby two or more RFID-tagged products within a certain distance of each other may impact scanner readings. Translating the 2% error rate to shipments of the company's finished products could mean that for every lot produced (*i.e.*, 30,000 vials), scanner errors could occur for 600 vials.

A two-dimensional data matrix bar code could represent a better tracking and tracing alternative for the company's product. The company is still in the process, however, of determining the best method of printing bar codes on the cartons. Due to printing and manufacturing errors, it discards a large number of packaging cartons made for use with its drug. As a result, should the company print serialized identifiers on each package unit, it would likely lose a significant percentage of the serialized identifiers before product shipment. The company has not yet resolved how to track the identifiers lost during manufacturing or how to safeguard that information from use by counterfeiters. Consequently, several critical steps remain before the company can

comply with the California requirements, including selecting technology vendors and changing its manufacturing packaging process.

*Outstanding Issues.* The company believes that two outstanding issues stand in the way of its efforts to comply by January 1, 2009. First, the company is concerned about the development of an industry standard for an interoperable system. Manufacturers are currently adopting different solutions that best accommodate their operations within certain budgetary constraints. But, without an industry standard for interoperability between manufacturers and wholesalers, the company is at risk of developing and implementing a technology that might not be adopted by trading partners or others in the industry and, therefore, may not achieve compliance with the statute. The company is not in a position to alternatively pursue several solutions. It has only one product and relatively limited resources. Any investment in a technology that is not ultimately accepted by the industry would significantly drive up the company's costs, which it would need to recoup from consumers. Moreover, were the company required to change its approach at a later date, it would incur substantial costs without any benefit to the public health – costs that can cripple small companies.

Additionally, the company, like several other companies, has questions about the Board's interpretation of the statute, particularly questions regarding the statute's requirement that all changes of "ownership" be reflected on a pedigree. Given that the company's drop-shipment model never results in changes of possession, which might expose the drug to a risk of diversion, it believes that the Board should interpret a change in possession, rather than a transfer of title, as "change of ownership" within the meaning of the statute. The company will need additional time to determine if this interpretation is shared by its wholesalers as well as by the Board before making related decisions about how to comply.

*Feasibility of Deadline.* Because of the outstanding issues described above, the company believes that California patients will not benefit were the Board to force compliance with serialization and track and trace requirements by January 1, 2009. Compliance by January 1, 2011 is much more feasible because it will provide time for the company along with other members of the industry to: (1) establish a standard interoperable technology and implement that technology in a cost-efficient manner; and (2) work to resolve outstanding issues surrounding the implementation of unit serialization and track and trace as applied to drop-shipped products.

The additional time will also give the company the opportunity to fully validate and test its reconfigured equipment and facilities, a necessary step that is required by FDA's current good manufacturing practice regulations. Validation also will be important in resolving any manufacturing integrity issues arising from newly outfitted packaging, labeling, and serialization systems. This is a time-consuming process that can take several months to complete and can only be started once the company has resolved the outstanding issues.

Members of the California Board of Pharmacy  
January 9, 2008

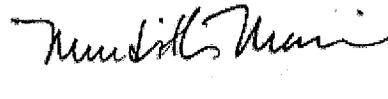
Finally, delaying implementation past January 1, 2009 will not result in a security threat to patients taking the company's injectable drug product. Because the company has implemented an extremely tight distribution system that limits physical possession of its product to two entities – its 3PL and the end user – the company has never had a counterfeiting or diversion incident. And, its investment in this system demonstrates its commitment to product security coupled with patient access.

\* \* \* \*

Given the complexity that the company and the rest of the industry have encountered in addressing issues raised by the electronic track and trace and serialization requirements of the California statute and the lack of a uniform industry standard in the available technology, we respectfully request that the Board extend the January 1, 2009 implementation date.

We thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Meredith Manning".

Meredith Manning



www.lilly.com



Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285  
U.S.A.

Phone 317 276 2000

January 9, 2008

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

To the Members of the California State Board of Pharmacy,

The intent of this letter is to respectfully request the Board of Pharmacy exercise its authority provided by section 4163.5 to "extend the date for compliance to implement electronic technologies to track the distribution of dangerous drugs within the state."

Eli Lilly and Company is committed to safely delivering our medicines to patients and we share the Board of Pharmacy's belief that protecting the integrity of the pharmaceutical supply chain is essential.

Eli Lilly and Company will be in a position to provide manufacturer-initiated electronic pedigrees for all our products by January 1, 2009. We already provide lot-level serialization to our wholesale and retail trading partners and later this year, we will also have the ability to provide pallet level serialization to our downstream trading partners.

*Many steps are required before item-level serialization can begin: Technology limitations and other open data standards directly affect the pace of implementation:*

- While lot level serialization exists today – as required by the FDA's cGMPs – the extension of this serialization effort to the case, or even the unit level, requires a tremendous number of activities by all supply chain partners. The implementation of unique identification beyond the lot and pallet level will require significant changes to current manufacturing processes and facilities, many of which will require the development of guidance and/or pre-approval from the FDA. Changes to Lilly's labeling and packaging may also require prior FDA approval.
- The deployment of an 'interoperable system' across the entire pharmaceutical supply chain is a required prerequisite to implementation of the California pedigree law and is necessary to support the passing of pedigree and serialization information. Significant data ownership and access issues must be resolved prior to item-level serialization, including relating to data exchange between supply chain partners, and processes for verification of serial numbers.

The attached document provides more specific information related to Eli Lilly and Company's significant efforts to secure the pharmaceutical supply chain.

We thank you for your consideration.

Sincerely,



Robert A. Luginbill  
Vice-President, Manufacturing Strategy and Planning  
Eli Lilly and Company

Firm name  
December 19, 2000  
Page 2 of 3

#### Attachment

Additional information requested by the California State Board of Pharmacy as outlined in the "Template for Submissions Regarding Implementation Date of California ePedigree Laws"

#### a) A Sampling of Demonstrated Efforts by Lilly to date:

- o Lilly has been an active member of several cross-industry forums (both national and global) collaborating on necessary business practices and data standards to comply with emerging pedigree legislation. Industry groups include HDMA (Healthcare Distribution Management Association), PhRMA (Pharmaceutical Research and Manufacturing Association), EFPIA (European Federations of Pharmaceutical Industries Associations), etc. Lilly is a formal member of GS1, the global standards setting body working to develop globally recognized standards for collecting, communicating and data sharing real time data of individual items across the supply chain.
- o Eli Lilly and Company scientists have collaborated with Michigan State University's School of Packaging to test potential RFID tag read rates on pharmaceutical products.
- o Lilly scientists collaborated with the Drug Product Technical Committee of PQRI (Product Quality Research Institute) to author a technical report to the FDA on the 'Potential impact on product quality due to exposure of biologic drug products to RFID tags and readers. (Report to FDA of PQRI Working Group, by Robert H. SeEVERS, PhD, Eli Lilly and Company, December 1, 2005)
- o Lilly actively contributed to the development of Privacy Best Practices for Deployment of RFID Technology, a global standards-setting initiative sponsored by the Center for Democracy and Technology.
- o Lilly's distribution operations made the necessary IT investments and were able to successfully meet the requirements associated with Florida's pedigree requirements. Lilly provides electronic ASN's (advance ship notifications) to our downstream wholesale and retail customers by leveraging our lot tracking capabilities.
- o Lilly has been piloting an active radio frequency enabled temperature monitoring devices (active RFID) on all shipments of finished product between Lilly distribution centers in the US.
- o Eli Lilly and Company's animal health division has served in a lead role in working with other animal health manufacturers to develop a global standard for unit level coding of animal health products. By first quarter 2008, all Elanco products will all have two-dimensional Datamatrix (2D) barcodes on final packages with the capability of creating unique item level serialization.
- o Lilly was the pioneer pharmaceutical manufacturer to embark on an innovative pilot with a London-based firm, Aegate, in Belgium that allows pharmacists to authenticate product at the point of dispensing. The pilot takes advantage of the fact that all Belgian pharmaceutical products are uniquely serialized with a government issued sticker. The Belgian pilot was deemed a success and has been expanded to Greece.
- o Lilly employed a leading third party ePedigree consultant group (division of SupplyScope) to assist in the development of a comprehensive corporate strategy regarding ePedigree compliance and the global product serialization for human health products.
- o Resources have been committed to ensure that Lilly will be capable of initiating electronic pedigrees in the US by the summer of 2008. In addition, Lilly is making the necessary investment to serialize all pallets shipped from Lilly's distribution centers in the US by January 1, 2009.

#### b) Evidence that Additional Time is Required for Implementation:

- o Item level serialization requires that open standards be developed and adopted in a number of areas. Specific standards that must be developed include: RFID high frequency item level serialization, serialization number format for RFID, discovery configuration and installation, returns processing, etc. These standards must also address complex issues surrounding data integrity, interoperability and compatibility across the supply chain.
- o The standards described above have not been developed and/or ratified, and will not likely be available until mid-2008 – at the earliest – and possibly as late as 2009 (source: EPCglobal)

Firm name

December 19, 2000

Page 3 of 3

- o Once these standards are finalized, technology solution vendors will need to be certified to these standards and products built to conform to these standards. These steps must be completed before item-level serialization can begin.
  - o The breadth of Lilly's portfolio and the complexity of its supply chain will require significant changes to current manufacturing processes and facilities, many of which are biologics and will require the development of guidance and/or pre-approval from the FDA in order to serialize product at the unit level. Analysis conducted by leading external pedigree consultants of our packaging and IT operations indicates that it will take Lilly 5+ years to serialize all products.
- c) Evidence that a delay in the compliance date would serve the public's interest:
- o Significant data ownership and access issues must be resolved prior to wide-scale deployment of item-level serialization, including the development and ratification of open standards. Eli Lilly and Company could embark on an effort to serialize all its products using a particular standard, but if the rest of the pharmaceutical supply chain chooses to adopt a different set of standards, the serialization effort will have failed to accomplish the goal of protecting patients.
  - o The recently-enacted FDA Amendments Act of 2007 (FDAAA) directs the FDA to develop – no later than March 27, 2010 – a standardized numerical identifier to be applied 'at the package or pallet level' to prescription drug products. The proliferation of differing state and federal requirements in this area would create confusion and could potentially negatively impact the access of medicines to patients.



McKesson Corporation  
One Post Street  
San Francisco CA 94104

January 9, 2008

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

**Re: Request for a Delay in California's ePedigree Implementation Date to 2011**

Dear Ms. Herold:

On behalf of McKesson, a major healthcare company based in California, I am pleased to submit comments to the California Board of Pharmacy on the California ePedigree Law (Business and Professions Code, 4163.5).

For 175 years, McKesson has led the industry in the delivery of medicines and healthcare products to drug stores. Today, a Fortune 18 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, 10,000 extended care facilities, 700 home care agencies, the Department of Veterans Affairs, the Department of Defense and other government facilities. Our employees, including the nearly 2,500 who reside in California, provide products and services that improve the quality of care, reduce unnecessary costs, eliminate medication errors, synthesize information for physicians, and free pharmacists to counsel patients.

McKesson has long been an industry leader in developing and implementing cutting-edge technology to enhance the security of the pharmaceutical supply chain. We were the first pharmaceutical wholesaler to fully automate our warehouses and distribution networks with radio frequency and scanning technology. Today, we are again taking the lead as we work with pharmaceutical manufacturers and major retailers to test radio frequency identification (RFID) technology that will track pharmaceutical products from the manufacturer to the wholesaler to the pharmacy and facilitate the creation of ePedigrees. This technology represents the next step in our continuous efforts to further secure the integrity of the pharmaceutical supply chain.

**McKesson Position**

McKesson supports the California ePedigree Law and the Board's efforts to facilitate compliance across the pharmaceutical supply chain. It is our firm belief that pharmaceuticals should be serialized at the point of manufacture and that ePedigrees should track the products from the manufacturer through the wholesaler to the healthcare dispenser. We are concerned, however, that a significant majority of our manufacturing suppliers will not be ready to comply with the 2009 ePedigree implementation date. If the law were implemented next year, McKesson would not be able to deliver vital medications throughout the state. The health and safety of Californians would be best served if the ePedigree implementation date is delayed until 2011.

As a member of the Healthcare Distribution Management Association (HDMA), McKesson supports the association's comments and recommendations on the California ePedigree Law. Further, we would like to submit to the Board the following information to support the aforementioned recommendation to delay the implementation date.

### **Justification for Delay**

McKesson has actively worked with our manufacturer and pharmacy partners over the past several years to assist the supply chain community in better understanding the requirements of the California law. In 2006, we launched and financed the "On Track" pilot project, a collaborative effort among manufacturers, distributors and retailers, which provided critical insights and data into the process of moving serialized pharmaceuticals from one trading partner to another. Last year, we hosted multiple meetings with our public and private sector partners to focus on best practices to secure the pharmaceutical supply chain through serialization and ePedigrees. Most recently, we convened over 25 manufacturers, pharmacies and distributors to enhance industry collaboration and to identify those trading partners that are interested in conducting pilot projects to drive greater compliance with the California ePedigree Law.

Over the past year, we have reached out to over 650 pharmaceutical suppliers that conduct business in California regarding their ability to comply with the ePedigree Law. Over 100 suppliers have indicated they will be ready by 2009; however, the vast majority of manufacturers did not respond or indicated they would not be able to comply by this date. We understand many manufacturers have just commenced efforts to explore the feasibility of product serialization. These suppliers do not have the technical capability within their companies to address the difficult requirements of establishing a serialization process and implementing an interoperable ePedigree system by 2009.

In a presentation to the Board of Pharmacy on October 24, 2007, an external technology expert on serialization and pedigree implementation stressed that it would require 18 months for a manufacturer to implement a serialized pedigree solution across their entire product line. Based on McKesson's extensive experience with pedigrees, we concur with this estimate. If a manufacturer has not already initiated the planning process and selected a technology vendor, they will not meet the January 1, 2009 requirement. Further, these companies will need additional time to implement and test the ePedigree solutions to assure interoperability with their distribution and retail partners.

McKesson has agreed to consult and provide process expertise to many of our suppliers to support their pilot activities; however, we can only work with a limited number of manufacturers at one time. Our experience with other data exchange activities has demonstrated that establishing the initial data linkages is an enormously time consuming process. While the manufacturer community will need additional time to serialize products and pass ePedigrees to the wholesale community, McKesson will be concurrently assisting our pharmacy customers in their efforts to comply with the law.

As you know, McKesson's role in the supply chain is to warehouse pharmaceutical products in our distribution centers to meet the next day requirements of over 3,000 hospital and pharmacy customers in the state. If these healthcare providers place their orders by 8:00 p.m., the medicines will be delivered by the next morning. This system has been streamlined to provide maximum efficiency, the highest product service level and the lowest cost to our customers. On a typical day, our California pharmaceutical distribution centers receive and deliver over 400,000 individual units of medicine.

Without a delay in the ePedigree implementation date, McKesson would be placed in the very difficult and untenable position of having to refuse receipt and shipment of a vast majority of the vital medicines needed by Californians. We are deeply concerned about the potential impact to patients, our customers and our company if this were to occur.

**Conclusion**

McKesson respectfully urges the Board of Pharmacy to delay the implementation date of the ePedigree Law until 2011. The health and safety of Californians will be best served by a delay. The additional time granted will provide McKesson and our trading partners the critical time and knowledge needed to implement the law. With your support, we can realize the vision of the Board to further assure the safety of medicines delivered to Californians.

We will keep you and members of the Board of Pharmacy informed on industry's progress towards complying with the California ePedigree Law. Please do not hesitate to contact me if you have any additional questions or concerns. Thank you for your consideration of this important matter.

Sincerely,

Ronald N. Bone  
Senior Vice President, Distribution Support  
McKesson Pharmaceutical

Cc: John Figueroa, President, McKesson Pharmaceutical

# **McKESSON**

*Empowering Healthcare*

September 4, 2007

Regarding: California Pedigree Readiness

Dear McKesson Supplier,

This letter is being sent to all suppliers from whom McKesson purchases pharmaceutical products in or into the state of California. Attached is McKesson's Frequently Asked Questions (FAQ) to California's pedigree law. For additional information please refer to <http://www.pharmacy.ca.gov/>.

McKesson encourages all Suppliers to review the regulations and contact the California Board of Pharmacy regarding your company's capabilities and concerns. McKesson also requests as your company reviews these regulations you keep McKesson up to date on your plans. Please send your readiness plans and updates to [Rebecca.Samples@mckesson.com](mailto:Rebecca.Samples@mckesson.com). Rebecca may also be contacted 972 446 4186.

Please do not hesitate to email McKesson if the response to your question is not addressed or if you need greater detail.

[Pedigree.Questions@McKesson.com](mailto:Pedigree.Questions@McKesson.com).

Respectfully,

Ronald N Bone  
SVP Distribution Support

CC Greg Yonko  
Saul Factor





## MedImmune

January 16, 2008

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

RE: REQUEST FOR ELECTRONIC PEDIGREE EXTENSION

Dear Members of the California State Board of Pharmacy:

I am writing on behalf of MedImmune, Inc. to request that the California State Board of Pharmacy (Board) formally consider a two year delay in the implementation of California Business and Professions Code Sections 4064 and 4163 relating to electronic pedigree (e-pedigree).

MedImmune is a leading biotechnology company that strives to provide better medicines to patients and new medical options for physicians. Dedicated to advancing science and medicine to help people live better lives, the company is focused on the areas of infectious diseases, cancer and inflammatory diseases. The company's marketed infectious disease products include Synagis® (palivizumab) and FluMist® (Influenza Virus Vaccine Live, Intranasal), with additional products in clinical testing. The company employs approximately 3000 employees worldwide and is headquartered in the state of Maryland.

The company is taking the e-pedigree law in California very seriously and is concerned with delivering medicine to patients safely and efficiently. To that end, we have undertaken the following tasks in order to work towards a January 1, 2009 implementation date:

- *Established an internal project team comprised of representatives of the Supply Chain, Information Technology, Trade and Distribution, Development, Quality, Regulatory Affairs, Legal Affairs, and Government Affairs Departments. The purpose of the team is to evaluate the technology options for Serialization/Track and Trace, explore pilots and implement solutions to become e-pedigree compliant.*
- *MedImmune has been evaluating the technology solutions that meet the current industry standards for pedigree messaging, Serialization/Track and Trace solutions. While the pedigree messaging standard has been established, industry standards for Track and Trace are not complete. MedImmune is working diligently to identify solutions and to begin pilots with some of our current products in the second half of 2008.*

MedImmune's supply chain operations involve multiple third parties – including, but not limited to, contract manufacturing service providers for fill/finish, packaging and labeling operations, wholesalers, distributors, and specialty pharmacies. Implementation of any of the technology solutions is a complex process that involves ensuring that appropriate data capture devices and appropriate inter-operable computer systems are available for data capture, data management and exchange with all of MedImmune's supply chain partners. For example, the data capture processes need to be validated in controlled environments (refrigerated or frozen conditions) in which MedImmune's products are handled. Many of our supply chain partners are in the nascent stages of identifying, adopting and implementing solutions and we are actively working with them to evaluate technology options and solutions. Our goal is to adopt and implement the most robust solution that allows MedImmune to meet the requirements of California's e-pedigree law. Implementation by 2009 is a short time frame and will not allow MedImmune adequate time to complete our pilots, validate the processes of data collection and exchange, and implement solutions with our partners in the complex supply chain.

MedImmune is very concerned about the use of RFID technology for e-pedigree in California and its potential impact on its Biologic products. At present, we are not aware of any conclusive scientific evidence that demonstrates current RFID technology will pose little to no risk to Biologic medicines. Until such evidence has been established, the company cannot place products, utilizing RFID technology, in the marketplace without first demonstrating that RFID will not impact the quality, safety or efficacy of the products. We strongly believe that an additional delay to 2011 would allow the current e-pedigree requirement to be fully tested and implemented without jeopardizing the product or placing patients in harms way.

Finally, it is MedImmune's understanding that certain modifications or other changes to a product's Food and Drug Administration (FDA) approved packaging and labeling will require FDA review and approval. MedImmune is concerned that, due to the sheer volume of products that will require FDA review and approval, most companies will not be able to receive FDA approval within the next twelve months. Thus, a two-year delay would give companies' time to submit and the FDA sufficient time to review and approve the e-pedigree labeling for the thousands of product currently in the marketplace.

Thank you in advance for your consideration of our comments and MedImmune appreciates the Board formally considering a delay in the implementation of e-pedigree. Should you have any questions or need additional information, please contact Jamie Lacey, Senior Director, Public Relations, at (301) 398-4035, or visit our website at [www.medimmune.com](http://www.medimmune.com).

Sincerely,



Kevin McNelly  
Vice President, Supply Chain  
MedImmune, Inc

Cc: Virginia Herold, Executive Director, State Board of Pharmacy



P H A R M A

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MGI PHARMA  
5775 West Old Shakopee Road  
Suite 100  
Bloomington, Minnesota 55437-3174

(Telephone) 952-346-4700  
(Facsimile) 952-346-4800  
[www.mgipharma.com](http://www.mgipharma.com)

January 8, 2008

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

To the Members of the California State Board of Pharmacy:

As members of California's pharmaceutical supply chain, wholesalers, retailers, and providers are committed to safely and efficiently delivering medicines to patients. MGI PHARMA INC. takes very seriously our responsibility to provide millions of patients the drugs they need to prevent and treat diseases and illnesses. We share your belief that protecting the integrity of the pharmaceutical supply chain is essential.

At MGI, our work on the implementation of pedigree is progressing. We have taken a path forward that hopefully avoids any potential disruption on supply of critical medications to California patients as it enables downstream trading partners to position drug inventory with pedigree records. In addressing this very complex project, MGI is trying to address the serialization of cases and then, unit serialization with the latter work taking significantly more time.

The drug distribution history is an essential component to maintaining patient safety. MGI is committed to protecting those whom we serve, but we believe it will not be possible to implement electronic technologies to track the distribution at the serialized individual unit level of the distribution of prescription drugs within California by January 1, 2009. Accordingly, we respectfully request the Board of Pharmacy exercise its authority pursuant to Section 4163.5 of the Business and Professions Code to extend the date for compliance with the electronic pedigree requirements.

MGI appreciates all the hard work the Board has put into this effort, and we believe we have made substantial progress. But a failure to extend the deadline would place patient safety at risk by jeopardizing access to medicines for millions of Californians who depend on prescription drugs to prevent and treat cancer and other important diseases and conditions.

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

Sincerely,

Raymond Frost  
Director, Government Affairs  
MGI PHARMA, INC.





January 9, 2008

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

**RE: Request for a delay in the January 2009 implementation date of California's electronic pedigree requirements**

To The California Board of Pharmacy:

Mylan Inc. is one of the world's leading quality generic and specialty pharmaceutical companies. Following a significant expansion that was completed in 2007, Mylan offers one of the industry's broadest and highest quality product portfolios, a robust product pipeline and a global commercial footprint through operations in more than 90 countries.

Mylan is committed to working to ensure that the domestic and international pharmaceutical supply chain is secure and that public health is protected. Toward that goal, we have been actively engaged in seeking appropriate and effective means to address the threat of counterfeit and substandard medicines. Over the past four years, Mylan has committed significant resources to building an infrastructure that would provide a platform to support serialization, electronic pedigree and compliance with California requirements. In addition, we have done analysis of additional work that must be done in order to provide serialized and pedigreed product at the unit level. To date, Mylan has made substantial expenditures and committed thousands of hours of work in our efforts to build an infrastructure and to work toward compliance.

We greatly appreciate the work of the California Board of Pharmacy toward protection of public health and look forward to working with the Board and its staff on electronic pedigree and other issues. The challenges to compliance with California's electronic pedigree requirements, as we currently understand them, remain significant even though our efforts over the past four years have helped us to make major advancements toward our ability to comply. Our analysis, however, shows us that compliance with unit level serialization by January 2009 is not feasible and we respectfully request the Board to exercise its discretion and grant a delay immediately.

Below, we provide an overview of efforts to date and an outline for ongoing and future efforts toward compliance with California's electronic pedigree requirements.

### Mylan Efforts Toward Compliance/Understanding of California Requirements

*3a. A specific demonstration of all efforts expended thus far by the requesting party or parties, including timelines or specifications showing date(s) on which such efforts began and progress thus far, methods employed, costs and employee hours expended, and similar data, as well as a detailed demonstration of specific barriers or obstacles to compliance by January 1, 2009, including timeline(s) and specification of efforts between date of submission and January 1, 2009, any partial compliance to be achieved, etc.;"*

The following section includes a chronological summary of serialization efforts expended to date by Mylan. Some efforts were educational while others are barriers to achieving the January 1, 2009 compliance date. The most significant barrier was the implementation of an Enterprise Resource Planning (ERP) system in May of 2007. This effort was required to enable our ability to implement serialization but also consumed human and financial resources.

- **Engaged 3<sup>rd</sup> Party Consultant: June 2005 – March, 2006.**

Mylan performed a transdermal RFID serialization study, which resulted in: developing a strategy to equip packaging lines for serialization, RFID tag selection and placement, IT infrastructure requirements and pilot preparation. This study was performed to address Customer requirements on 4 SKUs. Taking into account the significant increase in packaging cost due to the addition of RFID tags, lack of standards and evolving technologies the decision was made to delay implementation.

- **Florida Pedigree Compliance Implementation: April – July 2006**

Mylan implemented a Florida pedigree application solution which was integrated to our legacy ERP system. This implementation was feasible due to the existence of several commercially available applications. Mylan's experience with this project has provided useful information as we consider California requirements.

- **Mylan ERP Implementation: June 2005 – June 2007**

Mylan went live on a leading ERP system in May of 2007 after two years of preparation. While the decision to implement was not made exclusively to address California ePedigree Law, the project did influence Mylan's ability to meet the January 1, 2009 compliance date in the following ways:

1. The Mylan legacy platform lacked integration, scalability and vendor support. For this reason, Mylan replaced the legacy ERP systems. The integrated ERP platform provides the foundation to support projects and technologies such as serialization, pedigree and Advance Ship Notices (ASNs). Without making this investment Mylan could not support unit serialization across our current customer and product base.
2. The significant investment in the ERP system diverted resources (staff and funding) required for a serialization program.

The team consisted of a significant number of Mylan resources and an equal number of implementation consultants.

- **Advanced Ship Notice (ASN): July 2007 – October 2007**  
With the implementation of an integrated world class ERP system Mylan is now positioned to respond to industry serialization requirements. ASNs, which historically were not provided, are now transmitted. This solution uses a manual method to apply and scan serialized labels. The current serialization effort will become scaleable across our customer base with the ASN Automation project set to kick-off in early 2008
- **ASN Automation: January 2008 – September 2008**  
The next phase of the project will scale ASN functionality to additional customers. This project will automate case and pallet level serialization for all Mylan trading partners. This project could potentially provide partial compliance by providing pallet and case level serialization using a document model pedigree.
- **Rx SafeTrack: May 2007 - Present**  
During 2007, Mylan has played an active role in the joint industry RxSafeTrack initiative, which was created as a forum for the industry to address challenges to track & trace efforts and find solutions. Mylan is a member of the executive committee and the steering committee of this initiative. Mylan will continue to support RxSafeTrack efforts, while understanding the difficulty in identifying a potential timeline for broad industry acceptance and utilization of track and trace technologies.
- **GPHA Pedigree Task Force: April 2007 - Present**  
During 2007, Mylan has played an active role in the Generic Pharmaceutical Association's Pedigree Task Force that is focused on developing consensus among generic manufacturers for how best to comply with California pedigree law.

### **Importance of Extension of the Implementation Date**

*3b. As an extension of or part of the same timeline(s), a specific demonstration of steps/efforts necessary between January 1, 2009 and January 1, 2011 that make it possible to comply by 2011 where it would not be possible to do so by 2009, i.e., evidence that this additional time is required for implementation, including costs to be expended, specific milestones to be accomplished by which dates, etc.;*

There are several key factors that influence which approach Mylan will take to address compliance. These requirements are critical inputs to the solution Mylan will implement to address this important issue. Implementing systems before standards/products are available and consensus is reached in the industry will increase risk and cost in the supply chain. It may also result in disruption of the supply chain without providing any additional security against counterfeiting.

Critical areas of concern where consensus is important are:

1. The Electronic Product Code Information System (EPCIS) standard is emerging as the solution of choice for wholesalers to comply with California pedigree law, but the complete portfolio of standards required for EPCIS implementation is, to date, incomplete. An example of such a non-ratified standard includes the EPCIS Discovery Service. The latest estimate for these collective standards to be ratified by EPCglobal is

sometime during 2008. Given that timeline, to expect an industry wide track and trace solution by January 1, 2009 is not feasible. This would lead to the need for a commercially available alternative to EPCIS track and trace (e.g. document model).

2. There is a lack of consensus from trading partners on the use of the document model as an alternative to EPCIS track and trace. While both methodologies require mass serialization there are significant investments required to implement the document model solution over an EPCIS Discovery Service.
3. Migration to unit serialization throughout the pharmaceutical industry has been inconsistent due to lack of clarification from retailers and wholesalers as to what data carriers (2D barcode or RFID tag) are acceptable for California compliance and what is required for use in internal supply chain processes. Consensus of requirements by the major pharmaceutical wholesalers is a required prerequisite to the effective implementation of mass serialization processes by manufacturers.

#### **Steps/Efforts to Compliance:**

With the ERP system successfully implemented and providing a platform to support serialization, Mylan can now focus on other business initiatives including compliance with California serialization. With experience from our transdermal assessment and input from suppliers Mylan estimates that compliance will have additional ongoing costs of tens of millions of dollars depending on technology used. Our estimates show that utilization of RFID tags would be five times the cost of barcodes.

Mylan intends to move forward with the following activities:

1. A 3<sup>rd</sup> party assessment to establish a timeline and plan for compliance. February – May 2008.
2. ASN automation project: January 2008 – September 2008.

Until this assessment is complete, we cannot give an accurate estimate of a timeline for compliance. However, it is safe to conclude from what we learned from our transdermal study in 2005/06, that unit level serialization across 45 lines by Jan 1, 2009 is not achievable. This is further complicated by the diversity of products packaged within Mylan's production facilities. These products represent multiple dosage forms and package types, including bottles, blister cards, aerosols, tubes, transdermal patches and injectables. Mylan operates a distribution center that will require the installation of serialization technology to adhere to the product pedigree and tracking requirements of both California and our major trading customers. With this level of complexity full compliance of all product lines by 2011 will be a challenge.

#### **Implementation in January 2009 Could Inadvertently Threaten to Public Health**

*3c. In order to show that any delay in implementation would be consistent with a first priority of the Board to protect the California public, a specific articulation or demonstration of how public protection would be served by delay, including any evidence that January 1, 2009 compliance would be detrimental to this interest or that a January 1, 2011 compliance date would better serve this interest, any anticipated developments between 2009 and 2011 that would better serve the Board's first priority to protect the public, and any additional interim measures*

*which a requesting party is committed to taking between 2009 and 2011 to further drug distribution security pending compliance on January 1, 2011.*

A change of this scale should be implemented in a coordinated and controlled manner to maintain product and supply integrity. The impact within and between trading partners is substantial. If implementation is not coordinated in a reasonable manner, supply of affordable quality products will be put at risk. If the January 2009 compliance date is upheld, the industry will find itself with varying degrees of readiness and multiple solutions.

The result could be supply chain disruptions, shortages of needed medicines, lack of availability of needed medications as well as confusion for the supply chain and consumers. The inability of even a small group of patients to acquire needed medications could have significant harm. When Medicare Part D was first implemented, numerous Californians had difficulty acquiring medications due to the new rules and regulations. Lack of availability of even limited numbers of medications due to lack of compliance with California's e-pedigree policies could affect significant numbers of California patients and would be counterproductive to the Board goals.

Without established industry standards and trading partner consensus, it is likely companies distributing pharmaceutical products will attempt to implement company specific solutions at the expense of an industry-wide interoperable track and trace model. This scenario runs contrary to the standardized processes currently utilized within pharmaceutical manufacturing distribution (GxP) and it is difficult to visualize, in this environment, achieving an interoperable track and trace solution across the industry.

An extension by the Board will allow standards to emerge, technology to develop and trading partners to reach consensus.

Mylan respectfully requests the Board of Pharmacy to immediately render a decision to delay the January 2009 implementation date for electronic pedigree.

Sincerely yours,

A handwritten signature in cursive script that reads "Harry A. Korman". The signature is written in dark ink and is positioned above the printed name and title.

Harry A. Korman,  
President, North America



The logo for the National Association of Chain Drug Stores (NACDS) features the acronym "NACDS" in a bold, serif font, centered within a dark rectangular box with a horizontal line above and below the text.

NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES



January 9, 2008

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

Dear Members of the California State Board of Pharmacy:

#### **Introduction**

On behalf of the members of California Retailers Association (CRA), California Pharmacists Association (CPhA), and the National Association of Chain Drug Stores (NACDS), who collectively operate nearly 100% of California's approximately 5,300 retail pharmacies, we thank the California State Board of Pharmacy ("Board") for the opportunity to comment on industry readiness for the January 1, 2009 implementation/compliance date for electronic pedigree requirements. Our members are the face of the pharmaceutical supply chain to California's citizens. For decades, pharmacists have been among the most trusted health care professionals. Our members are concerned, first and foremost, about the care and welfare of our patients.

#### **Industry Efforts to Date**

We have worked with renewed diligence over the past five years with both state and the federal governments, as well as with our trading partners to ensure that our patients receive safe and pure medications. We have instituted new business practices, participated in studies, and explored new technologies that have resulted in a highly secure pharmaceutical supply chain. We are working with GS1 and EPCglobal to develop standards that can further enhance distribution security within the supply chain.

Although we have always been diligent about securing the pharmaceutical supply chain, our activity in this area reached an unprecedented level of exposure in July 2003 when FDA requested industry input on how better to prevent counterfeit product from entering the supply chain. We organized a work group of over 50 companies – retailers, distributors, and manufacturers -- and provided a report to FDA Chairman Mark McClellan in November of that year. Many of the key findings from our report were incorporated into FDA Guidelines that were published the following summer. A copy of our report is attached to this document.<sup>1</sup> As a result of these efforts, the industry initiated a pilot project called Jump Start that was facilitated by Accenture.

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<sup>1</sup> Please note that the document represents efforts up to that time. Some of the document's conclusions and recommendations may not have industry support or consensus at this time.

Jump Start was designed to test the feasibility of RFID technology, determine how "ready" the technology was to meet the needs of the supply chain, and its utility to detect and thwart counterfeit product from entering the supply chain. The project was beneficial because it identified areas where the technology needed improvement, created a collaborative relationship with the FDA, and gave participants a chance to discuss technology adoption issues across the supply chain. A second Jump Start program was also initiated that included new participants as well.

In 2006 and 2007, a number of participants in the pharmaceutical supply chain participated in programs called On Track I and On Track II. Again, these research efforts were designed to assess the technology and business process challenges of serialization of products in the pharmaceutical supply chain.

Currently, we are engaged in a program called Rx SafeTrack. This initiative has participation of all segments of the pharmaceutical supply chain. These participants are actively engaged in evaluating technologies and business processes that will need to change in order for companies to handle multiple data carriers.

Our organizations and members have also spent countless hours working with EPCglobal in developing standards for EPC tags and the network it supports. In fact, we recently submitted a letter to GS1 US Healthcare to clarify a concern that has recently arisen regarding the possibility that a serial number could be different when it is read based on the data carrier from which it is read. If this is true, then it would require a great amount of work on the drug pedigree messaging standard to allow for both numbers to be included on the pedigree, as some manufacturers may decide to use both RFID and two-dimensional data matrix bar code on the same item.

We have sponsored several education conferences and included programming on the California law in conferences to help the industry understand the pedigree requirements and steps needed in order to comply with the requirements. Finally, senior level executives from our member companies have appeared before the Board to present their concerns and to update the board on the status of compliance efforts.

In addition to the above-mentioned collaborative efforts, our members have individually instituted new business practices, such as buying practices that require distributors to only sell products to a pharmacy that were directly purchased from a manufacturer. The safety and security this practice provides has been recognized by nearly half the states, and is more commonly known as the "Normal Channel of Distribution." These states have adopted legislation exempting from pedigree requirements prescription drug distributions within the Normal Channel of Distribution because of the safety and product integrity assurances that are inherent in these business practices.

#### **Industry Concerns**

Despite these efforts, it is clear that the full pharmaceutical supply chain will not be ready in time to meet the January 1, 2009 deadline of an interoperable electronic pedigree system that records each transaction resulting in change of ownership of a prescription drug. However, our concerns go beyond whether our supply chain partners will be ready by the deadline. Our primary concerns are as follows:

- Retail pharmacy is at the end of the supply chain and thus is completely dependent on upstream trading partners with respect to compliance with the electronic pedigree

requirements. The larger chain pharmacies have many upstream partners among manufacturers and distributors while most individual pharmacies do not have a business relationship with any pharmaceutical manufacturers. These pharmacies need to rely on their distributors to help them to comply with the electronic pedigree requirement. Presently, many pharmacies have no way of knowing how items will be serialized or how the pedigree will be sent. Most likely, we will not know until close to the compliance deadline, which will provide us with no time to prepare for our own compliance.

- There is a requirement for the system to be interoperable. It is unclear if all or just part of the system must be interoperable. This lack of clarity will result in manufacturers implementing numerous different approaches to serialization of their products and distributors looking for alternative options to comply with electronic pedigrees. This uncertainty adds not only significant cost at the levels of the supply chain below manufacturers, but also adds a great deal of complexity to receiving a pedigree, whether in a pharmacy or in a pharmacy distribution center. Unless there is one interoperable system from manufacturer to pharmacy, pharmacies and pharmacy distribution centers will need to purchase myriad equipment to read the data carriers that store the pedigree information, such as RFID tags, two-dimensional barcodes, or variations thereof. Having to comply with numerous pedigree technologies and read myriad data carriers will add significant costs to both equipment procurement and labor costs. Various types of equipment will have to be purchased, employees will have to be trained on the various types of equipment, and new business processes will have to be developed.
- As with the adoption of any new process or technology, there will be “bugs” in both the technology and business process redesign that cannot be anticipated until the industry reaches full scale production of product serialization.
- Concerns at the pharmacy level are more sensitive, as pharmacies are the only members of the pharmaceutical supply chain that must balance their resources between electronic pedigree compliance and direct patient care.

We believe that requiring compliance from pharmacies, the final link in the supply chain, on the same date as those above pharmacy in the supply chain must comply, will result in the industry being unable to address problems following implementation. Pharmacists and pharmacy personnel would be distracted with complex compliance issues, thus taking time away from providing pharmacy services to their patients.

Moreover, pharmacies would be responsible for “enforcing” the product and pedigree compliance of previous possessors of that product. If a product and a pedigree don’t match, they would not be able to accept the product into inventory until further research was done on the product. This research would take precious time from already busy pharmacists and pharmacy personnel, allowing less time for professional pharmacy responsibilities, such as patient counseling and prescription processing.

#### Need for Extension

We believe that an extension of the implementation date at the pharmacy and pharmacy distribution center level would provide for better patient protection than implementation at the same time as for manufacturers and distributors. An extension would allow pharmacies to implement technologies based on what is being implemented by the manufacturers and wholesalers, and would allow for trading partners to resolve “bugs” in the system so as not to compromise patient safety.

Consequently, we must respectfully request the Board exercise its authority, pursuant to Section 4163.5 of the Business and Professions Code to extend the date for compliance with the electronic pedigree requirements to January 1, 2011. Further, we request your assistance in seeking an extension of the implementation date for pharmacy distribution centers and pharmacies for one additional year, to January 1, 2012. This extension would allow pharmacies and pharmacy distribution centers to adopt and implement the necessary technologies and for the technology and business process changes to be resolved among manufacturers and wholesalers to avoid additional confusion at pharmacy distribution centers and pharmacies. This extension would allow pharmacies to start receiving pedigrees and pedigree-related information, ensure that processes in place are working properly, without having to balance compliance with new pedigree requirements against providing necessary patient care.

**Conclusion**

We thank the Board for the opportunity to share our concerns about the looming electronic pedigree compliance deadline. We ask that the Board extend the compliance deadline to January 1, 2011 for manufacturers and wholesalers. Further, we ask for the Board's assistance in extending the implementation date to January 1, 2012 for pharmacies and pharmacy distribution centers.

Sincerely,



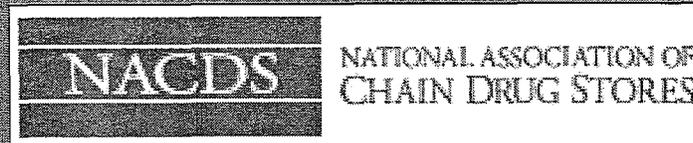
Lynn Rolston  
Chief Executive Officer  
California Pharmacists Association



Heidi Barsuglia  
Director of Government Affairs  
California Retailers Association



Kevin N. Nicholson, R.Ph., J.D.  
Vice President, Pharmacy Regulatory Affairs  
National Association of Chain Drug Stores



**NACDS Leadership Council**  
**Counterfeit Prescription Drug Initiative**  
Industry Points of View on Counterfeit Prevention

Alexandria • November 20, 2003

## Document Purpose

- As part of the FDA's counterfeit prevention initiative for prescription drugs, Commissioner Mark McClellan asked NACDS President, Craig Fuller, to assist the effort by providing the valued perspectives and insights of NACDS members.
- To support this request, NACDS commissioned the development of an interim report to assess the situation and a final report to provide potential solutions. The NACDS Leadership Council volunteered representatives from their companies to participate in developing an industry point of view on potential solutions to the prescription drug counterfeiting problem in the United States. 51 Participants from all supply chain segments, representing 24 NACDS Leadership Council companies, helped formulate an industry perspective.
- The purpose of this document is to provide the Food and Drug Administration (FDA) with an industry point of view on actions that can help combat the introduction of counterfeit pharmaceuticals into the United States drug distribution system.
- These perspectives were developed based on input from representatives of NACDS Leadership Council companies, including manufacturers, wholesalers, and community pharmacies. These perspectives are based on opinions across supply chain participants and may not reflect the positions of specific participants in certain instances.
  - The NACDS Leadership Council companies may not be in complete agreement with all statements and recommendations made
  - The NACDS Leadership Council companies may have further statements and recommendations that they would like to make to the FDA on behalf of their individual organizations
- The FDA should use this information as a directional barometer for current supply chain sentiment.
  - Detailed cost benefit analyses have not been conducted in conjunction with this document
  - Cost implications, across the supply chain, require further consideration and review prior to executing any recommendations contained in this document

## Contents

- **Executive Summary**

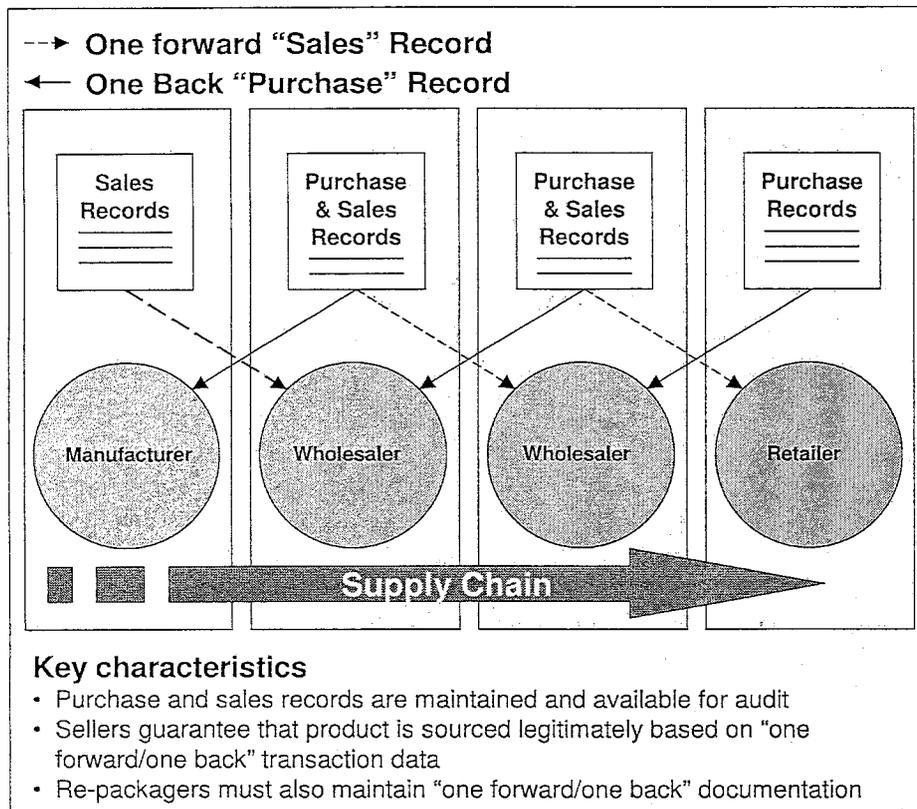
- Project Background

- Industry Recommendations

- Next Steps

In the short-term, a “One Forward/One Back” approach to drug authentication would help ensure accountability for each step in the supply chain.

## One Forward/One Back Authentication Model



<sup>1</sup>Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities.

## Interim Track and Trace Assurance

- Supply chain members must maintain transaction documentation for the immediate previous source and the immediate subsequent recipient of drug products
  - FDA should mandate for high risk drug class(es) – FDA will specify exactly what drugs will require “one forward/one back” authentication
  - Analogous to the system adopted by food distributors as part of Public Health Security And Bio-Terrorism Preparedness And Response Act of 2002
- “One forward/one back” requirements extend from the manufacturer to the pharmacy company but not to store level or patient purchaser
- Regulators have the right to audit the “one forward/one back” transaction records all the way back to the manufacturer (e.g., spot checks, counterfeit investigations)
- Re-packagers<sup>1</sup> will be required to support the “one forward/one back” authentication requirements
- Seller contractually guarantees that the invoiced prescription drugs came from a specific supplier or set of suppliers and gives purchaser the right to audit the previous transaction(s)

## Counterfeiting is a growing problem in the U.S. prescription drug supply chain that will require a multi-faceted prevention approach.

### Current Situation

- Both legal and illegal arbitrage opportunities have become prevalent in the U.S. prescription drug supply chain due to the unprecedented prices and volume of today's breakthrough drugs, a complex/non-linear supply chain, and multi-channel pricing.
- These arbitrage opportunities have gained the attention of legitimate players and criminals alike, creating perverse incentives that support grey market activity across the supply chain.
- Stopping drug diversion and counterfeiting is a difficult task. Gaining control over counterfeit drug flow may require significant revision to the regulation, structure and practices of the U.S. supply chain.
- Although drug counterfeiters today are more sophisticated and better organized than ever before, there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats.
- There is no single "magic bullet" against the growing number of sophisticated counterfeiters:
  - A multi-pronged strategy will prove more effective in securing the drug supply than any single method
  - A "one-size-fits-all" approach is unlikely to work for all parts of the complex prescription drug supply system and could drive significant costs
- Resolving the U.S. counterfeit drug problem will require participation and collaboration by players across the supply chain, adequate legislation and law enforcement, and the implementation of emerging technologies.

**Although counterfeit penetration estimates vary significantly, even the lower estimates are significant, representing at least \$7 billion of the global drug market.**

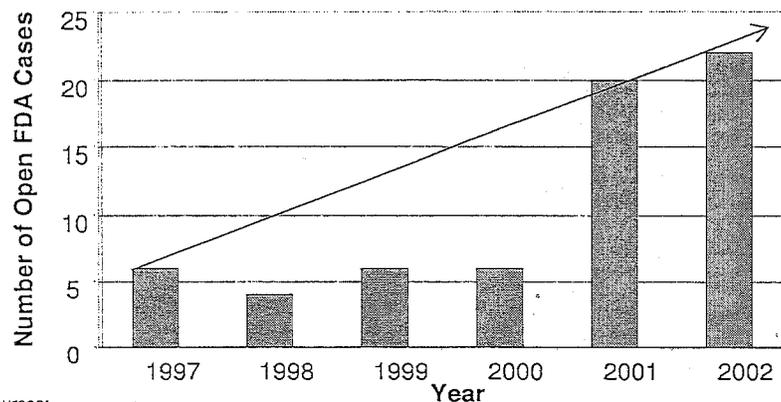
## Counterfeiting: A Growing Problem

### Dollar Value of Counterfeit Drug Estimates

| Est. % Counterfeit Drugs | Dollars of Market* |
|--------------------------|--------------------|
| 2% (IFPMA estimate)      | \$6.5 B            |
| 4%                       | \$13.1B            |
| 6%                       | \$19.6 B           |
| 8% (WHO estimate)        | \$26.2 B           |
| 10%                      | \$32.7 B           |

\* Based on global drug market of \$327 billion.<sup>1</sup>

### Increase in Counterfeit Drug Cases



Sources:

- 1) "What's in that Pill?" Business Week, June 18, 2001
- 2) FDA website

## Counterfeiting Facts

- Counterfeiting is difficult to detect and investigate; therefore, estimates on counterfeit activities vary.
  - The International Federation of Pharmaceutical Manufacturers Association (IFPMA) in Geneva estimates that 2% of the drugs sold each year are counterfeit.
  - The World Health Organization (WHO) estimates that 5-8% of drugs worldwide are counterfeit.<sup>1</sup>
- Based on these estimates, counterfeit drugs could represent \$7 billion - \$26 billion of the \$327 billion global drug market.
- The FDA counterfeit drug investigations have increased to at least 20 per year since 2001, after averaging only about 5 per year through the late 1990's.<sup>2</sup>
- FDA investigations have so far netted 44 arrests and 27 convictions with a number of criminal investigations ongoing.<sup>2</sup>

**It is important to define the different types of counterfeiting before reviewing potential solutions.**

## Counterfeiting Defined

| Type        | Description   | Example  |
|-------------|---|--|
| Fake Drugs  | Drugs without APIs <ul style="list-style-type: none"> <li>• Drugs missing active ingredients</li> </ul>   | Neupogen, a cancer drug, containing only saline solution (2001)  |
|             | Diluted Drugs <ul style="list-style-type: none"> <li>• Diluted products</li> </ul>  | Epogen, a cancer and AIDS drug, with 20 times less the active ingredient (2002)  |
|             | Accurate Knock-offs <ul style="list-style-type: none"> <li>• Drugs with accurate compositions made through reverse engineering</li> </ul>                                 | Fake Dolex, generic aspirin, manufactured in Columbia (2001)   |
|             | Contaminated Drugs <ul style="list-style-type: none"> <li>• Drugs with unintentional, lethal impurities</li> <li>• Drugs with intentional, lethal contaminants</li> </ul> | Tampered Gamimune, an immunity drug, with extremely high levels of bacteria (2002)<br>A children's cough syrup containing up to 60% antifreeze leading to 89 deaths (1995) |
| Fake Labels | <ul style="list-style-type: none"> <li>• Labels with wrong drug name</li> </ul>   | Combivir labels placed on Ziagen tablets and vice versa (2002)   |
|             | <ul style="list-style-type: none"> <li>• Labels misrepresenting product potency</li> </ul>  | Vials of 2,000 U/mL Procrit, an antiviral, relabeled as 40,000 U/mL (2003)   |
|             | <ul style="list-style-type: none"> <li>• Labels extending the expiration dates</li> </ul>   | Antibiotics in Venezuela with 2 years added to its shelf life (~1999)  |

**Based on economic incentives and lack of effective policies and regulations, significant arbitrage opportunities exist to create a gray market that enables/supports counterfeiting activities.**

## Counterfeiting Enablers

|                     |   |
|---------------------|---|
| Business Practices  | <ul style="list-style-type: none"> <li>• <b>Financial incentives that work contrary to the strategic intent of the manufacturer/primary wholesaler.</b> Increased drug orders from thousands of licensed wholesalers, legitimate or illegitimate, translate to increased sales commissions.</li> <li>• <b>Repackaging for resale.</b> Businesses that resell prescription drugs to other unaffiliated business entities, sometimes break drugs down to pill and vial levels destroying the manufacturing packaging integrity and creating an entry point for diverted and counterfeit drugs.</li> <li>• <b>Economic incentives and difficulty in identifying counterfeits at the wholesaler level.</b> The Institutional Pharmacy (IP) diversion mechanism allows wholesalers to buy drugs at a lower price and sell them at a profit. Since there is little incentive for the wholesale market to assume responsibility for the source of the drugs purchased, counterfeit drugs can be easily introduced at this point.</li> <li>• <b>Lack of process to verify institutional pharmacy sales.</b> IP supplier can claim that it services 1,000 beds, and IP will receive manufacturers' discounts. No entity is accountable for confirming that the beds actually exist or that the number of IPs listed under a single institution is accurate.</li> </ul> |
| Regulatory Measures | <ul style="list-style-type: none"> <li>• <b>No visibility or monitoring of IP transactions or records.</b> IP can sell unchecked extraordinary amounts of drugs through its illegal diversion mechanism.</li> <li>• <b>Loophole in Authorized Distributor of Record (ADR) designation.</b> ADRs are exempt from providing pedigree papers causing ADR wholesalers to not provide pedigree for drugs purchased from other wholesalers, which may allow concealed counterfeit and diverted drugs to reach end-users.</li> <li>• <b>Low barriers for criminals to enter the wholesale market.</b> Weak licensing process allows individuals to easily enter the wholesale market.</li> <li>• <b>Inadequate administrative penalties for drug counterfeiting and diversion.</b> Profits in the millions can be made from diverted or counterfeit drugs, while fines, according to former Florida legislation, could only range to \$5,000 for the most severe violations. If licenses are revoked, criminals can easily get another license from another state.</li> <li>• <b>Inadequate criminal penalties for drug counterfeiting and diversion.</b> First-time offenders diverting drugs from a hospital or a charity could be prosecuted only for a second degree misdemeanor with a maximum sentence of 60 days incarceration and a \$500 fine.</li> </ul>   |

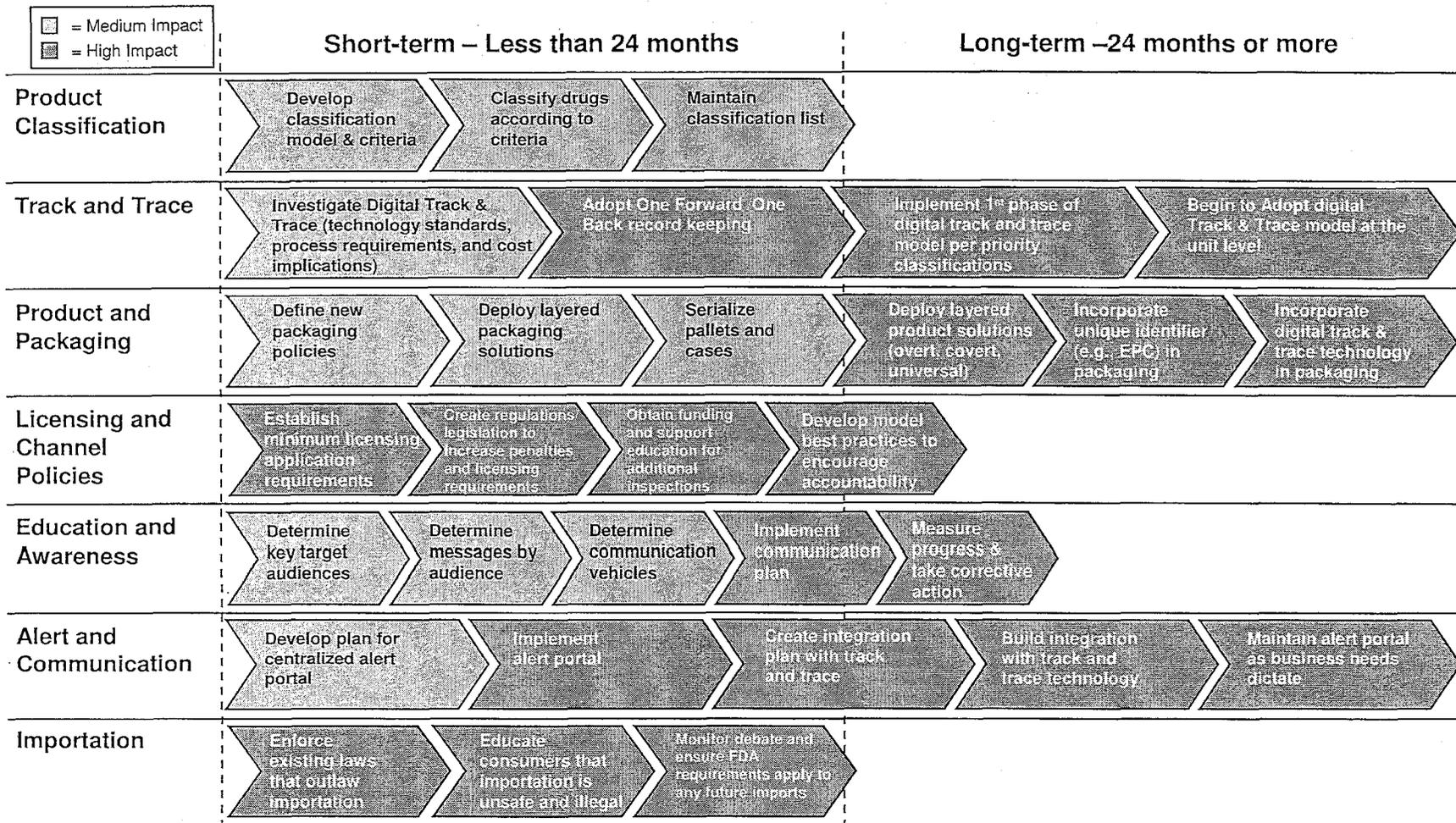
## The FDA and industry should collaborate to define an anti-counterfeit plan to prevent and minimize risks related to counterfeit prescription drugs.

### Industry Recommendations

- The FDA and industry should collaborate to define a **uniform prescription drug classification** that categorizes drugs according to counterfeiting risk and patient safety criteria. The classification should help focus resources on current and future high-risk drugs and provides a common approach for prioritizing anti-counterfeiting activities across products.
- The industry should proactively develop and implement a **technology-enabled track and trace** system that extends beyond the 'one-step forward, one-step back' method to ensure drug authenticity throughout the supply chain.
- Industry participant should implement **multi-level anti-counterfeiting measures** for original and secondary packaging of high risk drugs.
- The industry participants should create market-based model best practices for **purchasing and channel sales policies** to discourage counterfeiting and support FDA-minimum licensing requirements, tougher penalties, and frequent inspections.
- The FDA should collaborate with industry to launch a comprehensive **anti-counterfeiting education and awareness** campaign that informs all stakeholders in the pharmaceutical supply chain, as well as the public, about the personal and financial risks associated with counterfeit drugs.
- The FDA should develop and manage a centralized **counterfeiting alert and communication** system and process that effectively informs supply chain members about new counterfeiting activity.
- The FDA should work with Federal and State agencies to **enforce existing importation laws and educate** consumers, as well as legislators and companies, on the safety risks and illegality associated with drug importation.

Ultimately, an industry-wide digital track and trace system should be developed to monitor supply chain product flow and be complemented by new laws, regulations and enforcement to reduce drug counterfeiting.

## NACDS Counterfeit Prescription Drug Initiative Migration Plan



The NACDS Leadership Council initiated a two-phase effort to assemble an industry perspective on policy and technology solutions for preventing prescription drug counterfeiting.

## Phases 1 and 2: Objectives and Outcomes

### Phase 1

Assess Current Situation  
and Value Chain Landscape

08/11 – 09/08

#### Objectives

- Achieve a common understanding of the existing situation across key segments of the prescription drug supply chain
- Gain awareness on the types of counterfeiting and where they occur within the supply chain
- Identify preliminary regulatory, business practice, and technology prevention gaps
- Understand relevant counterfeiting cases and prevention measures

#### Outcomes

- Interim report submitted to the FDA to provide an overview of the counterfeiting situation across the U.S. prescription drug supply chain
- Prevention gaps that exist
- Preliminary list of improvement opportunities

### Phase 2

Capture Industry Perspectives and  
Recommended Migration Path

10/06 – 11/14

- Refine and gain agreement on list of prevention opportunities identified in Phase 1
  - Consider the strategic, financial, and operational implications associated with each prevention opportunity
  - Qualitatively assess the tolerance/ability across the supply chain to institute change and pay for implementation and ongoing operational costs
  - Provide industry insight to the FDA on realistic/feasible short- and long-term prevention solutions
- 
- Uniform industry point-of-view and insights for FDA review on realistic/viable solutions required to prevent counterfeiting
  - Perspective on short-term and long-term solution migration path and industry mobilization

Three collaborative working groups were established for Phase 2 to create an industry perspective on short- and longer-term prevention methods.

## Working Groups and Focus

|   | Regulatory and Enforcement Measures  | Business Policies and Practices<br><small>(to the extent allowed by anti-trust laws)</small>  | Technology Prevention Measures   |
|---|--|---|--|
| <b>Team Charter</b>                           | <ul style="list-style-type: none"> <li>Refine and gain agreement on legislative and regulatory changes that will be required to ensure counterfeit prevention across supply chain segments</li> <li>Develop point of view on realistic short- and longer-term solution migration path</li> </ul>   | <ul style="list-style-type: none"> <li>Refine and gain agreement on the high potential business practice and policy actions that can be taken by each supply chain segment</li> <li>Develop point of view on realistic short- and longer-term solution migration path</li> </ul>  | <ul style="list-style-type: none"> <li>Refine and gain agreement on high potential technologies that can be implemented to enable counterfeit prevention capabilities</li> <li>Develop point of view on realistic short- and longer-term solution migration path</li> </ul>  |
| <b>Primary Subjects Discussed<sup>1</sup></b> | <ul style="list-style-type: none"> <li>Implement more stringent wholesale licensing process</li> <li>Increase inspections of wholesalers, institutional pharmacies and re-packagers who repackage for resale</li> <li>Increase regulation of internet pharmacies</li> <li>Increase administrative and criminal penalties with enforcement measures</li> <li>One forward/One back track and trace methods</li> <li>Minimize illegal drug importation</li> </ul> | <ul style="list-style-type: none"> <li>Consider opportunities to ensure safe and efficient wholesale distribution practices</li> <li>Develop counterfeiting alert and action processes to deploy Chaindrugstore.net as an alert system and communication tool to streamline information across the supply chain</li> <li>Educate regulators on counterfeit drug activity</li> <li>Educate public on risks associated with using drugs from alternative retail channels</li> <li>Develop layered anti-counterfeiting or authentication taggants at a package and product level</li> <li>Investigate Unit of Use packaging as an opportunity to eliminate fraudulent repackaging and reduce counterfeiting</li> </ul> | <ul style="list-style-type: none"> <li>Incorporate a digital technology-supported tracking functionality into a national database/repository of Rx drugs and transactions</li> <li>Incorporate lot tracking functionality into a national database/repository for Rx drugs and transactions</li> <li>Deploy Chaindrugstore.net as an alert system and communication tool to stream line information across the supply chain</li> </ul> |

<sup>1</sup> These statements represent the primary subject matter discussed during meetings and conference calls and are NOT necessarily the teams' points of view or recommendations

**51 Participants from all supply chain segments, representing 24 NACDS Leadership Council companies, helped formulate a collective industry perspective.**

## Current Working Group Participation

### Regulatory and Enforcement Measures

#### Facilitators

- Don Bell (NACDS)
- Mary Ann Wagner (NACDS)
- Ken Dickman (Accenture)

#### Leadership Council Company Representatives

- Bruce Gordon (Albertsons)
- Gary Dolch (EVP - Quality and Regulatory Affairs, Cardinal Health)
- Richard Kirkendall (VP - Global Regulatory Compliance, Cardinal Health)
- Stephen Reardon (Cardinal Health)
- Mike Ayotte (Director, Govt. Affairs, CVS/pharmacy)
- Matthew Leonard (VP Pharmacy Purchasing, CVS/pharmacy)
- Ralph Progar (VP, Pharmacy Relations, Eckerd)
- Sandy Sifferlen (Legal Counsel QA, Eli Lilly)
- John DelGiorno (VP, Government Affairs, GlaxoSmithKline)
- Anita Ducca (Healthcare Distribution Management Assoc.)
- Sherry Haber (VP, Government Affairs, Healthcare Distribution Management Assoc.)
- Mark Polli (Dir., Pharmacy Services, Hannaford Bros.)
- Courtney Billington (VP, Operations Excellence, Johnson & Johnson)
- Paul Daly (VP, Technical Operations, Johnson & Johnson)
- Juanita Hawkins (VP, Quality Assurance, Johnson & Johnson)
- Karen Paul (Ops Excellence Leader, Johnson & Johnson)
- Dave Fong (Long Drug Stores)
- Frank Scorpiniti (Long Drug Stores)
- Michael Weintraub (NDC)
- Jim Carey (Executive Director, Health Policy, Novartis Pharmaceuticals)
- Jeff Chasnow (Senior Corporate Counsel, Pfizer)
- Phil Keough (Sr. VP, Pharmacy Operations, Rite Aid)
- Michael Yount (Gov Affairs Attny, Rite Aid)
- Dennis O'Dell (Corporate VP, Health Services, Walgreens)

### Business Policies and Practices

#### Facilitators

- Steve Perlowski (NACDS)
- Ken Dickman (Accenture)
- Tony Ebbole (Accenture)

#### Leadership Council Company Representatives

- John Fegan (VP, Pharmacy, Ahold USA)
- Bruce Gordon (Albertsons)
- Dan Salemi (Dir., Pharmacy Svcs., Albertsons)
- Rodney Bias (Director, Corporate Security, AmerisourceBergen)
- Chris Zimmerman (VP, Corporate Security, AmerisourceBergen)
- Matt Cullen (Director of Trade Administration, Aventis)
- Rodney Newfrock (Sr. Mgr., Pharmacy Development, Aventis)
- Mark Parrish (Group President, Cardinal Health)
- Felix Zyra (Director, Pricing, Eckerd)
- John Phillips (Mgr. Trade Accounts, Eli Lilly)
- Jack Fish (VP, Sales and Operations, GlaxoSmithKline)
- Mark Polli (Dir., Pharmacy Services, Hannaford Bros.)
- Lisa Clowers (VP, Supply Chain and Technology, Healthcare Distribution Management Assoc.)
- Courtney Billington (VP, Operations Excellence, Johnson & Johnson)
- Paul Daly (VP, Technical Operations, Johnson & Johnson)
- Juanita Hawkins (VP, Quality Assurance, Johnson & Johnson)
- Dave Fong (Long Drug Stores)
- Frank Scorpiniti (Long Drug Stores)
- Ralph Petri (Sr. VP, Pharmacy and Logistics, Kerr Drug)
- Joe Courtright (May's)
- Greg Yonko (Sr. VP, Purchasing, McKesson)
- David Bellaire (EVP Research, NDC)
- Michael Weintraub (NDC)
- Tom McPhillips (VP, U.S. Trade Group, Pfizer)
- Mark deBruin (Sr. VP, Pharmacy Svcs., Rite Aid)
- David Vucurevich (VP, Pharmacy Purchasing, Rite Aid)
- Mike Bettiga (Sr. VP, Retail Health, Shopko)
- Dennis O'Dell (Corporate VP, Health Services, Walgreens)

### Technology Prevention Measures

#### Facilitators

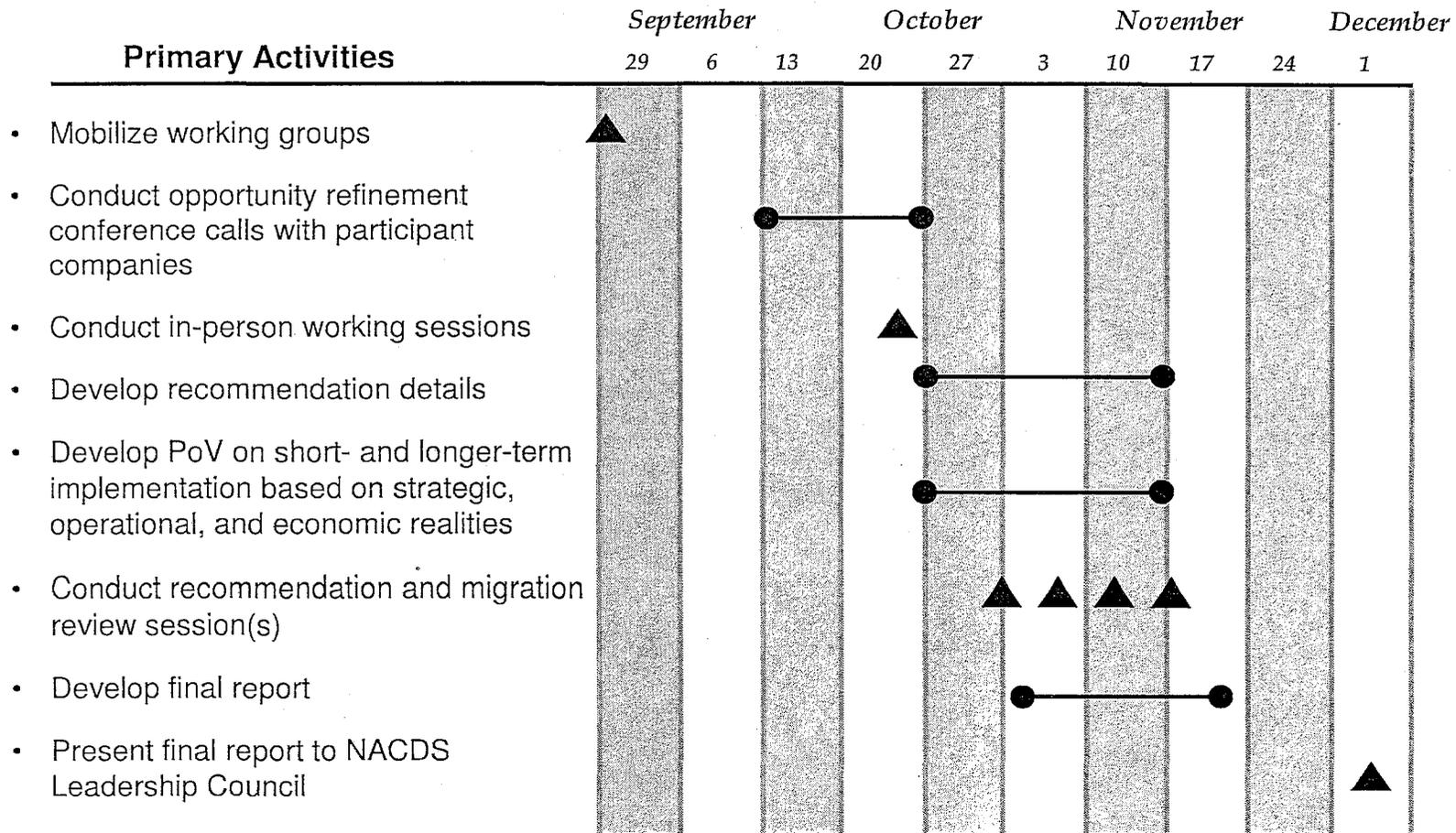
- Todd Grover (Chaindrugstore.net)
- Mike Mojica (Accenture)
- Scott Albrecht (Accenture)

#### Leadership Council Company Representatives

- Bruce Gordon (Albertsons)
- Michael Scrase (Director IT Business Integration, Cardinal Health)
- Dr. Rafik Bishara (Director, Quality Management, Eli Lilly)
- Paul Clayton (VP, Regional Logistics, GlaxoSmithKline)
- Mark Polli (Dir., Pharmacy Services, Hannaford Bros.)
- John Howells (Assoc. Dr., E-Business Dev., Healthcare Dist. Mgt. Assoc.)
- Paul Daly (VP, Technical Operations, Johnson & Johnson)
- Courtney Billington (VP, Operations Excellence, Johnson & Johnson)
- Juanita Hawkins (VP, Quality Assurance, Johnson & Johnson)
- David Howard (Dir. Package Development, Johnson & Johnson)
- Dave Fong (Long Drug Stores)
- Frank Scorpiniti (Long Drug Stores)
- Joe Courtright (May's)
- Keith Mallonee (CIO, McKesson)
- Michael Weintraub (NDC)
- Rich Hollander (Director, Pharmacy Services, Pfizer)
- Don Davis (Sr. VP, Chief Info Officer, Rite Aid)
- Scott Culver (Director, Pharmacy Warehousing, Wal-Mart)
- Dennis O'Dell (Corporate VP, Health Services, Walgreens)

Developing the collective industry perspectives required a series of meetings and joint conference calls over an eight week period.

## Phase 2 Time Line



## Contents

- Executive Summary

- Project Background

- **Industry Recommendations**

- Next Steps

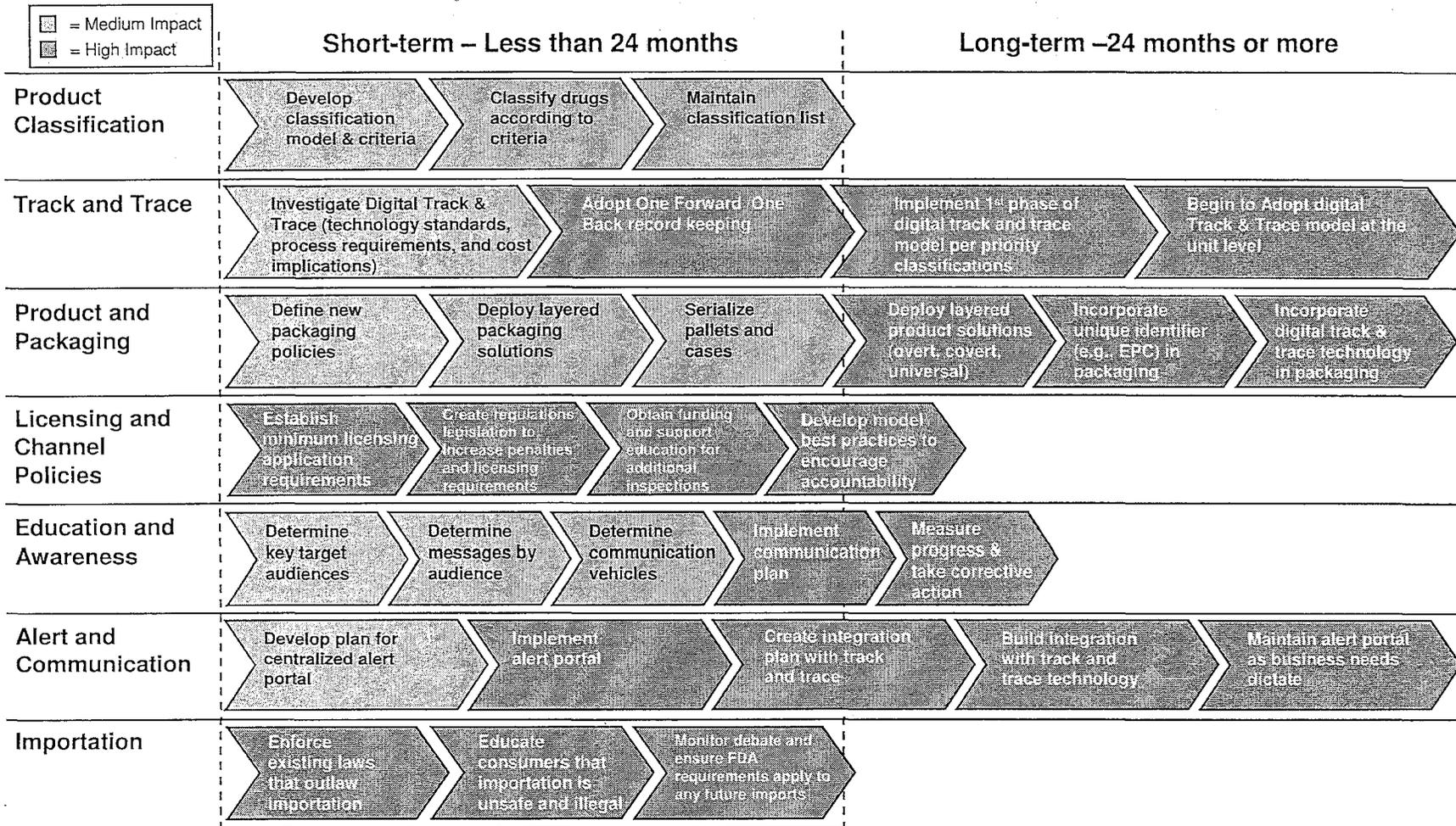
**NACDS Leadership Council company representatives developed a set of recommendations that when implemented together should significantly reduce the U.S. drug-counterfeiting problem.**

## **Industry Recommendations**

- The FDA and industry should collaborate to define a **uniform prescription drug classification** that categorizes drugs according to counterfeiting risk and patient safety criteria. The classification should help focus resources on current and future high-risk drugs and provides a common approach for prioritizing anti-counterfeiting activities across products.
- The industry should proactively develop and implement a **technology-enabled track and trace** system that extends beyond the 'one-step forward, one-step back' method to ensure drug authenticity throughout the supply chain.
- Implement **multi-level anti-counterfeiting measures** for original and secondary packaging of high risk drugs.
- The industry participants should create market-based model best practices for **purchasing and channel sales policies** to discourage counterfeiting and support FDA-minimum licensing requirements, tougher penalties, and frequent inspections.
- The FDA should collaborate with industry to launch a comprehensive **anti-counterfeiting education and awareness** campaign that informs all stakeholders in the pharmaceutical supply chain, as well as the public, about the personal and financial risks associated with counterfeit drugs.
- The FDA should develop and manage a centralized **counterfeiting alert and communication** system and process that effectively informs supply chain members about new counterfeiting activity.
- The FDA should work with Federal and State agencies to **enforce existing importation laws and educate** consumers, as well as legislators and companies, on the safety risks and illegality associated with drug importation.

Ultimately, an industry-wide digital track and trace system should be developed to monitor supply chain product flow and be complemented by new laws, regulations and enforcement to reduce drug counterfeiting.

## NACDS Counterfeit Prescription Drug Initiative Migration Plan



**Product classification recommendations call for the FDA to work with Industry to define high risk drug classification criteria and for the FDA to maintain an aggregate drug classification list.**

## Recommendation Categories

| Category                                   | Recommendations  |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
| <b>Track and Trace</b>                     | <ul style="list-style-type: none"> <li>• Revise PDMA Requirements to adopt 'One Forward, One Back' Transaction Authentication</li> <li>• Create digital Track and Trace model</li> </ul>   |
| <b>Product and Packaging</b>               | <ul style="list-style-type: none"> <li>• Revise FDA packaging regulations</li> <li>• Do not mandate unit-of-use packaging for anti-counterfeiting measures</li> <li>• Develop model best practices for anti-counterfeiting measures</li> </ul>   |
| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• Develop a centralized alert portal</li> </ul>   |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**Developing a standard anti-counterfeiting drug classification system that enables appropriate focus across drugs with different risk priorities is important for efficient and effective change.**

## **Product Classification – Summary**

- Treating all prescription drugs equally for anti-counterfeiting purposes is cost-inefficient; only a limited number of drugs have the significant volume or profit incentives sought by counterfeiters.
- Introducing an anti-counterfeiting product classification and implementing solutions that vary in degree by drug class will reduce the cost pressures to industry participants by prioritizing the deployment of resources accordingly.
- With no current industry model, the FDA should establish an “industry work group” and take the initiative to facilitate creation of a uniform product classification model that uses:
  - Statistically-driven predictive modeling to identify high-risk product segments
  - Qualitative experience to develop classification criteria that complement statistical/quantitative modeling
- FDA regulation and market-based business practices should use the classification system as an integral part of anti-counterfeiting program implementation.
- As track-and-trace technology such as EPC and RFID evolves, the product classification system should be rendered obsolete. However, the classification system should be used for the phased implementation of RFID.

**Today, there is no uniform tool that helps government or industry prioritize anti-counterfeiting efforts; state legislators and industry are beginning to set different precedents.**

## **Product Classification – Situation and Complications**

- Some prescription drugs carry a higher risk of counterfeiting than others (e.g., high-priced injectables and HIV drugs).
- Many supply chain members, based on their experience, currently categorize products for anti-counterfeit scrutiny because subjecting all prescription drugs to more intensive evaluation would be cost prohibitive and inefficient.
- As with most counterfeiting criminal activity, drug counterfeiters continuously adjust their practices to overcome known business practices and regulations; therefore, it is important to have an evolving classification system that enables supply chain participants to focus their activities.
- Without a standard drug classification system, it is conceivable that each company and state will address drug prioritization/counterfeiting problems differently with varied results.

**Classifying drugs by counterfeiting risk probability will allow the FDA and industry to focus time, resources, and efforts on a limited, but evolving, set of products.**

## Product Classification – Recommendations

| Regulation and Business Practices | Recommendation   | Components   | Objectives  | Implications for Success   |
|-----------------------------------|--|--|---|--|
|                                   | <b>FDA and Industry Define High-Risk Classification Criteria</b> | <ul style="list-style-type: none"> <li>• The FDA and industry should collaborate to develop a statistically driven, qualitatively refined anti-counterfeiting drug classification criteria               <ul style="list-style-type: none"> <li>– Multi-variant, statistical analysis can be used as a predictive model for drug classification</li> <li>– Qualitative criteria, such as product attributes (e.g., injectables), should complement the quantitative model</li> <li>– The FDA should establish an industry working group to create drug classification definitions and criteria</li> </ul> </li> <li>• Manufacturers, distributors and wholesalers should use the drug classification criteria to create their own list of high risk drugs               <ul style="list-style-type: none"> <li>– Industry participants should use the classification to help prioritize their own anti-counterfeiting efforts</li> <li>– Use classification method to help prioritize product for conversion to a longer-term track and trace system</li> </ul> </li> <li>• Access to ongoing criteria updates should be provided through electronic alert and communication system</li> </ul> | <ul style="list-style-type: none"> <li>• Develop a tool that helps establish a common basis for prioritizing and/or classifying drugs for the purpose of implementing anti-counterfeiting measures</li> </ul> | <ul style="list-style-type: none"> <li>• Product categorization according to risk would require constant maintenance to keep up with shifts in criminal activity and introduction of new drugs</li> <li>• The FDA needs to facilitate industry collaboration to develop and implement classification system (i.e., development, maintenance, use, evolution to digital track and trace)</li> </ul> |

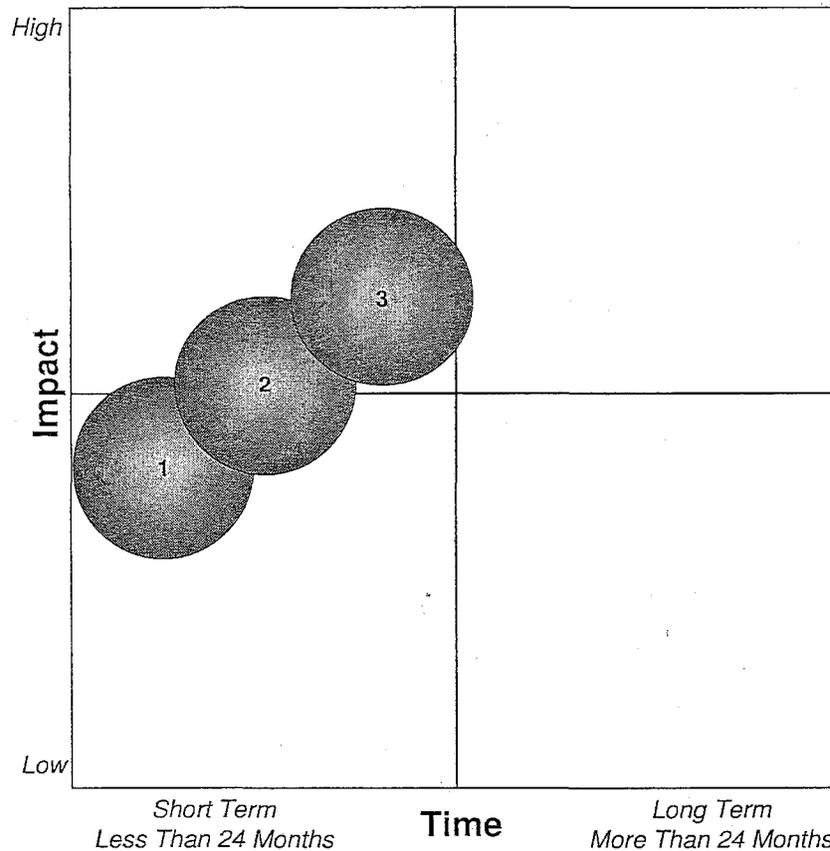
**The FDA should maintain an aggregate, centralized list of drugs categorized by the drug classification to help facilitate implementation of required anti-counterfeiting measures for specified drugs and classes of drugs.**

## Product Classification – Recommendations

| Recommendation  | Components  | Objectives   | Implications for Success   |
|---|---|--|--|
| <div data-bbox="134 711 170 1219" data-label="Text" style="writing-mode: vertical-rl; transform: rotate(180deg);">Regulation and Business Practices</div> <p><b>FDA Keeps and Maintains an Aggregate Drug Classification List</b></p> | <ul style="list-style-type: none"> <li>• FDA should use the drug classification criteria to categorize all prescription drugs into a centralized list</li> <li>• FDA should maintain and continually update this aggregate list of prescription drugs by risk category until an industry wide digital track and trace system is implemented               <ul style="list-style-type: none"> <li>– Provide industry participants with a list of specific drugs effected by any FDA mandates (drugs may differ by mandate)</li> <li>– Communicate to industry participants about updates to the list of drugs effected by any mandates (drugs may be added or subtracted)</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Develop methodology to ensure that all drugs are NOT treated equally and to ensure the appropriate focus across different classes of drugs</li> </ul> | <ul style="list-style-type: none"> <li>• An effective modeling and review process will need to be developed</li> <li>• Measures must be taken to prevent counterfeiters from gaining access to the aggregate drug classification listing and to ensure that the listing is not publicly available</li> <li>• The FDA should continually evaluate the need for the classification as the national, digital track and trace system drives the list toward obsolescence</li> <li>• FDA and industry will need to work together to determine how the aggregate classification list is best maintained and updated</li> <li>• This centralized, national classification drug listing is needed to create consistency in the handling of certain drugs as it will pre-empt differing state laws and requirements intended to promote anti-counterfeiting measures</li> </ul> |

**Product classification can be defined fairly quickly, enabling an immediate focus on anti-counterfeiting activity.**

## Product Classification – Migration Plan



### Critical Steps

1. Develop statistically driven, qualitatively refined anti-counterfeiting drug classification model and criteria ~ Complete and implement by early 2004
2. Classify all new and existing drugs
3. Update the classification listings on a regular basis (e.g., monthly) and inform industry of specific products affected by FDA requirements.

**Track and Trace recommendations include revising PDMA to establish new authentication requirements in the short-term, while pursuing a digital track and trace model in the long-term.**

## Recommendation Categories

| Category                                   | Recommendations  |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
| <b>Track and Trace</b>                     | <ul style="list-style-type: none"> <li>• Revise PDMA Requirements to adopt 'One Forward, One Back' Transaction Authentication</li> <li>• Create digital Track and Trace model</li> </ul>   |
| <b>Product and Packaging</b>               | <ul style="list-style-type: none"> <li>• Revise FDA packaging regulations</li> <li>• Do not mandate unit-of-use packaging for anti-counterfeiting measures</li> <li>• Develop model best practices for anti-counterfeiting measures</li> </ul>   |
| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• Develop a centralized alert portal</li> </ul>   |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**Drug counterfeiting can be significantly reduced by using new Track and Trace practices and capabilities that replace current pedigree practices.**

## **Track and Trace – Summary**

- The ability to ensure the authenticity of prescription drugs is essential in preventing the threat of counterfeit prescription drugs.
- In the short-term, adoption of new industry practices and, in some instances, FDA regulation will be required to improve drug authenticity through track and trace.
  - One forward one back authentication practices
  - Revision of PDMA authentication requirements
- Ultimately, ensuring drug authenticity will require the development of a digital track and trace capability across the U.S. prescription drug supply chain.
- Future track and trace technologies that ensure drug authenticity will require the development of industry minimum standards and adoption of new IT systems infrastructure based on cost/benefit analyses.
- A well-choreographed approach to industry regulation, changes in business practices, and adoption of new technology is necessary for enabling track and trace capabilities in both the short- and longer-terms.

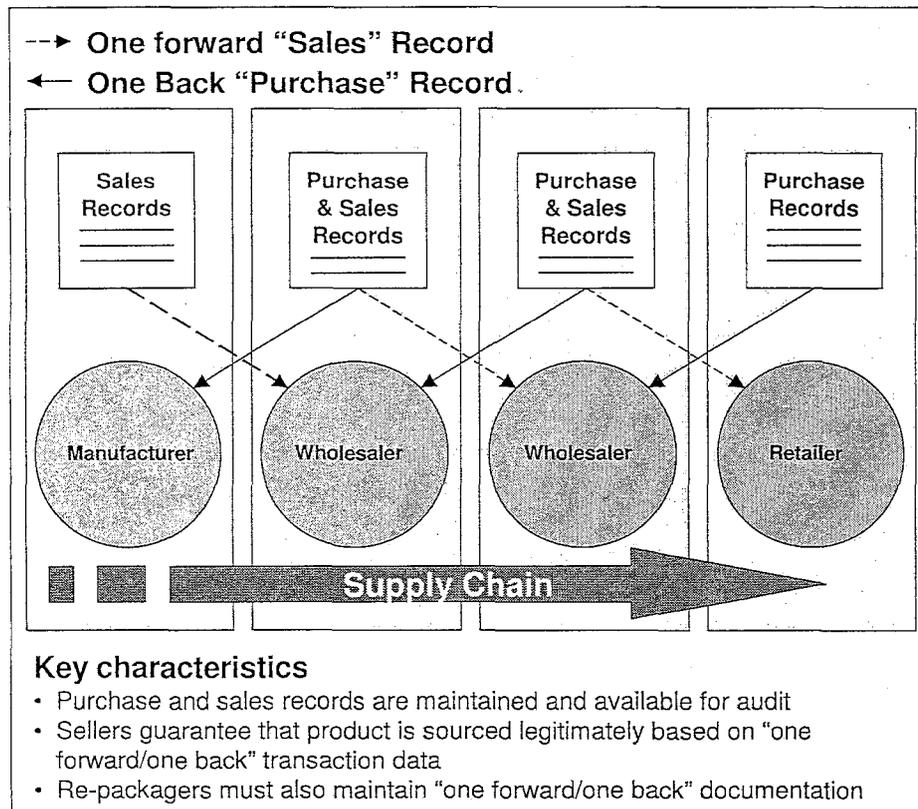
**Today, prescription drug wholesalers and retailers have limited ability to ensure the authenticity of the drugs they receive.**

## **Track and Trace – Situation and Complications**

- Current legislation, PDMA, has loopholes that allow diverted and/or counterfeit drugs to enter the system, severely crippling the ability to provide trusted authentication throughout the supply chain.
  - ADRs (manufacturers' Authorized Distributors of Record) are not required to obtain authentication documentation from manufacturers, making comprehensive documentation impossible in this channel
  - ADR definition is also loosely defined, enabling the majority of wholesalers to attain an ADR status
- Paper pedigree documents are expensive and ineffective because they are costly to maintain and easier to counterfeit than the drugs themselves.
- Current business practices do not support an industry-wide ability to track and trace drug flow because transaction records are not required, preventing a complete picture of product flow across the supply chain.
- Current technology deployed across the supply chain does not enable digital track and trace capabilities that can ensure authenticity of drugs and flag suspect shipments.

In the short-term, a “One Forward/One Back” approach to drug authentication would help ensure accountability for each step in the supply chain.

## One Forward/One Back Authentication Model



<sup>1</sup>Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities.

## Interim Track and Trace Assurance

- Supply chain members must maintain transaction documentation for the immediate previous source and the immediate subsequent recipient of drug products
  - FDA should mandate for high risk drug class(es) – FDA will specify exactly what drugs will require “one forward/one back” authentication
  - Analogous to the system adopted by food distributors as part of Public Health Security And Bio-Terrorism Preparedness And Response Act of 2002
- “One forward/one back” requirements extend from the manufacturer to the pharmacy company but not to store level or patient purchaser
- Regulators have the right to audit the “one forward/one back” transaction records all the way back to the manufacturer (e.g., spot checks, counterfeit investigations)
- Re-packagers<sup>1</sup> will be required to support the “one forward/one back” authentication requirements
- Seller contractually guarantees that the invoiced prescription drugs came from a specific supplier or set of suppliers and gives purchaser the right to audit the previous transaction(s)

**Ensuring the authentication of prescription drugs will require changes to current PDMA legislation, FDA regulations, and the way in which supply chain participants document business transactions with each other.**

## Track and Trace – Recommendations

| Recommendation  | Components  | Objectives  | Implications for Success  |
|---|---|---|---|
| <div data-bbox="132 727 170 1235" style="writing-mode: vertical-rl; transform: rotate(180deg);">Regulation and Business Practices</div> <p><b>Revise PDMA Authentication Requirements to Adopt One Forward, One Back Transaction Authentication</b></p> | <ul style="list-style-type: none"> <li>• Revise PDMA requirements utilizing a “one forward/ one back” approach for high risk drugs where each company in the distribution chain is required to document from whom they bought drugs and to whom they sold the same drug</li> <li>• One forward/one back approach should be required for only the high risk drug class(es)</li> <li>• Eliminate current ADR exemptions and paper pedigree requirements from “one forward/one back” regulations to ensure that track and trace requirements are consistent throughout the supply chain</li> <li>• As drugs are resold throughout the supply chain, an invoice and/or other supporting transaction documentation must certify the supplier and receiver of the product.</li> <li>• Seller contractually guarantees that the invoiced prescription drugs came from a specific supplier or set of suppliers and gives purchaser the right to audit the previous transaction</li> <li>• Enable regulators and ensure right of purchaser to audit “one forward/one back” authentication to confirm legitimacy</li> <li>• Re-packagers' should also be subject to “one forward/one back” requirements and authentication</li> </ul> | <ul style="list-style-type: none"> <li>• Improve reliability in the short-term until electronic track and trace authentication solutions can be deployed</li> <li>• Revise PDMA to require “one forward/one back” track and trace methods</li> <li>• Facilitate an efficient counterfeit investigation process</li> </ul> | <ul style="list-style-type: none"> <li>• “One forward/one back” must be supported by consistent and aggressive wholesale licensing requirements across all 50 states since ADR and paper pedigree will be eliminated</li> <li>• Limit to products that are classified as being at higher risk for counterfeiting</li> <li>• Manufacturers, wholesalers and retailers as well as re-packagers<sup>1</sup> will need to follow the track and trace authentication rules</li> <li>• Need to ensure ability to process product returns               <ul style="list-style-type: none"> <li>– Enabling product returns is difficult under a “one forward/one back” approach since retailers and wholesalers cannot confirm in all instances exact product source</li> <li>– Industry participants will have to work together to establish model best practices for returns</li> </ul> </li> </ul> |

<sup>1</sup>Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities.

**Future track and trace authentication technology will require enhanced infrastructure and reporting standards that enable an efficient and intelligent tracking model.**

## Track and Trace - Recommendations

| Recommendation   | Components  | Objectives   | Implications for Success  |
|--|---|--|---|
| <b>Create Digital Track and Trace Model<sup>1</sup></b><br>(Industry-Based Authentication Technology Infrastructure) | <ul style="list-style-type: none"> <li>• Develop a technology enabled, industry-wide track and trace system that records and stores transactional data on products that move throughout the supply chain</li> <li>• Record product transactions throughout each step in the supply chain               <ul style="list-style-type: none"> <li>– Receipt and shipment of product</li> <li>– Packaging and repackaging of product</li> </ul> </li> <li>• Utilize an accepted standard mechanism for unique serialization of product/ packaging</li> </ul> | <ul style="list-style-type: none"> <li>• Create a safe and secure supply chain model that quickly identifies and helps prevent counterfeit activity</li> </ul> | <ul style="list-style-type: none"> <li>• Supply chain participants should work collaboratively with government to develop market-based, industry standards on key components and business practices of the digital track and trace model               <ul style="list-style-type: none"> <li>– Create standards and develop certification program for third-party organizations that maintain and govern transaction data usage (e.g., access, use, confidentiality, etc.)</li> <li>– Communicate with and keep the FDA informed on standards, progress and plans</li> <li>– Work with UCC and EPCglobal to define minimum standards and set dates for industry adoption of desired model once feasibility studies have been completed and an agreed upon direction has been established</li> </ul> </li> <li>• Industry should develop cost benefit analyses for implementation of the digital model at the “unit level” to address such questions as: what is the cost (fixed and variable), who is going to pay for the model, and how will the cost be passed along?</li> <li>• Digital track and trace unique identifiers will need to be de-commissioned to prevent reuse of the unique ID (e.g., “marked as inactive” in the central database)</li> <li>• In instances where units of use are tagged, physical de-commissioning of the tag must take place prior to consumer leaving the store</li> </ul> |

Technology

<sup>1</sup> Multiple technology options exist and various factors such as implementation cost, ongoing operational cost, market demand and technology advancements need to be considered before determining an industry approach to technology deployment. For example, 2D Barcode symbology and RFID were discussed as possible technologies for the standard serialization mechanism and will require further investigation to effectively consider possible implications for success. This will require that a cost/benefit analysis be done and consider: market opinions, potential for adoption and implementation costs (one time and on-going), etc.

(Continued)

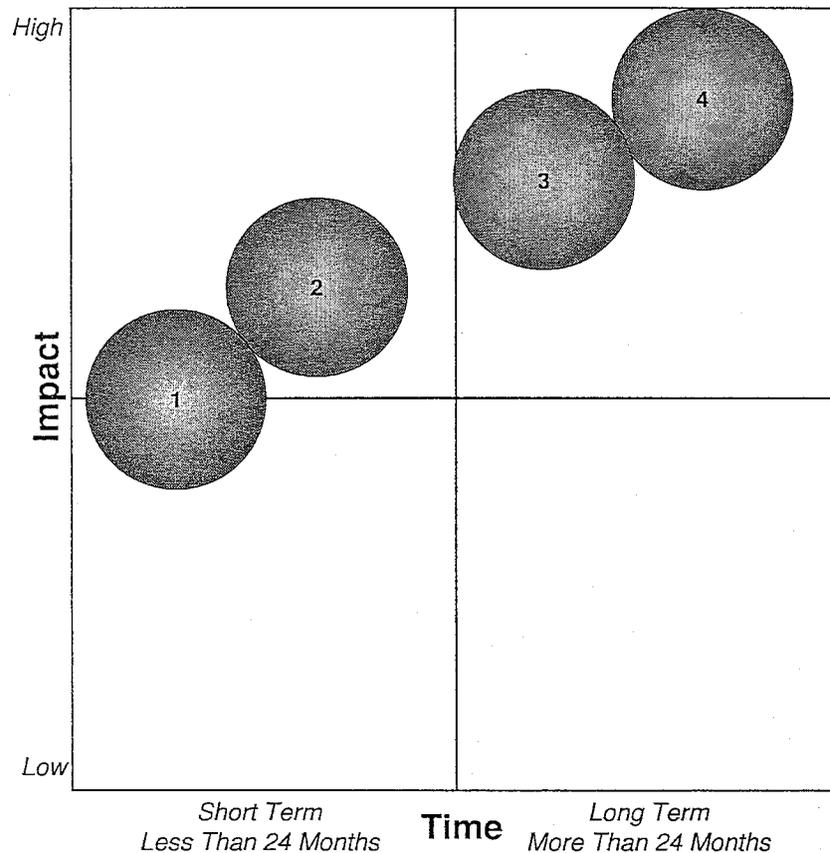
## Track and Trace - Recommendations

| Recommendation  | Components   | Objectives   | Implications for Success   |
|---|--|--|--|
| <b>Create Digital Track and Trace Model</b><br>(Authentication Technology Infrastructure) | <ul style="list-style-type: none"><li>• Construct a centralized technical infrastructure (database, applications, monitoring, management, etc.) that is maintained by a third-party to safeguard and govern data use<ul style="list-style-type: none"><li>– Maintain authentication data</li><li>– Identify anomalies in the transaction data</li><li>– Alert appropriate stakeholders if anomalies are identified</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Create a safe and secure supply chain model that quickly identifies and helps prevent counterfeit activity</li></ul> | <ul style="list-style-type: none"><li>• Deploy digital track and trace technology to high-risk drug classes first, according to established classifications</li><li>• Both individual companies and third-party administrators will need to accurately estimate transaction volume to determine the required infrastructure to handle current and future volume.</li><li>• Supply chain members will require an affordable technology solution that integrates with their current systems</li><li>• FDA should work with industry to develop a point of view on the impact that any proposed track and trace solutions might have on the physical environments throughout the supply chain (e.g., emission of radio frequency (RF) waves at the distribution center or store environment where unique identifier/tag "reading" would take place)</li></ul> |

Technology

Track & Trace methods can be instituted over the short- and long-term by aligning and evolving industry regulation, business practices and technology.

## Track & Trace – Migration Plan



### Critical Steps

1. Industry, in conjunction with FDA, begins investigation into potential technology standards, business process requirements, and economic/cost implications for the digital Track and Trace Model
2. Rewrite and facilitate adoption of PDMA language to eliminate pedigree requirement and enact "one forward/one back" record keeping
3. Implement first phase of digital Track and Trace Model according to product classification and initial scope as defined by the industry
4. Adopt digital Track and Trace Model at the unit level according to technology standards, business process requirements, market acceptance, and product classification priorities

**Product packaging recommendations call for revised packaging regulations and development of model best practices, but do not mandate unit of use packaging for anti-counterfeiting measures.**

## Recommendation Categories

| Category                                   | Recommendations  |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
| <b>Track and Trace</b>                     | <ul style="list-style-type: none"> <li>• Revise PDMA Requirements to adopt 'One Forward, One Back' Transaction Authentication</li> <li>• Create digital Track and Trace model</li> </ul>   |
| <b>Product and Packaging</b>               | <ul style="list-style-type: none"> <li>• Revise FDA packaging regulations</li> <li>• Do not mandate unit-of-use packaging for anti-counterfeiting measures</li> <li>• Develop model best practices for anti-counterfeiting measures</li> </ul>   |
| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• Develop a centralized alert portal</li> </ul>   |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**While changes in packaging standards can reduce counterfeit drug entry, market-driven model best practices can provide additional obstacles to counterfeiting.**

## **Product and Packaging - Summary**

- The integrity and effectiveness of product packaging anti-counterfeiting measures varies across the supply chain.
- Multi-level, anti-counterfeiting measures for original and secondary packaging of high-risk drugs should be required to further ensure patient safety and enable authentication when confronted with potential counterfeit situations.
- While the FDA has identified Unit-of-Use packaging as a potential anti-counterfeiting solution, unit-of-use packaging costs tend to outweigh the benefits and the packaging tends to be more susceptible to counterfeiting than the drugs themselves.
- Counterfeiting can be minimized by adopting model best practices and technologies that build upon minimum FDA requirements and anticipate and address advances in counterfeiting.

**Many complications result from the wide variety of packaging used across the supply chain and the limited use of anti-counterfeiting technologies.**

## **Product and Packaging - Situation and Complications**

- Some drugs are packaged with safety and anti-counterfeit features -- drugs with lesser packaging technologies are at greater risk of counterfeiting.
- Commonplace packaging technologies (e.g., safety seal, color coding, or bar coding) used alone do not necessarily provide sufficient protection from counterfeiting.
- Re-packaging practices in the U.S. may render manufacturing and other tagging efforts ineffective because packages are broken down to the pill or vial level and then repackaged.
- Some re-packagers<sup>1</sup> do not follow the FDA's Guidelines for Solid Oral Dose Forms.
- Though the FDA has identified unit of use packaging as a potential anti-counterfeiting measure, it is not cost efficient and does not necessarily prevent counterfeits.
  - Many prescription drug therapies do not easily lend themselves to unit-of use-packaging and standardized dispensing quantities
  - Blister packages can be counterfeited
  - In the U.S., unit-of-use packaging has been successful only for some drugs (e.g., Pfizer Z-Pak®) where key factors have warranted it
  - Manufacturers should consider, as part of product development, unit of use packaging as an extra line of defense for new drugs

<sup>1</sup>Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities.

**Minimum packaging standards are required to ensure patient safety; these standards should include multi-level anti-counterfeiting measures for original and secondary packaging of high-risk drugs.**

## Product and Packaging - Recommendations

| Recommendation  | Components  | Objectives  | Implications for Success   |
|---|---|---|--|
| <b>Revise FDA Packaging Regulations</b>   | <u>Layered Solutions</u>  | <ul style="list-style-type: none"> <li>• Ensure minimum packaging standards across all supply chain members</li> <li>• Require anti-counterfeiting measures for high risk product</li> <li>• Reduce opportunity for commingling diverted/counterfeit with legitimate drugs</li> </ul> | <ul style="list-style-type: none"> <li>• FDA will need to develop an audit and validation process to ensure that layered anti-counterfeiting measures have been deployed</li> <li>• To be effective, drug packaging regulations/laws must apply to all members of the supply chain</li> </ul>                  |
|   | <u>Re-Packaging</u>   | <ul style="list-style-type: none"> <li>• Ensure minimum packaging standards across all supply chain members</li> <li>• Require anti-counterfeiting measures for high risk product</li> <li>• Reduce opportunity for commingling diverted/counterfeit with legitimate drugs</li> </ul> | <ul style="list-style-type: none"> <li>• Re-packaging regulations need to be aligned with manufacturer packaging regulations to ensure drug authenticity</li> <li>• Need to determine a cost-effective manner for wholesalers and re-packagers<sup>1</sup> to maintain track and trace authenticity</li> </ul> |
| <sup>1</sup> Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities. | <ul style="list-style-type: none"> <li>• Require manufacturers to implement multi-layered, anti-counterfeit technology programs across high risk drug classes</li> <li>• FDA maintains the power to inspect and ensure that a multilayered anti-counterfeiting measures program is in place</li> <li>• Require regulation of companies that repackage for resale in distribution channels, not companies that repackage for internal use</li> <li>• Require destruction of old packaging to prevent reuse of the manufacturer's original packaging and labeling (e.g., contracts with crushing and grinding companies)</li> </ul> |   |  |

Regulations

# Unit-of-use packaging is not cost effective as a general anti-counterfeiting technique.

## Product and Packaging - Recommendations

| Recommendation                              | Components  | Objectives   | Implications for Success  |
|---|---|--|---|
| <b>Do Not Require Unit-of-use Packaging</b> | <ul style="list-style-type: none"> <li>• Do not mandate unit-of-use packaging for all drugs as a form of authentication as the benefits do not outweigh the costs                             <ul style="list-style-type: none"> <li>– Retooling will increase costs for the manufacturers and distributors</li> <li>– Unit-of-use only offers tamper protection and not authentication</li> <li>– Blister packaging can be counterfeited</li> <li>– Making blister packaging child resistant, while still being accessible to the elderly, is a challenge</li> </ul> </li> <li>• Unit-of-use packaging should be driven by market demand to meet the needs of consumer or supply chain participants</li> <li>• Manufacturers should consider, as part of product development, unit-of-use packaging as an extra line of defense for new drugs</li> </ul> | <ul style="list-style-type: none"> <li>• Avoid increasing the cost of healthcare without accruing benefit</li> </ul> | <ul style="list-style-type: none"> <li>• The FDA should monitor progress of unit-of-use standards in other countries to gain knowledge and evolve efficient application of unit of use practices in the U.S. where appropriate</li> </ul> |

Regulations

**The industry can anticipate and minimize counterfeiting by adopting model best practices and technologies that build upon minimum FDA requirements and evolve to meet advancements in counterfeiting.**

## Product and Packaging - Recommendations

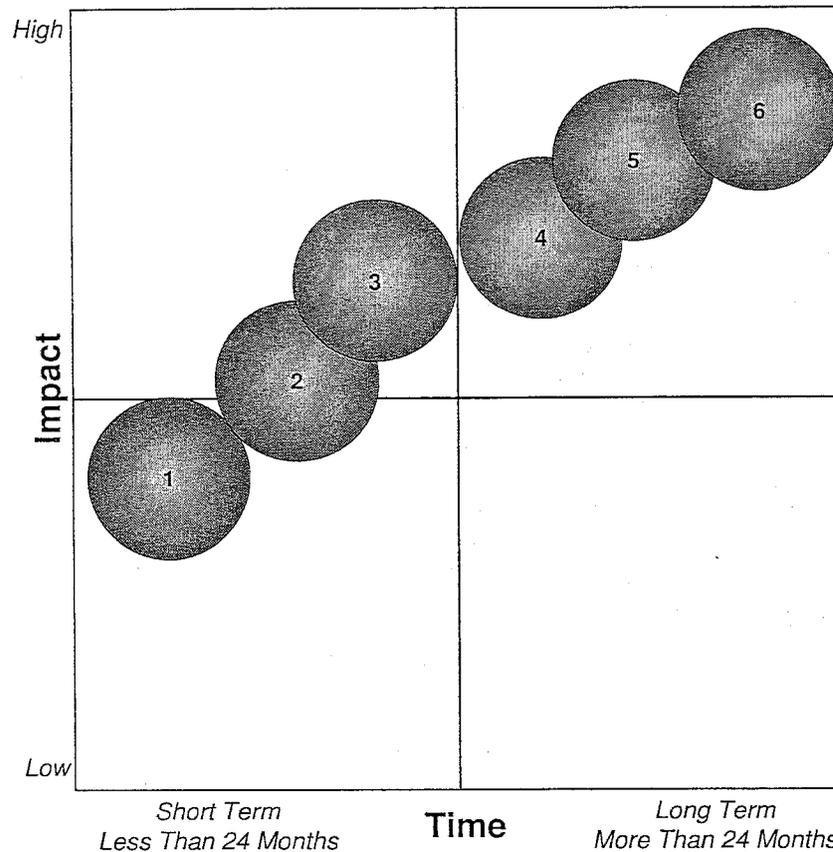
| Recommendation  | Components   | Objectives   | Implications for Success   |
|---|--|--|--|
| <b>Develop Model Best Practices For Anti-Counterfeit Technology</b> | <ul style="list-style-type: none"> <li>• Industry participants should develop multi-layered, anti-counterfeiting model best practices applicable to each segment of the supply chain               <ul style="list-style-type: none"> <li>– Specific layered, anti-counterfeiting/ authentication technologies for packaging and product, including overt, covert, and/or forensic level solutions/taggants/markers</li> <li>– Investigate use of dyes, printing technologies/ techniques, holography, tamper evident seals, and chemical/biological taggants</li> </ul> </li> <li>• Adopt a unique identifier and industry standard for serialization and define process for commissioning new identifier for repackaged product (e.g., EPC)</li> </ul> | <ul style="list-style-type: none"> <li>• Introduce multi-layered, anti-counterfeiting measures into the supply chain to reduce counterfeiting</li> <li>• Enable more efficient authentication of product during counterfeiting investigations</li> <li>• Provide a back-up and complimentary mechanism to future digital track and trace capabilities</li> </ul> | <ul style="list-style-type: none"> <li>• Supply chain members should adopt recommended model 'best' practices</li> <li>• Re-packagers<sup>1</sup> will need to learn and deploy new capabilities to meet minimum packaging standards</li> <li>• Changes in packaging should accommodate future technical innovations</li> <li>• While the FDA may provide guidance on the application of unique identifier "tags", the FDA should NOT require that the newly tagged product/packaging be resubmitted for FDA approval</li> <li>• FDA should work with industry to develop a point of view on the impact that any proposed track and trace solutions might have on the physical environments throughout the supply chain (e.g., emission of radio frequency (RF) waves at the distribution center or store environment where unique identifier/tag "reading" would take place)</li> </ul> |

Business Practices

<sup>1</sup> Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities.

Common packaging standards across the supply chain can be implemented in the short-term while model best practices can evolve over 2-3 years to include anti-counterfeiting technologies at the package and product levels.

## Product and Packaging – Migration Plan



### Critical Steps

1. Define new packaging policies
2. Deploy multi-level anti-counterfeiting packaging measures – overt and covert solutions/taggants/markers for packaging (e.g., dyes, printing techniques/ technologies, holography, tamper proof seals)
3. Lay ground work for unique identifiers (e.g., EPC) by beginning serialization of pallets and cases
4. Deploy overt, covert, and/or forensic level solutions/taggants/markers for product (e.g., dyes, printing techniques/technologies, and chemical/biological agents)
5. Incorporate unique identifiers (e.g., EPC) in packaging
6. Incorporate electronic authentication/ track and trace technology in packaging

**Licensing and channel policy recommendations call for FDA minimum licensing requirements, more inspections, increased penalties and model best practices for purchasing and channel sales.**

## Recommendation Categories

| Category                                   | Recommendations  |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
| <b>Track and Trace</b>                     | <ul style="list-style-type: none"> <li>• Revise PDMA Requirements to adopt 'One Forward, One Back' Transaction Authentication</li> <li>• Create digital Track and Trace model</li> </ul>   |
| <b>Product and Packaging</b>               | <ul style="list-style-type: none"> <li>• Revise FDA packaging regulations</li> <li>• Do not mandate unit-of-use packaging for anti-counterfeiting measures</li> <li>• Develop model best practices for anti-counterfeiting measures</li> </ul>   |
| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• Develop a centralized alert portal</li> </ul>   |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**The FDA and industry trade associations need to create an environment that both discourages counterfeiting through tougher standards and promotes accountability through regulation and model best practices.**

## **Licensing and Channel Policies – Summary**

- Current commercial practices in purchasing and selling often enable product diversion and counterfeit entry points in the U.S. drug supply chain.
- State and federal governments must collaborate in developing stricter and more standard wholesale licensing requirements. This could include:
  - Strengthening the federal minimum standards for wholesaler licensing
  - Creating a federal “floor” for minimum standards
  - Encouraging uniform state licensing standards
- Create a national clearinghouse (database) with information on wholesaler licensure status, debarments, and exclusions.
  - Should be accessible to state agencies
  - Should enable manufacturers, suppliers, pharmacies, and other businesses to search the database before agreeing to conduct business with a particular wholesaler

**Preventing counterfeit drug flow will require action by the FDA and industry to remove, where appropriate, financial incentives for counterfeiting and other illegal activities.**

## **Licensing and Channel Policies – Situation and Complications**

- Limited barriers exist for criminals to enter the wholesale market.
  - Wholesaler licensing requirements and enforcement vary by state-level
  - Many states do not require a rigorous application and due diligence process, allowing individuals with criminal records to legally distribute prescription drugs
- Existing inspection and due diligence processes are often insufficient to detect criminal activity.
  - Inspectors are not sufficiently trained on what to look for
  - Number of inspectors is severely inadequate to monitor wholesaler activity
- Federal and state penalties for prescription drug counterfeiting are insufficient and do not serve as an adequate criminal deterrent.
  - Drug counterfeiters can get 1 year in prison plus \$1,000 fine for the 1st conviction, then 3 years in prison plus \$10,000 fine for the 2nd offense
  - In contrast, counterfeiting a drug label is a trademark violation that can result in 10 years in prison

**Minimum licensing requirements and a robust application process will force illegitimate wholesalers out of business.**

**Licensing and Channel Policies – Recommendations**

| Recommendation   | Components   | Objectives  | Implications for Success   |
|--|--|---|--|
| <p><b>Require FDA Minimum Wholesaler and Repackager Licensing Requirements</b></p> | <ul style="list-style-type: none"> <li>• Require detailed and robust application requirements that place more stringent requirements on non-public companies that do not already have SEC oversight</li> <li>• Require detailed background checks for applicant and related parties to determine personal history (e.g., financial, criminal history, etc.)</li> <li>• Involve pharmacists and/or other trained personnel in licensing decision process to ensure standards required for safety, etc.</li> <li>• Require site inspection prior to licensing and unannounced post licensure spot checks to ensure that a legitimate site actually exists</li> <li>• Require every wholesaler to employ at least one professional with recognized training in storing and transporting drugs as well as compliance with applicable laws</li> <li>• Mandate standard record keeping to support a standardized counterfeit drug investigation process</li> <li>• Require applicants to post national performance bonds that total \$100,000</li> </ul> | <ul style="list-style-type: none"> <li>• Eliminate licensing of people or institutions who have criminal records or lack relevant qualifications</li> </ul> | <ul style="list-style-type: none"> <li>• States may need federal assistance to coordinate and fund upfront due diligence and subsequent enforcement of licensing regulations</li> <li>• The FDA may need to provide educational resources to enable effective execution of application activities such as background checks and inspections</li> </ul> |

Legislation/Regulation

<sup>1</sup> *Repackagers are defined as those businesses that repackage product for resale to other unaffiliated business entities.*

**Stiffer penalties are a critical tool in deterring counterfeit activities, imposing significant personal and financial risk on would-be criminals.**

## Licensing and Channel Policies – Recommendations

| Recommendation            | Components  | Objectives  | Implications for Success  |
|---------------------------|---|---|---|
| <b>Increase Penalties</b> | <ul style="list-style-type: none"> <li>• Increase federal penalties for counterfeiters and revise the federal sentencing guidelines to reflect the huge potential harm of drug counterfeiting</li> <li>• Require a minimum level of penalties at the Federal level to ensure adequate disincentive for counterfeit activity. States could choose to be more aggressive with penalties according to their situation and policy</li> <li>• Impose greater civil and criminal penalties for diversion and inaccurate reporting of bed numbers by Institutional Pharmacy (IP) suppliers</li> <li>• When criminal penalties are not applicable, consider non-monetary penalties for non-compliance with various regulations/requirements               <ul style="list-style-type: none"> <li>– Temporary restriction on sale of certain products until infractions are remedied</li> <li>– Temporary closure until infractions are remedied</li> </ul> </li> <li>• Create/increase penalties for companies that do not perform proper due diligence or knowingly do business with counterfeiters</li> <li>• FDA should create a centralized database that companies can refer to as part of their upfront and ongoing due diligence process (e.g., check the database/exclusions list for companies that have had licensing infringements)</li> </ul> | <ul style="list-style-type: none"> <li>• Deter counterfeiters by increasing fines and jail time for infractions</li> <li>• Shrink the market for counterfeit drugs by penalizing the companies or individuals that knowingly do business with counterfeiters</li> </ul> | <ul style="list-style-type: none"> <li>• Need increased minimum penalties across federal and state laws</li> <li>• Requires increase in investigations and prosecutions to enforce regulations and levy increased penalties</li> <li>• Penalties should be high enough to outweigh the potential profit of counterfeiting</li> <li>• Require institutions and 340(B) program providers to report all drug purchases and certify that none of the purchased drugs were resold or diverted</li> <li>• National clearinghouse database could be created in conjunction with NABP               <ul style="list-style-type: none"> <li>– Criteria must be developed for exclusion listing</li> <li>– Database should be populated by authorities who have power to exclude</li> </ul> </li> </ul> |

Legislation/Regulation

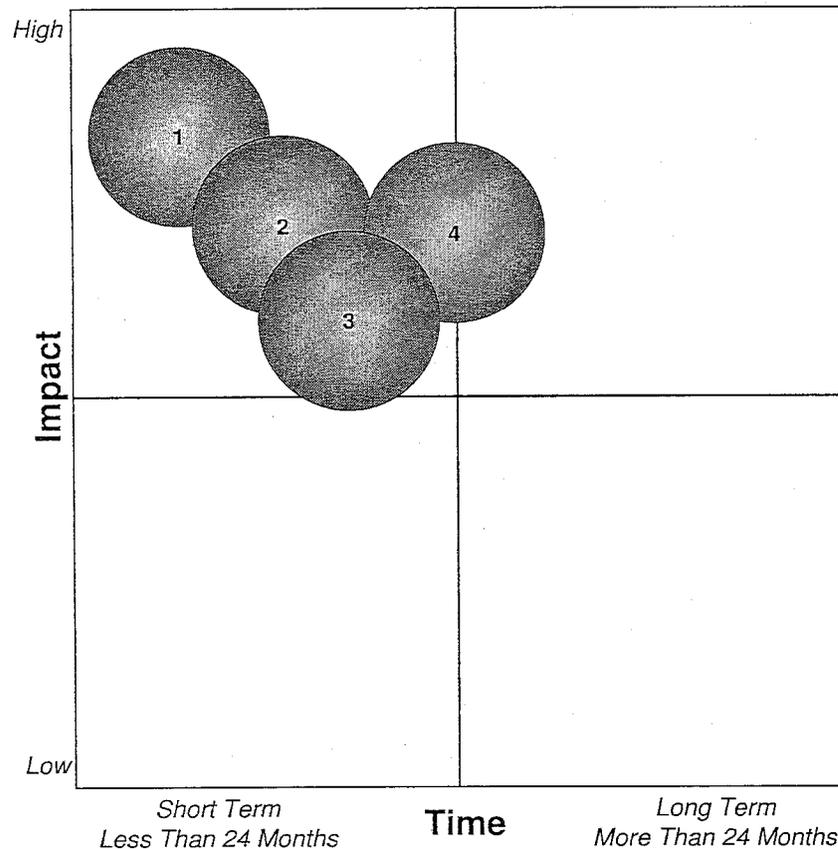
**Enforcing tougher regulations will provide added weight and legitimacy to FDA efforts and motivate companies to adopt model best practices that deter counterfeiting.**

## Licensing and Channel Policies – Recommendations

|                       | Recommendation  | Components  | Objectives   | Implications for Success   |
|-----------------------|---|---|--|--|
| <b>Enforcement</b>    | <b>Increase Inspections</b>   | <ul style="list-style-type: none"> <li>• Authorize periodic and unannounced inspections of wholesaler operations by federal and/or state agencies that are conducted on a reasonable basis and do not interrupt the normal course of business</li> <li>• Educate inspectors on methods of counterfeiting so that they are better prepared when conducting inspections</li> <li>• Increase funding for inspections, investigations and prosecutions</li> <li>• Heighten inspections of physical site security</li> <li>• Give FDA the right to inspect institutional pharmacy records without notice</li> <li>• Increase inspections at international mail facilities and collaborate with international couriers to detect illegal imports</li> <li>• Simplify standards of inspection to make inspections easier to execute</li> </ul> | <ul style="list-style-type: none"> <li>• Reduction in counterfeiting activity through enhanced enforcement of new and existing regulations</li> <li>• Train companies to “police themselves” by creating a mindset that inspections can happen at any time</li> </ul>  | <ul style="list-style-type: none"> <li>• State and federal agencies may need funding assistance to increase staff, training and number of inspections</li> <li>• Need legislation to grant agencies the proper authority for inspections of records, facilities, and international mail</li> <li>• Give FDA more authority to investigate and prosecute foreign companies - Give FDA jurisdiction over any company that intends an effect in the US, not just companies that make overt act of actual effect in US (e.g., if companies sell counterfeits and they know buyer intends to import into the US)</li> </ul> |
| <b>Best Practices</b> | <b>Develop Model Best Practices For Purchasing and Channel Sales Policies</b> | <ul style="list-style-type: none"> <li>• Industry derived, voluntary model best practices should be established by appropriate trade associations (e.g., NACDS, HDMA) to include:               <ul style="list-style-type: none"> <li>– Non-price-related provisions of supplier agreements</li> <li>– Voluntary accreditation procedures to ensure supplier integrity</li> <li>– Voluntary reporting, etc.</li> </ul> </li> <li>• FDA should not mandate model best practices</li> <li>• Include a statement on transaction documentation that authenticates that the product originated from a legitimate manufacturer</li> </ul>  | <ul style="list-style-type: none"> <li>• Create model best practices that emphasize accountability for drugs that a company sells</li> <li>• Develop model best practices that create a system of checks and balances throughout the supply chain</li> <li>• Allow trade associations to determine model best practices</li> </ul> | <ul style="list-style-type: none"> <li>• Business practices will be impacted by new “one forward/one back” authentication requirements and wholesaler licensing requirements</li> <li>• Model practices must be financially feasible for industry to adopt them</li> </ul>   |

Due to the multi-faceted nature of the recommendations (legislative, regulatory, and monetary), implementing changes in purchasing and sales channel policy will take time.

## Licensing and Channel Policies – Migration Plan



### Critical Steps

1. Establish more stringent minimum requirements for licensing application and approval
2. Create regulations/legislation at federal and state level for increased penalties
3. Secure additional funding and support education programs to increase the number and quality of inspections
4. Develop model best practices that encourage accountability for drugs bought and sold

**Education and awareness recommendations include developing and coordinating education resources while reaching target audiences with specific messages according to a communication plan.**

## Recommendation Categories

| Category                                   | Recommendations  |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
| <b>Track and Trace</b>                     | <ul style="list-style-type: none"> <li>• Revise PDMA Requirements to adopt 'One Forward, One Back' Transaction Authentication</li> <li>• Create digital Track and Trace model</li> </ul>   |
| <b>Product and Packaging</b>               | <ul style="list-style-type: none"> <li>• Revise FDA packaging regulations</li> <li>• Do not mandate unit-of-use packaging for anti-counterfeiting measures</li> <li>• Develop model best practices for anti-counterfeiting measures</li> </ul>   |
| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• Develop a centralized alert portal</li> </ul>   |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**Alerting and educating all stakeholders about counterfeit pharmaceutical products is essential for combating the problem.**

## **Education and Awareness – Summary**

- The average consumer is not aware of the breadth of drug counterfeiting, nor the consumer safety and supply chain financial implications, in the market today.
- The FDA, trade associations, and pharmaceutical industry have a responsibility to the public to provide education and awareness about drug counterfeiting.
- Education and awareness should be targeted and distributed to all players within the industry (consumers, manufacturers, wholesalers, retailers, institutions, law makers and policy makers).
- Public awareness of drug counterfeiting will assist in the identification and capture of criminals as well as increase consumer safety.
- FDA should focus consumer awareness and related communication on issues that consumers can control so that inordinate concern is not created where action cannot be taken.

**U.S. consumers generally trust that the prescription drugs they purchase through established retail and institutional channels are safe and effective and are unaware of the potential for counterfeiting.**

## **Education and Awareness – Situation and Complications**

- Drug counterfeiting is a growing problem and many consumers are not aware of the issues or consequences.
- Drug counterfeiting hurts all stakeholders – consumers, manufacturers, wholesalers, retailers and institutions.
- Education on the facts, issues, instances, trends, and negative impacts of counterfeiting is limited since no centralized source of information currently exists.
- Striking the right balance of informing, without overly alarming, consumers is a key element of education and awareness.

**Due to the abundance of sales channels for prescription drugs, an education campaign must be wide-ranging and a joint effort between the FDA and industry stakeholders.**

## Education and Awareness – Recommendations

| Recommendation                                    | Components   | Objectives   | Implications for Success   |
|---|--|--|--|
| <b>Develop and Coordinate Education Resources</b> | <ul style="list-style-type: none"> <li>• The FDA should collaborate with trade associations to educate key stakeholders</li> <li>• Education should be delivered through all available consumer touch points (e.g., healthcare professionals, retailers, FDA resources)</li> <li>• Educational programs should empower stakeholders to understand, identify, and act on counterfeiting situations as well as be proactive in creating awareness of key facts (e.g., unexpected drug appearance, taste, and/or effects)</li> <li>• FDA should focus consumer awareness/communication on issues that consumers can control and avoid undue alarm on issues that are outside their realm of control (e.g., risk in purchasing foreign or internet drugs)</li> <li>• Integrate educational content with centralized alert information to establish one source for reliable and current information (e.g., a portal with links to stakeholders and relevant information)</li> <li>• The FDA should recommend, develop, and make available high priority education content through e-learning modules directed at specific stakeholders</li> </ul> | <ul style="list-style-type: none"> <li>• Educate each stakeholder (manufacturer, wholesaler, retailer, consumer) on the nature and scope of the problem</li> <li>• Help centralize information to facilitate easy access to educational materials</li> </ul> | <ul style="list-style-type: none"> <li>• Effective education and awareness will require adequate funding for educational programs and their promotion</li> <li>• Education priorities and content guidelines will need to be established and evolve as additional counterfeiting activity occurs</li> <li>• Educational programs should empower stakeholders to understand, identify, and act on counterfeiting situations but should not undermine consumer confidence</li> </ul> |

Business Practices and Policies

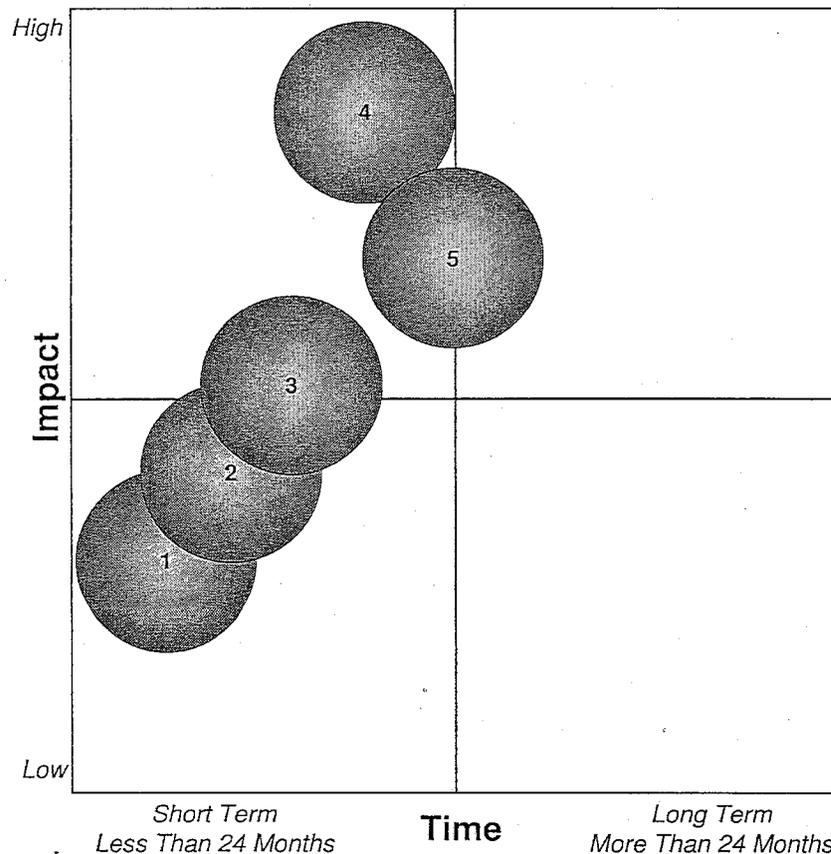
**A strong communication effort to all stakeholders about their role and responsibility in the pharmaceutical supply chain will help reduce counterfeiting.**

## Education and Awareness – Recommendations

| Recommendation  | Components   | Objectives   | Implications for Success  |
|---|--|--|---|
| <div data-bbox="142 854 174 1081" style="writing-mode: vertical-rl; transform: rotate(180deg);">Communication</div> <p><b>Create a Communication Plan</b></p> | <ul style="list-style-type: none"> <li>• Determine key messages by target audience:               <ul style="list-style-type: none"> <li>– Manufacturers: how can they ensure integrity in their products?</li> <li>– Wholesalers and retailers: what role can they play in the supply chain to keep it tight and secure?</li> <li>– Consumers: how can they help protect themselves and their families? What are the existing laws?</li> <li>– Policy makers: what are the facts and statistics related to public health risk?</li> </ul> </li> <li>• Leverage multiple audience touch points:               <ul style="list-style-type: none"> <li>– Mass media public service announcements</li> <li>– Centralized portal with general counterfeiting information and examples</li> <li>– Seminars/town hall meetings</li> <li>– Educational brochures for retail pharmacies to display in the store</li> <li>– Informational inserts that call out "red flag" symptoms or attributes included with prescriptions for high risk drugs</li> <li>– Articles in pharmaceutical trade newsletters and publications</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Reach target audiences in an effective and efficient manner</li> <li>• Increase awareness of issue and specific actions to protect consumers</li> </ul> | <ul style="list-style-type: none"> <li>• Need to secure adequate funding for the successful execution of the plan</li> <li>• Continually update messages, as appropriate</li> </ul> |

**Awareness and corrective action can be increased in the short- and long-term by using a variety of communication vehicles.**

## Education and Awareness – Migration Plan



### Critical Steps

1. Determine the key target groups (manufacturers, wholesalers, retailers, consumers, institutions and policy makers)
2. Determine the key messages to communicate to each target group
  - Manufacturers: how can they ensure integrity in their pharmaceutical products?
  - Wholesalers and retailers: what role can they play in the supply chain to keep it tight and secure?
  - Consumers: how can they help protect themselves and their families? What can they look for to ensure a safe prescription product? What is a red flag?
3. Determine effective and efficient communication vehicles for delivering the messages to target groups
4. Deliver messages / implement programs
5. Measure progress and take corrective actions

**Recommendations for alert and communication procedures are focused on the development of a centralized alert portal.**

## Recommendation Categories

| Category                                   | Recommendations  |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
| <b>Track and Trace</b>                     | <ul style="list-style-type: none"> <li>• Revise PDMA Requirements to adopt 'One Forward, One Back' Transaction Authentication</li> <li>• Create digital Track and Trace model</li> </ul>   |
| <b>Product and Packaging</b>               | <ul style="list-style-type: none"> <li>• Revise FDA packaging regulations</li> <li>• Do not mandate unit-of-use packaging for anti-counterfeiting measures</li> <li>• Develop model best practices for anti-counterfeiting measures</li> </ul>   |
| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• <b>Develop a centralized alert portal</b></li> </ul>  |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**An efficient communication platform utilized by all industry members will allow for quick notification of, and responsive action to, counterfeit situations.**

## **Alerts and Communication Procedures – Summary**

- A common communication platform for alerts does not exist within the industry, causing delays in delivering and difficulty in understanding critical information.
- A centralized alert communication portal (e.g., Chaindrugstore.net), that leverages market practices for recall notifications, for use by all supply chain constituents will allow for timely and smooth dissemination of information.
- Developing counterfeiting alert and action processes that leverage the centralized alert system will ensure:
  - Proper information is conveyed in alerts
  - Only target audiences are notified
  - Delivery and confidentiality is maintained
  - Timely action can be taken to control further distribution of counterfeit drugs
- Enabling future track and trace technologies that interface with the alert portal should be a long-term goal to facilitate comprehensive knowledge throughout the industry.

**The number and variety of current systems for delivering alerts discourage companies from issuing communications because information is commonly received by the incorrect audience and misunderstood.**

## **Alerts and Communication Procedures – Situation and Complications**

- Current alert and communication capabilities exist but are inadequate because they:
  - Are not centralized nor coordinated between all stakeholders
  - Do not prioritize audiences or ensure that all necessary audiences receive information (sometimes retailers find out about recalls from their customers)
  - Do not allow for multiple levels of communication with specific stakeholders
- Some alert communications have unintended negative results and discourage future alerts.
  - Unfounded market fear, causing disruption of patient healthcare
  - Unnecessary drug returns, imposing significant costs on manufacturers

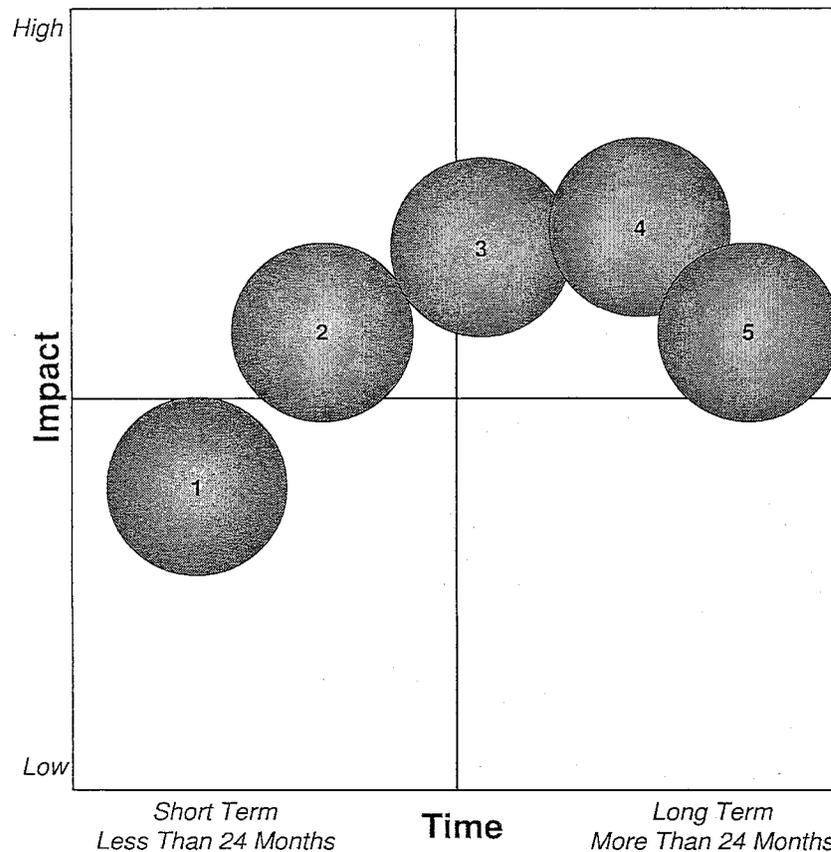
**Developing an effective alert portal that guarantees delivery of confidential information and encourages use by all industry members should be a high priority.**

## Alerts and Communication Procedures – Recommendations

| Communication Portal | Recommendation                          | Components   | Objectives  | Implications for Success   |
|----------------------|---|--|---|--|
|                      | <b>Develop Centralized Alert Portal</b> | <ul style="list-style-type: none"> <li>• FDA should facilitate centralization and coordination of alert communications through an industry information exchange such as Chaindrugstore.net</li> <li>• Alert and communication procedures should be fact-based and effective in their intent while minimizing market fear               <ul style="list-style-type: none"> <li>– Enable multiple levels of alert to differentiate “warehouse,” “retail,” and “emergency” (e.g., red and yellow)</li> <li>– Use both push and pull communications to reach and engage stakeholders</li> <li>– Ensure that information provided is clear, coherent, and timely</li> </ul> </li> <li>• Establish various alert types and enable restricted alert delivery/access by specific recipients for some alert types</li> <li>• Future track and trace authentication technologies (e.g., RFID) should reflect alert and communication processes in their design</li> <li>• The FDA and industry groups should continue to identify and categorize scenarios requiring alert and communication of counterfeit activities</li> <li>• Develop and leverage industry model best practices for recall notifications, as appropriate</li> </ul> | <ul style="list-style-type: none"> <li>• Provide timely information via a centralized channel for all members of the supply chain</li> <li>• Ensure delivery of alerts</li> </ul> | <ul style="list-style-type: none"> <li>• The industry must participate and maintain the centralized alert system</li> <li>• Effective alert systems will require collaboration among stakeholders and definition of situation requirements</li> <li>• Target audiences must be defined and restricted distribution capabilities must be developed so end users trust the confidentiality of the system</li> <li>• Technology is required to improve the timeliness and effectiveness of alert communication</li> <li>• Investigate and consider how existing resources can be utilized to establish a more robust alert capability (e.g., Medwatch.gov, Chaindrugstore.net)</li> </ul> |

Using a centralized, confidential alert portal and knowledge base will decrease recall expenses and increase consumer protection.

## Alerts and Communication Procedures – Migration Plan



### Critical Steps

1. Develop plan for centralized alert portal (e.g., Chaindrugstore.net)
2. Implement alert portal by building or expanding an existing website and educating industry members
3. Create integration plan for communication between track and trace technologies and alert portal
4. Build integration to track and trace technology as it is rolled out
5. Maintain alert portal as business needs dictate new functionality and new companies enter the market

**Importation recommendations are focused on maintaining and enforcing existing prescription drug importation laws while educating consumers about the related patient safety risks.**

## Recommendation Categories

| <b>Category</b>                            | <b>Recommendations</b>   |
|--|--|
| <b>Product Classification</b>              | <ul style="list-style-type: none"> <li>• The FDA and industry define high-risk classification criteria</li> <li>• FDA keeps and maintains an aggregate drug classification list</li> </ul>   |
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| <b>Licensing and Channel Policies</b>      | <ul style="list-style-type: none"> <li>• Require FDA minimum wholesaler and re-packager licensing requirements</li> <li>• Increase penalties and inspections</li> <li>• Develop model best practices for purchasing and channel sales</li> </ul> |
| <b>Education and Awareness</b>             | <ul style="list-style-type: none"> <li>• Develop and coordinate education resources</li> <li>• Create a communication plan</li> </ul>  |
| <b>Alerts and Communication Procedures</b> | <ul style="list-style-type: none"> <li>• Develop a centralized alert portal</li> </ul>   |
| <b>Importation</b>                         | <ul style="list-style-type: none"> <li>• Enforce existing laws on drug importation for personal and corporate entities</li> <li>• Educate consumers about the risks and illegality of drug importation</li> </ul>                                |

**Importation of prescription drugs is illegal and presents safety risks to the entire drug supply as it creates a “weak link” in the current FDA-protected U.S. system.**

## **Importation – Summary**

- Illegally imported prescription drugs continue to be a source of counterfeit product that puts the entire US prescription drug system and its patients at risk.
- Law enforcement and education are critical to stopping the huge and growing illegal prescription drug import market and to closing the U.S. prescription drug “borders” to ensure patient safety.
- Any potential cost benefits associated with imported prescription drugs, are outweighed by the safety risks effecting the U.S. drug supply and individual consumer safety.
- Immediate action should be taken to enforce existing laws and to educate consumers on safety risks presented by illegally imported prescription drugs.
- If importation is legalized, require the importing pharmacies/distributors to follow all of the licensure laws and other anti-counterfeiting requirements imposed on domestic industry participants to maximize consumer safety.

**Illegally imported prescription drugs continue to be a potential source of counterfeit product that puts the entire U.S. prescription drug system and its patients at risk.**

## **Importation – Situation and Complications**

- Federal law prohibits the importation or re-importation of prescription drugs for personal use.
  - Importation is illegal because it is unsafe
  - Both present and past Secretaries of The US Department of Health and Human Services have concluded that they cannot certify the safety of imported drugs
- Many consumers are not aware of the safety risks or illegalities associated with imported drugs for personal use.
  - The FDA recently found counterfeit drugs in the majority of 1,153 spot-inspected mailed packages containing drugs from abroad
  - The importation of prescription drugs to the US by individuals or entities is illegal and, contrary to popular belief, there is no “personal use” exemption allowing individuals to import drugs for their own use
- Drug importation proposals provoke debate over drug safety as new legislation such as H.R. 2427 would rescind a provision of the 1987 PDMA law that was intended to protect consumers from the safety risks of illegally imported prescription drugs.
- Opening US borders to imported prescription drugs increases US consumer exposure to counterfeit drugs and the risk of not being protected by FDA standards.
  - Other nations, including Canada, do not guarantee the safety and quality of the drugs that they export<sup>1</sup>
  - Often, drugs thought to be purchased in one nation, are actually sourced from developing countries whose safety standards are insufficient and put consumers at risk

1. “The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter.” - Assistant Deputy Minister, Health Canada ~ Letter to Washington Post, May 9, 2003

**Existing laws against importing prescription drugs should be firmly enforced to prevent counterfeiting.**

**Importation – Recommendations**

| Law Enforcement | Recommendation   | Components   | Objectives   | Implications for Success   |
|-----------------|--|--|--|--|
|                 | <b>Enforce Existing Laws On Drug Importation For Personal And Corporate Entities</b> | <ul style="list-style-type: none"> <li>• Enforce existing laws that outlaw the importation of prescription drugs by individuals</li> <li>• Enforce existing laws that outlaw the importation of prescription drugs by corporate entities                             <ul style="list-style-type: none"> <li>– Unlicensed “store fronts”</li> <li>– Unlawful Internet pharmacies</li> </ul> </li> <li>• FDA should revisit the language/content of its enforcement discretion policy, which has been misread as legalizing personal importation</li> <li>• Establish standards that simplify the inspection process and enable customs/postal service/FDA to automatically return packages to “international pharmacies” stamped “return to sender”</li> <li>• Increase inspections at international mail facilities and collaborate with international couriers to detect and prevent illegal imports</li> </ul> | <ul style="list-style-type: none"> <li>• Protect the safety of the US prescription drug supply and system</li> <li>• Restrict activity by illegal internet pharmacies and “storefronts”</li> </ul> | <ul style="list-style-type: none"> <li>• Educate the public that personal use importation is illegal and unsafe</li> <li>• Take a proactive and aggressive approach to identifying and prosecuting illegitimate and unlicensed businesses</li> <li>• Encourage people to report adverse affects of drugs procured from internet pharmacies and/or suspicious Internet pharmacy activity (i.e., Report-a-Site feature in the VIPPS section of the NABP website)</li> <li>• Provide guidance to state attorney generals who are charged with enforcing each individual state’s laws</li> </ul> |

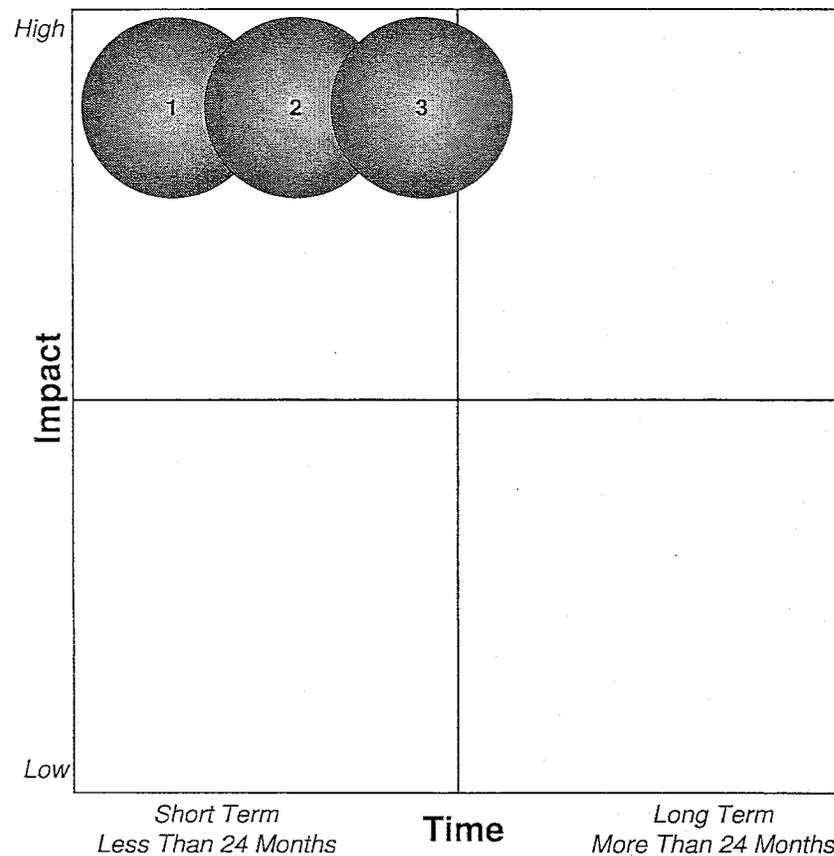
**Consumers need to be educated about the laws and safety risks associated with prescription drug importation so that they avoid counterfeit situations.**

## Importation – Recommendations

| Education and Awareness | Recommendation   | Components   | Objectives  | Implications for Success  |
|-------------------------|--|--|---|---|
|                         | <p><b>Educate Consumers About The Illegality And Risks Of Drug Importation</b></p> | <ul style="list-style-type: none"> <li>• Inform consumers that importing drugs is unsafe and illegal               <ul style="list-style-type: none"> <li>– Illegal internet pharmacies</li> <li>– US “storefronts” for foreign pharmacies</li> <li>– Personal importation from foreign pharmacies</li> </ul> </li> <li>• Include key messages in a communication plan               <ul style="list-style-type: none"> <li>– Internet pharmacies can be dangerous - “Look for the VIPPS seal and verify its authenticity by checking the verified internet pharmacies list at NABP.net” to identify legitimate internet pharmacies</li> <li>– Foreign sourced drugs do not offer FDA protection</li> <li>– Personal importation is illegal and punishable by law</li> <li>– Illegal imports have a greater risk of counterfeit or tampered product</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Prevent the usage of counterfeit drugs</li> <li>• Protect the safety of the American people</li> </ul> | <ul style="list-style-type: none"> <li>• Since the public is debating the merits of drug importation, the FDA should clearly inform interested parties about the safety risks associated with any proposed legislation</li> </ul> |

The integrity of the U.S. prescription drug market is dependent upon immediate and continued diligence in enforcing existing laws as well as educating the public about illegal imports and their impact.

## Importation – Migration Plan



### Critical Steps

1. Enforce existing laws that outlaw importation of prescription drugs
  - FDA should revisit and revise its enforcement discretion policy
2. Educate and make consumers aware that:
  - Importation is illegal
  - Drugs not sourced in the US are not protected by FDA minimum standards and may be counterfeit and unsafe
3. Monitor ongoing debate and ensure that any change in importation laws require stringent requirements equal to those required of licensed U.S. pharmacies and wholesalers

## Contents

- Executive Summary

- Project Background

- Industry Recommendations

- **Next Steps**

**The FDA should continue to work collaboratively with industry representatives to develop cost efficient and effective solutions that ensure drug authenticity and patient safety.**

## **Next Steps**

- NACDS Leadership Council will wait for the FDA 's report and recommendations scheduled for January, 2004 to determine additional programs that can pro-actively support industry and the FDA solution development.
- NACDS and many of its members will continue their active involvement in collaborative RFID pilots.

