Attachment 5

Proposed Questions and Answers on Emergency Contraception in California by Pharmacies

Questions and Answers about Emergency Contraception

In mid-August, the FDA reclassified Plan B from prescription status to over-the-counter status for emergency contraception for male and female buyers aged 18 and older. For patients 17 years and younger, Plan B remains a prescription drug.

In California existing law contains provisions that allow a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of drugs, including Plan B (California Business and Professions Code section 4052 and California Code of Regulations section 1746).

The following questions and answers provide guidance to patients and pharmacies.

How does FDA's reclassification of Plan B to over-the-counter status for women 18 and over affect California law?

For women and men age 18 and over, the pharmacy may sell Plan B emergency contraception (EC) without a prescription.

Who may sell Plan B drugs?

The law does not require any specific individual to sell the product – that is a pharmacist, pharmacist intern, pharmacy technician or clerk may sell it.

The directive states that Plan B may only be sold in a pharmacy staffed by a pharmacist. Plan B medication must be stored behind the pharmacy counter.

Does a pharmacist need to consult a patient when selling Plan B?

No, unless in the pharmacist's judgment consultation is warranted.

However, the board considers this to be an important change and an opportunity for pharmacists to assist patients with their understanding of this drug and its correct use. Pharmacists should be alert to any need for patient education and do whatever is needed and appropriate to be sure that patients understand this product.

Does the pharmacist need to keep records of dispensing to women/men over the age 18?

No.

The California EC protocol developed by the Board of Pharmacy and Medical Board of California lists a number of other products that can be used for EC and provided by a qualified pharmacist. Are these products now also over-the-counter when used for EC?

No. Only Plan B has been reclassified for OTC use for patients 18 and over.

Attachment 6

Modifications to E-Pedigree Requirements Contained in SB 1476 (Figueroa, Chapter 658, Statutes of 2006)

California Prescription Drug Pedigree

Judith K. Nurse, Pharm D
Supervising Inspector
CA State Board of Pharmacy

Pedigree Overview Existing Law 2004 (cont)

- CA Board of Pharmacy may delay implementation of pedigree until 1/1/08
- CA legislature may delay implementation of pharmacy pedigree until 1/1/09

Pedigree Overview Existing Law 2004

- 2004 legislation passed
- 1/1/2005 legislation enacted & some sections implemented
- 1/1/2007 original pedigree implementation date

Pending Legislation On Governor's Desk

- Purpose
  - Response to industry request to delay
  - Allow technology to mature and continue to develop
  - Develop standards for interoperability and unique identifiers
  - Ensure system developed protects public safety
  - Clarification of original legislation

CAUTION

- If Governor does not approve this legislation, the information discussed in the next 16 slides WILL NOT become law.
- California then reverts to existing 2004 law, implementing pedigree 1/1/2007 unless Board takes action to extend implementation date to 1/1/2008

Pedigree Definition

- "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug

Pending Legislation Governor's Desk (cont)_

- Governor deadline to sign legislation 9/30/06. If signed effective 1/1/07
- 1/1/2009 pedigree implementation date
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11
- Application of pedigree in pharmacies subject to review during Board's sunset review

Pedigree Definition Pending Legislation

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

Interoperable electronic system defined

- Electronic track and trace system
- For prescription drugs
- Uses unique identification number
- Established at point of manufacture
- Contained within standardized non-proprietary data format and architecture
- Uniformly used by manufacturers, wholesalers and pharmacies

Prescription Drug Information

- Drug name – trade or generic
- Quantity
- Dosage form
- Strength
- Container size
- Number of containers
- Expiration dates
- Lot numbers

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification

Transaction and Source Information

- Business name
- FDA manufacturing registration number or state license number as determined by the Board
- Principal address of the source
- Date of transaction
- Sales invoice number

Ownership Information

- For each prior owner of the drug the pedigree must contain:
  - Prescription drug information
  - Source information
  - Transaction information
  - Name & address of each person certifying delivery or receipt of prescription drug

Repackaging-a part of original pedigree

Single pedigree includes every change of ownership from initial manufacturer through the final transaction to a pharmacy or other person for furnishing, administering or dispensing the prescription drug, regardless of repackaging or assignment of another National Drug Code (NDC)Directory number

Pedigree Certification

- A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate

Pedigree tracking

- Pedigree tracks each prescription drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy.

Drug Returns

- Prescription drugs returned to the manufacturer or wholesaler are documented on the same pedigree document as the transaction that resulted in receipt of the drug by the party returning it.

Transactions not requiring a pedigree (cont)

- Injectable prescription drugs delivered directly by manufacturer to an authorized prescriber directly responsible for the administration of the injectable
  - may not be dispensed to a patient or patient's agent for self administration
  - Must be administered to patient by prescriber or other authorized entity receiving drug directly from manuracturer
  - Exemption expires 1/1/10 unless industry requests extension and Board grants to 1/1/11

Transactions not requiring a pedigree

- Samples –provision of prescription drug samples by a manufacture's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge

Reporting requirement

- Manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription drug in, or having been in, its possession is counterfeit or subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify CA Board in writing within 72 hours of obtaining knowledge.
  - Applicable only if drugs sold or distributed in or through the state of California

Related Existing Law

- All wholesalers selling into or located in CA must be licensed in CA (effective 1/1/05)
- Surety bond required for all licensed wholesalers
- Restrictions on pharmacy furnishing, manufacturers and wholesalers (effective 1/1/05)
- Wholesaler or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree (effective 1/1/09)

Pharmacy furnishing restrictions (cont)

- Patient or pharmacy pursuant to a prescription
- Health care provider authorized to purchase prescription drugs
- Pharmacy under common control

Pharmacy Furnishing Restrictions

- Pharmacy may only furnish prescription drugs to:
  - Wholesaler/manufacturer from whom the drug acquired
  - Pharmacy/wholesaler of common control – drugs may only be transferred to wholesaler by pharmacy if drugs originally purchased from commonly controlled wholesaler
  - Licensed wholesale reverse distributor
  - Pharmacy or wholesaler in sufficient quantity to alleviate a specific shortage

Other restrictions

- Manufacturer/wholesaler may only furnish to an authorized person
- Manufacturer/wholesaler/pharmacy may only furnish prescription drugs to a licensed business or prescriber
- Acquire prescription drugs only from a manufacturer or licensed wholesaler
- Effective 1/1/09, a wholesaler or pharmacy may not receive, sell, trade or transfer a dangerous drug without a pedigree

What do we do to prepare for 1/1/09

- Develop interoperability standards
- Develop unique identifier standards
- Participate in public CA Board of Pharmacy quarterly pedigree workgroup meeting
- Participate at pharmacy, wholesaler and manufacturer levels to assure compliance by 1/1/09

Questions?

Visit our Web site at

www.pharmacy.ca.gov

Or call us at (916) 574-7900

Attachment 7

EPCglobal's Presentation on the State of Pedigree and EPC/RFID Standards
September 28, 2006

California Board of Pharmacy

State of Pedigree and EPC/RFID Standards

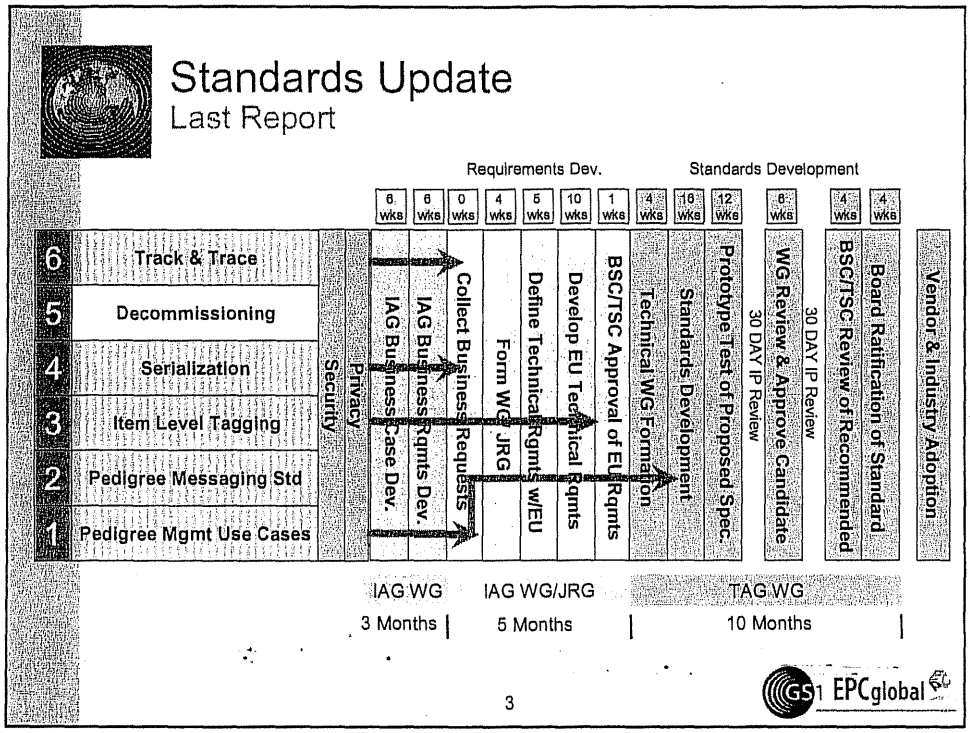
September 28, 2006

GS1 EPCglobal

Agenda

- Standards Progress
- Serialization and Tagging Progress
- Pedigree Prototype event

GS1 EPCglobal


Standards Update
Last Report
Requirements Dev.
Standards Development
6 wks
6 wks
0 wks
4 wks
5 wks
10 wks
1 wks
4 wks
16 wks
12 wks
6 wks
4 wks
4 wks
6 Track & Trace
5 Decommissioning
4 Serialization
3 Item Level Tagging
2 Pedigree Messaging Std
1 Pedigree Mgmt Use Cases
Security
Privacy
IAG Business Case Dev.
IAG Business Rqmts Dev.
Collect Business Requests
Form WG/JRG
Define Technical Rqmts w/EU
Develop EU Technical Rqmts
BSC/TSC Approval of EU Rqmts
Technical WG Formation
Standards Development
Prototype Test of Proposed Spec.
30 DAY IP Review
WG Review & Approve Candidate
30 DAY IP Review
BSC/TSC Review of Recommended
Board Ratification of Standard
Vendor & Industry Adoption
IAG WG
IAG WG/JRG
TAG WG
3 Months
5 Months
10 Months
3
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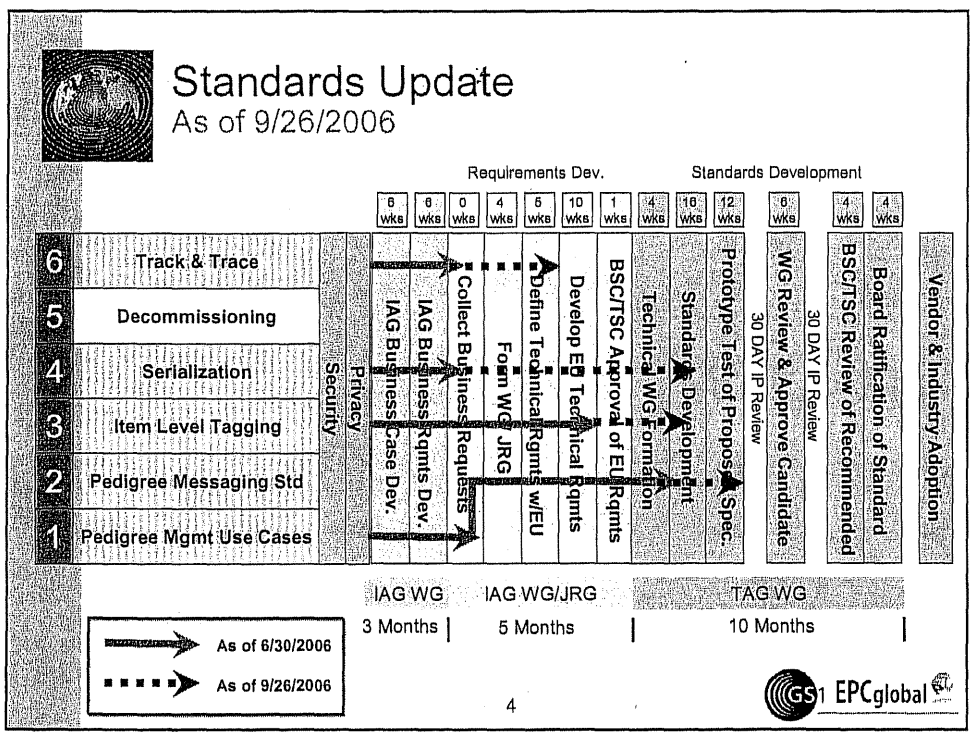
Standards Update
As of 9/26/2006
Requirements Dev.
Standards Development
6 wks
6 wks
0 wks
4 wks
5 wks
10 wks
1 wks
4 wks
16 wks
12 wks
6 wks
4 wks
4 wks
6 Track & Trace
5 Decommissioning
4 Serialization
3 Item Level Tagging
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Technical WG Formation
Standards Development
Prototype Test of Proposed Spec.
30 DAY IP Review
WG Review & Approve Candidate
30 DAY IP Review
BSC/TSC Review of Recommended
Board Ratification of Standard
Vendor & Industry Adoption
IAG WG
IAG WG/JRG
TAG WG
3 Months
5 Months
10 Months
As of 6/30/2006
As of 9/26/2006
4
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Standards Update

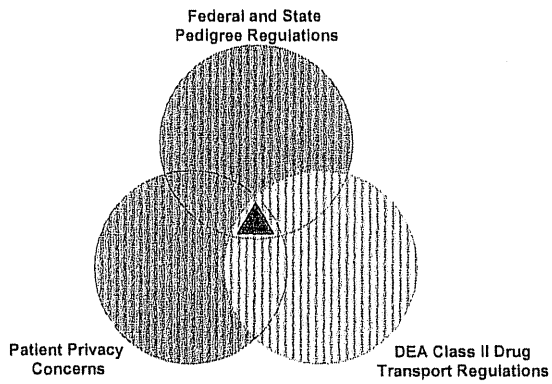
As of 9/26/2006

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

- Technical Requirements under way
- 2 GS1 standards identified as options
- May need 1 new standard for EPC that does not contain NDC
- Work with Industry Adoption WG and Industry Associations to establish direction
- Working group meeting this week to decide on tag feature alternatives for future EPCglobal HF standard (3qtr 2007)
- Completed Prototype event

Understanding Serialization & Tagging Options

Regulatory and privacy



Understanding Serialization & Tagging Options

Regulatory and privacy based requirements

FDA:
- Hits PDMA Dec 2006
- Allows for Normal Distribution Rules
- Pro EPC/RFID

Florida:
- Requires Pedigrees on all drugs Jun 2006
- Allows for Normal Distribution Rules
- Serialization not required
- Authenticate item before receipt

California:
- Requires Pedigrees on all Drugs (starts w/ Manuf) 2009
- Serialization Required
- Authenticate item before receipt

DEA:
- Sent letter to DEA
- Agreed to meet with us, scheduling meeting w/DEA

Manufacturers & Retail Pharmacies:
- Concerns that patients receive tagged drugs before infrastructure is in place
- Concerns of Single Drug manufacturers

Requirements

Serialization at Item level

RFID
(Bar Code would require opening of each case on loading dock)

Tag Data Standard
(No Product ID on Class II drugs)

Tag Data Standard
(Temporarily, no Manager number on sensitive drugs)

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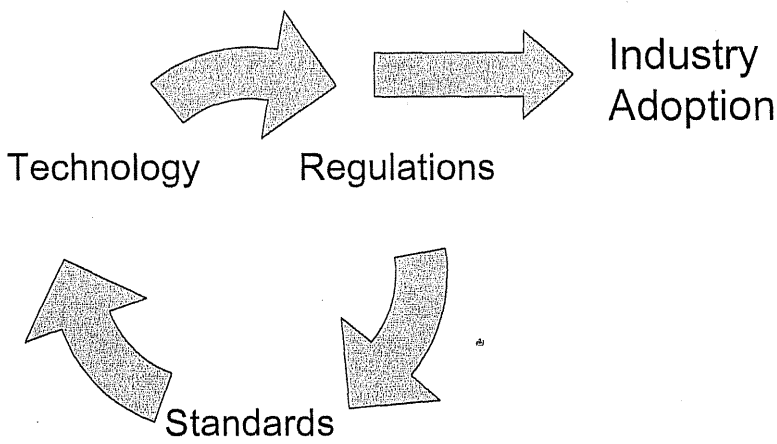
Interdependencies



8

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EPCglobal Pedigree Prototype Event

GS1 EPCglobal

EPCglobal Pedigree Prototype Event
Purpose and Format

Purpose
- To test the Last Call Working Draft version of the standard
- To ensure that different parties would interpret the standard in the same manner

Format
- Six companies were given seven of the most challenging scenarios and test data to create Pedigrees against
- Their Pedigrees were compared, line by line, with the expected outcome from the standard
- 42 Pedigrees in total were tested

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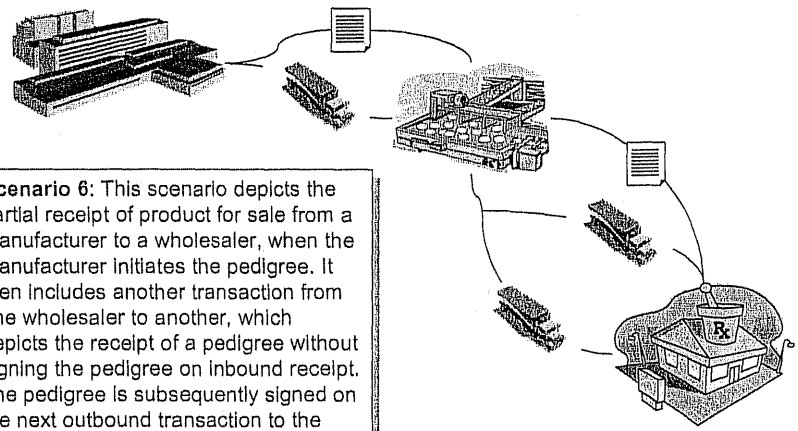
EPCglobal Pedigree Prototype Event
Sample Scenario



Scenario 6: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

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EPCglobal Pedigree Prototype Event
Participating companies

Participants

- Axway
- Cognizant
- Raining Data
- RFXcel
- SupplyScape
- VeriSign

Observers

- Accenture
- Cardinal Health
- EPCglobal
- Johnson & Johnson
- Tibco

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EPCglobal Pedigree Prototype Event
Outcome

- No Normative changes to the Standard
- List of explanatory changes to the Standard
- List of changes to the Guideline document
- An additional guideline scenario to the Guideline document

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Next Steps

- Walk Board of Pharmacy through Pedigree scenarios
- Host workshop for Regulators from States with electronic pedigree bills
- Industry Adoption WG formed
  - Working with Industry Associations on Serialization & Item Level Tagging issues
- Upcoming events:
  - EPCglobal US Conference
  - NACDS/HDMA RFID Conference
  - Ongoing work on
    - Serialization
    - Item Level Tagging
    - Track and Trace
    - Building alignment w/in GS1 Organization
- Provide regular status updates to CA BoP

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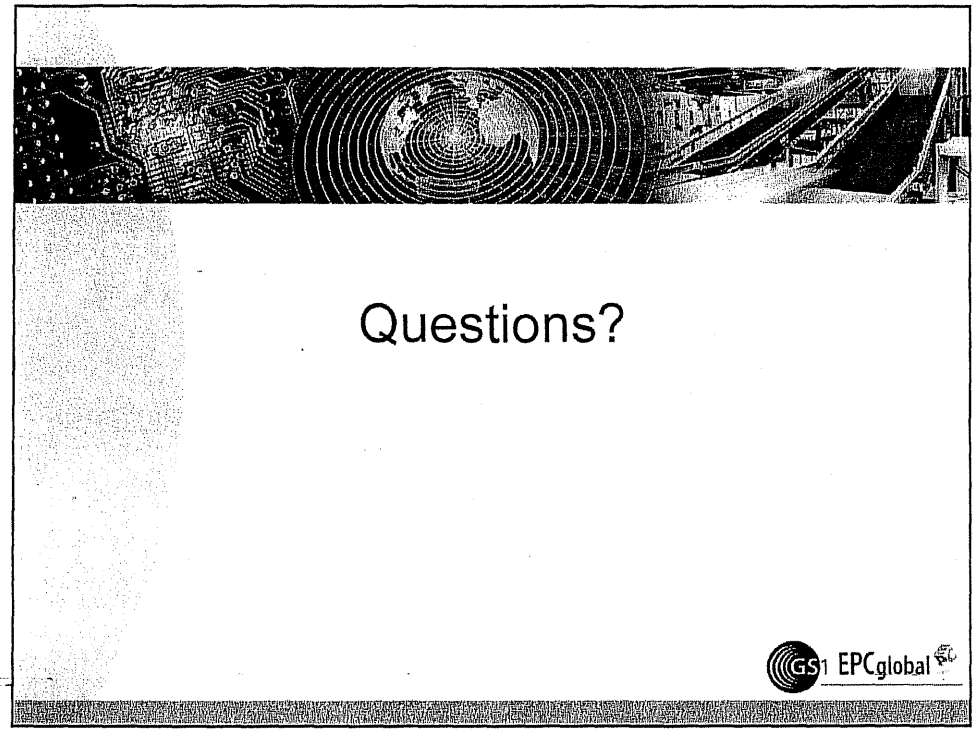
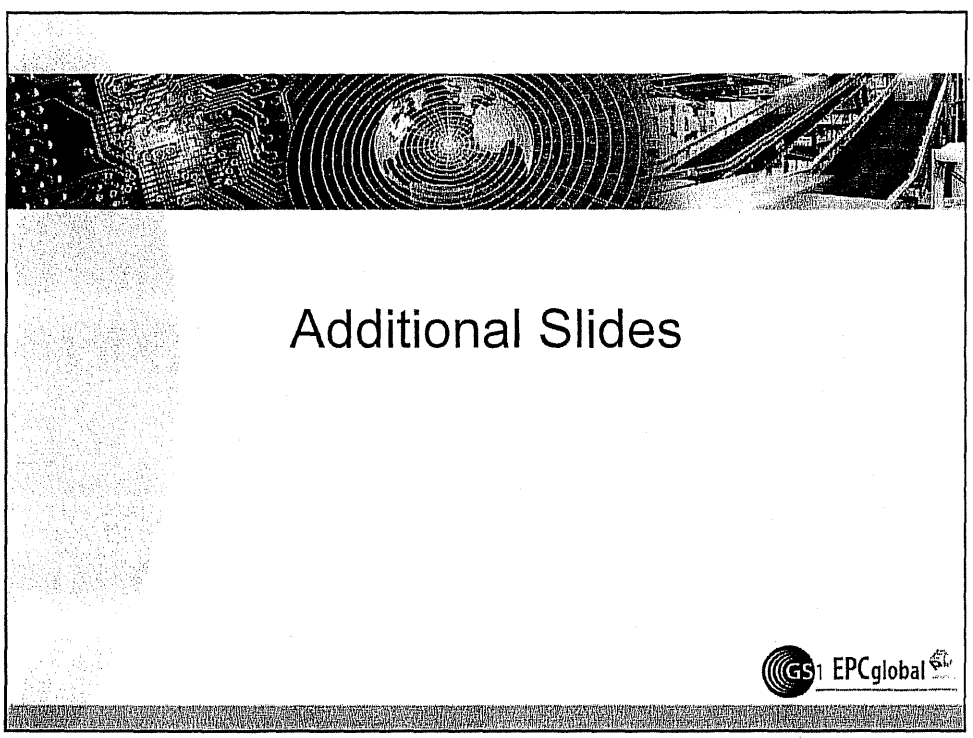

Questions?
GS1 EPCglobal


Additional Slides
GS1 EPCglobal

EPCglobal Pedigree Prototype Event

Scenarios

- **Scenario 1:** This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.
- **Scenario 2:** This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 3:** This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 4:** The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products
- **Scenario 5:** This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.
- **Scenario 6:** This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.
- **Scenario 7:** This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.

Understanding Serialization & Tagging Options

Proposed Serialization Alternatives

Coding Scheme	Description	Level
#1 [Name TBD]	-DEA requirement that may not be fully addressed by existing GS1 standards Entirely new schema for GS1 (similar to SSCC and GIAI tag formats) -96-bit encoding -Manager Code -No Product Code -Larger capacity serial number than SSCC -Could be fully ser. w/ Manager Code of Issuing Auth. -Could apply to controlled substances	-Item -Case -Pallet (option)
#2 SGTIN96	-Serialized Global Trade Identification Number -Existing and in use schema for GS1 -Contains Manager Code -Contains Product Code	-Item -Case -Pallet
#3-N National Code Support •when companies are ready to apply RFID tags and ship to these countries	-For non-GS1 code requirements -Structure follows national code's own structure; e.g. Bolini, Vignette, etc. -May or may not include Product Code -If GSIN/SGTIN is not sufficient -Goal is to have as few of these as possible	-Item -Case -Pallet

GS1 EPCglobal

Attachment 8

McKesson's On Track Pilot Project
Status Report
September 28, 2006

McKESSON

Empowering Healthcare

On Track Update

California Board of Pharmacy Enforcement Committee

September 28, 2006

On Track is an opportunity to:

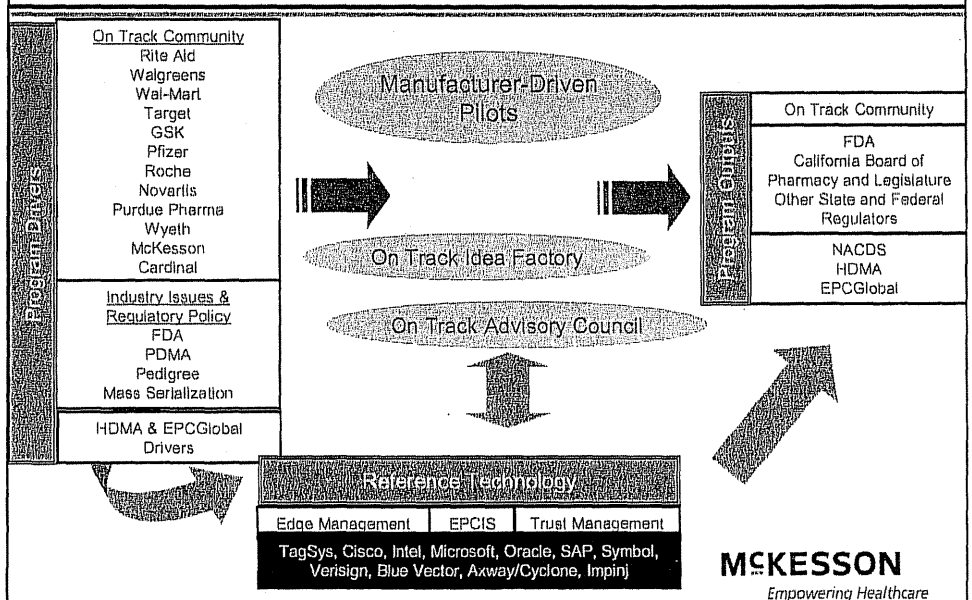
- Bring together trading partners and create a living laboratory across the supply chain to advance *product safety, item serialization, and the quality of healthcare*
- Leverage the learnings and momentums of industry leading companies to *reduce costs and development time*
- Gain *real-world experience* with product serialization in a *technology-agnostic* environment
- Leverage learnings into practical *commercial serialization installations*
- Provide *fact-based information* to the membership, the industry, the technology community and policy makers.

On Track is not:

- A group to set standards, policy or regulatory agendas

McKESSON
Empowering Healthcare

On Track Program



McKESSON
Empowering Healthcare

Critical Questions

1. Data Sharing
   - Safe and secure supply chain
   - ePedigree
   - Authentication
   - Standards
2. Track and Trace Visibility
   - ASN
   - Pallet-Case-Item hierarchy
   - EPCIS
3. Tag Data
   - NDC
   - Expiration date
   - Lot number
4. Tag Frequency and Read Ranges
   - Business benefits
   - Technology interoperability
   - Interoperability with existing equipment
5. Changes in Business Process
   - Distribution Centers
   - Pharmacies

Major tag study underway by TagSys, Symbol and Impinj

Source: On Track Idea Factory, Chicago, February 23, 2006

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Empowering Healthcare

Focus Areas of Learning

- ASN
- Authentication
- Business Process Analysis
- Consumer / Patient Education
- Decommissioning
- EPCIS Strategy
- ePedigree
- Reverse Logistics
- Tag Metrics
- Technology Interoperability
- Temperature Monitoring
- Track & Trace

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Empowering Healthcare

Value to Industry

- Information sharing within the community
- Usable facts and data around
  - Serialization technology readiness
  - Data sharing methodologies and needs
  - Interoperability challenges between supply chain participants
- Access to Reference Technology participants and experimentation results
- Next Steps
  - Gen 1 production pilots to continue through December 2006
  - Gen 2 production pilots to start in December 2006
  - Reference Technology outputs published October 2006

MCKESSON
Empowering Healthcare

Consumer Benefit

- Feedback from Manufacturers and Retailers on patient privacy issues
- EPCglobal's patient privacy findings
- Discussion on potential benefits to the consumer

MCKESSON
Empowering Healthcare

Attachment 9

Material Submitted by Stat Pharmacecuticals on the FDA Pedigree Requirements

September 29, 2006

Problem: Federal Pedigree Law, Prescription Drug Marketing Act **(PDMA)**

My name is Gene N. Alley, President and CEO of STAT Pharmaceuticals, Inc., a California pharmaceutical wholesaler, based in San Diego, and licensed in all 50 states. STAT has served office-based physicians nationwide since 1982, and currently has 25 employees. I am vice president of regulatory affairs for the National Coalition of Pharmaceutical Distributors, or NCPD, a relatively new non-profit trade association which was formed to provide a voice for all the small to medium sized pharmaceutical distributors relative to governmental actions that may impact their industry.

First and foremost, STAT Pharmaceuticals, and the NCPD supports the FDA's position to promote a federal pedigree program to ensure the integrity of the pharmaceutical supply chain. I wish to express my objections to the final form of the pedigree law that is set to become effective December 01, 2006, which is unfair and extremely detrimental to small business.

For those in the audience that have no clue what a drug pedigree is, it is a document that traces the movement of a prescription pharmaceutical, starting with the manufacturer and recording each company that is involved with the movement of the drug on its way to the pharmacist or doctor (aka, dispenser).

Some have contended that there has been more than adequate time for arguments to be made. However, the comment period has **never been effectively communicated** to the small and medium sized pharmaceutical distributor, which means the law was crafted **solely with the input of the 5 national mega billion-dollar drug wholesalers,** who already control 90% of the market.

Congress exempted these five and other "authorized" distributors (AD) from having to pass pedigrees, which created two distinct categories of drug distributors, an "uneven playing field" in the industry. By definition, you have either:

1. **Authorized Distributors (AD),** where the licensed distributor buys directly from the pharmaceutical manufacturer or .....
2. **Unauthorized Distributors,** where for a number of reasons the licensed distributor cannot purchase directly from the manufacturer and must purchase the same drug from an AD.

The Authorized Distributors are not required to pass pedigrees to the smaller distributors, and currently either unwilling to voluntarily provide pedigrees to us, or have attached a special pedigree fee so high that we will have to **raise our prices at least 15%** across the board to absorb the fee and stay in business. Who loses? The office-based physician, and the consumer. The decision to exempt those distributors that are responsible for handling over 90% of all pharmaceuticals in the US today **makes absolutely no sense at all**, nor is it effective in adding any additional security to the pharmaceutical supply. It in fact will allow serious loop holes for the crooks to enter illicit drugs into the marketplace.

The effect of exempting authorized wholesalers from the pedigree requirements **results in a complete inability** on the part of all unauthorized wholesalers to conduct any business at all because they are unable to obtain pedigree information back to the manufacturer from authorized wholesalers. Absent such information, the unintended consequence of the FDA Rule is that **the entire secondary wholesale industry will be completely and immediately destroyed** as soon as the FDA Rule becomes effective on December 1, 2006. **Not a single secondary wholesaler** can continue to lawfully operate because it can not obtain pedigree information from the exempted authorized distributor. We can buy all the drugs we want, but can not lawfully resell pharmaceutical product to anyone.

The **federal pedigree law** in its current form:

1. **Is unworkable and anti-small business.**
2. **Will actually decrease the security of the pharmaceutical supply chain.**
3. Cause **thousands of employees to lose their jobs.**
4. It will drive the legitimate specialty prescription pharmaceutical wholesalers out of business.

5. It will leave certain markets and consumers of prescription drugs **significantly underserved.**
6. **Drug prices will rise** to both the consumers and the healthcare practitioners due to lack of competition or the **excessive regulator burdens** saddled completely on the backs of small business.

On June 7, 2001, the FDA submitted its report to Congress. The report advised Congress, among other things, as follows: "The PDMA pedigree exemption for authorized distributors not only puts unauthorized distributors at a disadvantage, but also has the effect of wiping the slate clean each time prescription drugs pass through an authorized distributor." I believe that given today's prescription drug distribution system, the PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree **undermines the purpose of the pedigree by allowing for potential gaps in the distribution history.**

This law constitutes regulations that are excessively burdensome to small businesses, completely unfair, and slanted entirely in favor of big business, who have to do zero additional paperwork. Is 90% of the market not enough?

I contend that such destruction of the secondary wholesale industry violates the Fourteenth Amendment's Equal Protection clause because the disparate treatment between authorized distributors" and "unauthorized distributors" (i.e., non-authorized wholesalers) is not rationally related to the objective of the statute (and, indeed, is contrary to that objective). Moreover, such destruction is further unconstitutional in that it constitutes a taking of property (the business and assets of secondary wholesalers) without Due Process of Law.

Bill Hubbard, **former FDA associate commissioner** for policy and planning, said in an interview with The Pink Sheet (July 10, 2006 edition) that the AD provision creates an "unlevel playing field" in the industry and **suggests Congress should eliminate the provision.**

Another problem with the current PDMA language is that it states that there is a "normal" supply chain by which all drugs are delivered in the nation today, which is:

Manufacturer (MFR) > Authorized Distributor (AD) > Dispenser

This is erroneous in that for over 30 years, the supply chain in the physician and dental markets has been as follows:

Manufacturer (MFR) > Authorized Distributor (AD > Physician Distributor (PD) > Dispenser

STAT Pharmaceuticals, Inc. supports Congress's move to implement a federal pedigree program. That said, in an effort to ensure that all drugs get to all the providers and patients that need them, **the definition of 'normal distribution' needs to be thoughtfully revised, or the law needs to be the same for all distributors.**

What is needed immediately **TO SAVE JOBS and to INCREASE DRUG SUPPLY SAFETY is a stay** to December 1, 2008 so that the law can be reexamined in light of the conditions that exist today. Congress can then take up this issue in the spring of 2007 and get input from all healthcare distributors and not just the giants. The **Federal pedigree law needs to be a UNIVERSAL PEDIGREE SOLUTION,** requiring a pedigree back to the manufacturer by **EACH AND EVERY stakeholder** in pharmaceutical supply chain, or at the very least, a pedigree back to the authorized distributor is more than adequate.

Additional supporting documents are available via email upon request.

Thank you for your time and attention in this matter

September 22, 2006

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Prescription Drug Marketing Act Pedigree Requirements, Effective Date and Compliance Guide [Docket Nos. 1992N-0297, 1998N-0258]

We, the undersigned companies and trade associations, are pleased to have an opportunity to provide comments to, and seek immediate amendment of, the Draft Compliance Policy Guide ("CPG") 160.900 describing the FDA's Prescription Drug Marketing Act enforcement priorities, as issued by the FDA on February 14, 2006.

We are committed to assuring the integrity of the products in the marketplace. That is why we are not opposed to the FDA's decision to lift the stay of the final regulations implementing the PDMA pedigree requirements. (21 C.F.R.§§ 203(u) and 203.50. Because of the disruptions that may accompany the lifting of the stay, it is of critical importance that this was accompanied by your CPG. We commend the FDA on issuing a CPG that properly focuses on risk-based factors to determine enforcement priorities. However, the FDA should not assume that the lack of opposition to lifting the stay means that there are not broad concerns among affected parties about the potential of serious dislocations to markets and lasting harm to distributors that is likely to occur without additional guidance from FDA.

We, therefore, join with a wide array of companies who have already expressed concerns in their comments on the CPG about how the final rule will affect the overall pharmaceutical supply chain.

The PDMA requires each person involved in the sale of a drug, other than the manufacturer or the Authorized Distributor of Record ("ADR"), to provide a pedigree showing all transactions back to the manufacturer. The PDMA defines an ADR as a "distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturers' products." Rules implementing the PDMA define ongoing relationship as one in which the manufacturer and the distributor have entered into a "written agreement" authorizing a wholesaler to distribute the manufacturers' products. 21 C.F.R. § 203.3(u).

While we share the FDA's commitment to ensuring the integrity of prescription drugs, it is clear that many dislocations will occur by lifting the stay at a time when authorized distributors are exempted from pedigree requirements. For instance, the National Association of Chain Drug Stores noted in their comments that there is no way to assure that an entity has ADR status for particular drugs, which imposes significant compliance challenges for pharmaceutical purchasers.

Numerous other commentators, including the American Pharmacists Association (APhA) and other drug wholesalers, have detailed the anticompetitive effects that this rule will impose on the wholesaler industry. They point out that, as written, the law and regulations provide sole authority to the manufacturers to determine which wholesalers can receive ADR status, thereby allowing the manufactures to unilaterally decide which wholesalers will be subject to the PDMA pedigree requirements. Further, the law provides no requirements for ADRs to provide pedigrees to non-ADR wholesalers. Without such a requirement, it is unlikely that an ADR, or a manufacturer for that matter, would voluntarily supply a pedigree to a non-ADR for a particular product.

If ADRs refuse to provide pedigrees to non-ADR wholesalers, wholesalers would be forced to either disregard the law or cease conducting business. Close to 4,000 small wholesalers, including those who provide supplies to doctors and dentist offices, would be forced choose, on December 2, whether to continue in violation of PDMA or close operations, leaving only ADRs left in the supply chain.

The elimination of competition in this vital segment of the marketplace would likely lead to an increase in costs for consumers and would place patients' access to necessary medications at risk, particularly those patients relying on rural and independent drug stores. As APhA noted, "the closing of unauthorized distributors would undoubtedly create a disruption in the drug distribution system negatively affecting pharmacists' ability to secure medications."

While the FDA cannot eliminate these acknowledged anticompetitive effects due to the requirements of the law, it may ameliorate these effects by using its enforcement discretion to focus on those situations that are more likely to involve counterfeit or adulterated products. Accordingly, we request that the FDA amend the CPG to note that the FDA will focus its enforcement activities upon those situations where there is no pedigree back to an ADR. Amending the CPG along these lines would allow non-authorized distributors and wholesalers to continue to function until such time as Congress can address the practical complications that have arisen from the authorized distributor exemption.

Focusing enforcement on pedigree back to the ADR would be consistent with the risk-based enforcement approach the FDA has adopted in issuing the CPG. By exempting ADRs from the pedigree requirement, Congress and the FDA have made a clear determination that there is little risk of counterfeit drugs entering the market through ADRs. Therefore, it makes no sense to focus enforcement on an area of the distribution chain--sales to ADRs--that has been determined to pose a low-risk to the integrity of the supply chain.

We again commend the FDA's good faith efforts to improve the safety of the prescription drug supply chain, and fully support the risk-based approach toward enforcement. Amending the CPG to ensure that unauthorized wholesalers are able to comply with the pedigree requirements by providing a trail back to an ADR or a manufacturer will smooth the transition to the pedigree requirement and ameliorate dislocations in drug supply changes that may be caused following implementation.

Furthermore, it will substantially decrease the risks of counterfeit drugs entering the distribution chain without substantially injuring competition in the marketplace.

We urge the FDA to take immediate action on this request so that guidance will be available as distributors prepare for the December 1 deadline.

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September 28, 2006

Thank you for this opportunity. I realize that you do not enact legislation; rather you enforce the law as passed down to you.

My name is Gene N. Alley, President and CEO of STAT Pharmaceuticals, Inc., a California pharmaceutical wholesaler, based in San Diego, and licensed in all 50 states. STAT has served office-based physicians nationwide since 1982, and currently has 25 employees. I am vice president of regulatory affairs for the National Coalition of Pharmaceutical Distributors, or NCPD, a relatively new non-profit trade association which was formed to provide a voice for all the small to medium sized pharmaceutical distributors. We patterned our membership and ethical guidelines after the HDMA and the National Assoc. of Boards of Pharmacies. NCPD wants the "bad guys" out of the supply chain as well, but we are tired of being blamed for everything from Global Warming to the rise in the cost of a barrel of oil.

I would like to comment on CA's pedigree law as is, and also what the effects of pedigree laws in other states have meant to patients, healthcare providers and small and medium sized ethical pharmaceutical distributors around the country.

STAT Pharmaceuticals, Inc. and the NCPD support California's desire implement a UNIVERSAL pedigree program.

The **CA pedigree law needs to <u>remain</u> as is which requires a UNIVERSAL PEDIGREE SOLUTION,** requiring a pedigree back to the manufacturer **and not be induced** by other special interests to mimic the pedigree laws that have been enacted in Florida, Colorado, etc. already., as well as the upcoming federal pedigree law due to become active on 12/01/06. **<u>A manual version</u>** should be enacted 1/1/07 in lieu of the electronic requirement with certain minor additions to be discussed later. Absent a manual pedigree requirement now, ALL CA wholesalers will fall under the Federal law which becomes effective in December.

The requirement to have the pedigree go back to the manufacturer is realistic and is effective in adding security to the pharmaceutical supply chain, **BUT ONLY IF ALL** pharmaceutical distributors are required to do so. This is in the bill and needs to stay there.

Why are we concerned with the pedigree laws currently in force (FL, CO) and the soon to be Federal pedigree law?

1. **It is unworkable and anti-small business.**
2. **Will NOT guarantee drug safety; it has actually created a loop hole for the crooks.**
3. It will drive the legitimate specialty prescription pharmaceutical wholesalers out of business.
4. Cause **thousands of employees to lose their jobs.**
5. It will leave certain markets and consumers of prescription drugs significantly underserved.
6. **Drug prices will rise** due to lack of competition, to both the patient and the healthcare practitioner.

On June 7, 2001, the FDA submitted its report to Congress. The report advised Congress, among other things, as follows: "The PDMA pedigree exemption for authorized distributors not only puts unauthorized distributors at a disadvantage, but also has the effect of wiping the slate clean each time prescription drugs pass through an authorized distributor." I believe that given today's prescription drug distribution system, the PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree **undermines the purpose of the pedigree by allowing for potential gaps in the distribution history.**

California needs to lead the way in crafting fair, sensible, and effective legislation that will secure the pharmaceutical supply chain for all healthcare participants, AND to protect and serve the consumers at large.

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Unfortunately, the other states mentioned above along with Congress have chosen a different course and have exempted the so called "authorized" distributors (AD) from having to pass pedigrees, which created two distinct categories of drug distributors, an "uneven playing field" in the industry.

1. **Authorized (AD),** where the licensed distributor buys directly from the pharmaceutical manufacturer.
2. **Unauthorized,** where for a number of reasons the licensed distributor cannot purchase directly from the manufacturer and must purchase the same drug from an AD.

The largest of the Authorized Distributors are currently either unwilling to voluntarily provide pedigrees to the unauthorized distributors or one has offered to supply pedigrees at the exorbitant fee of $5000.00 per month, with no guarantee of delivery of product. They are attempting to eliminate all of the smaller law abiding drug distributors.

Samples of the NEGATIVE EFFECTS of the federal style law include:

1. One of the big 3 cancelled all distributor accounts in FL within a week of Florida's pedigree law that gave an exemption to all of the primary wholesalers.
2. Another of the big 3 has notified all of its distributors nationwide that they will charge $5000.00 per month for them to provide pedigrees, effective December 2006, a copy of which was just mailed to us on 9/26 with a decision due by 10/1. EXHIBIT A
3. Rabies in FL...Primary contracts dictates hospital or other facility can have only one primary wholesaler....
4. EXHIBIT E1
5. The effect of exempting authorized wholesalers from the pedigree requirements of the PDMA results in a complete inability on the part of all unauthorized wholesalers to conduct any business at all because they are unable to obtain pedigree information back to the manufacturer from authorized wholesalers. Absent such information, unauthorized wholesalers cannot lawfully resell any products and are, therefore, put completely out-of-business.

Bill Hubbard, **former FDA associate commissioner** for policy and planning, said in an interview with The Pink Sheet (July 10, 2006 edition) that the AD provision creates an "unlevel playing field" in the industry and **suggests Congress should eliminate the provision.**

Another problem with the current PDMA language is that it states that there is a "normal" supply chain by which all drugs are delivered in the nation today, which is:

Manufacturer (MFR) > Authorized Distributor (AD) > Dispenser

This is erroneous in that for over 30 years, the supply chain in the physician and dental markets has been as follows:

Manufacturer (MFR) > Authorized Distributor (AD > Physician Distributor (PD) > Dispenser

The office-based physician, podiatrist, dentist, etc. purchases prescription pharmaceuticals in very small quantities compared to that of a retail or hospital pharmacy. The physician medical/surgical supply distributor fills a vital need in the supply chain. It buys pharmaceuticals in much larger quantities, and is willing to provide them in the unit size for sale to the physician. It buys many of its drugs from the Authorized Distributor for subsequent sale to the physician.

The national billion dollar primary drug wholesalers, 4 of whom are represented in this room today, have stated that they have no interest in servicing the office-based physicians. That is where companies such as **STAT Pharmaceuticals** provide such a needed service. A case in point is during the last 7 years when Flu Vaccine was impossible to find, the big wholesalers offered no help to their customers. STAT Pharmaceuticals located flu vaccine repeatedly and even sent 500 doses to the White House. Again, while we actively support all efforts that will ensure that all drugs get to all the providers and patients that need them unadulterated, **the definition of 'normal distribution' needs to be thoughtfully revised, or the law needs to be the same for all distributors.**

As stated above, absent a California pedigree, the federal will apply on 12/01/06, which will effectively shut down my business, and the 100's like it throughout CA.

With that in mind, what Value do Small Distributors Provide?

1. Competition = Lower Drug Prices
2. Convenience = Time Savings = Cost Savings
3. Personalized Customer Service
4. Jobs = Tax Revenue
5. Better Credit Terms to Customers = Job Creation
6. Flexibility = Creativity = Resourcefulness

On June 7, 2001, the FDA submitted its report to Congress. The report advised Congress, among other things, as follows: "The PDMA pedigree exemption for authorized distributors not only puts unauthorized distributors at a disadvantage, but also has the effect of wiping the slate clean each time prescription drugs pass through an authorized distributor." I believe that given today's prescription drug distribution system, the PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree **undermines the purpose of the pedigree by allowing for potential gaps in the distribution history.**

I would be happy to discuss this issue further, and will make available supporting documents via email as requested.

California needs to lead the way in crafting fair, sensible, and effective legislation that will secure the pharmaceutical supply chain for all healthcare participants, especially the patients.

Sincerely and respectfully,

Gene N. Alley
President & CEO

Federal Solution: Request the FDA stay to December 1, 2008 the current law so that it can be revised in light of the conditions that exist today. Should you choose to let the legislation become law as is and suggest to us that we lobby congress after the fact, you will effectively **eliminate tens of thousands of jobs** and **thousands of small businesses**, enabling the huge corporations who currently control 95% of the business to monopolize the market.

September 25, 2006

RE: Federal Pedigree Law, Prescription Drug Marketing Act (PDMA)

Subject: The PDMA (**Prescription Drug Marketing Act**) in its current form **is unworkable, anti-small business, and will not guarantee drug safety.** It will drive the legitimate specialty prescription pharmaceutical wholesalers, some who have been doing business legally and ethically for over 20 years, out of business, **causing thousands of employees to lose their jobs**. It will leave certain markets for prescription drugs, and ultimately consumers of prescription drugs, significantly underserved. **Drug prices will rise** due to lack of competition, to both the patient and the healthcare practitioner.

Petition Request: A stay to December 1, 2008 so that the law can be revised in light of the conditions that exist today. Should you choose to let the legislation become law as is and suggest to us that we lobby congress after the fact, you will effectively **eliminate tens of thousands of jobs** and **thousands of small businesses**, enabling the huge corporations who currently control 95% of the business to monopolize the market.

Dear :

My name is Gene N. Alley, President and CEO, and I am writing you on behalf of STAT Pharmaceuticals, Inc., a California corporation. STAT has served office-based physicians nationwide since 1982, and currently has 25 employees.

I am writing you today because you are a member of the Health Sub-committee on Energy & Commerce, and I want to express my objections to the PDMA pedigree process that is set to become effective December 01, 2006. This legislation was passed in 1988 and the pedigree portion was continually stayed until the FDA announced on June 9, 2006 that there would be no more stays. This 19-year-old law is unworkable in the 21st century and need must be reexamined given the completely different dynamic that shapes our industry today. Additionally, the comment period has never been effectively communicated to the small and medium sized pharmaceutical distributor, which means the law was formed solely with the input of the national mega billion-dollar drug wholesalers.

In light of the above facts, I ask that you contact the FDA and request they continue the stay by at least 2 years until December 1, 2008 so that congress can learn the effects of what this measure has already done at the state level where similar law exists now, and what this measure will do to the small businesses on the Federal level, if this law is allowed to remain unchanged.

First and foremost, I applaud your efforts in implementing new regulations to track and monitor the movement of prescription drugs in the United States. I too, want a safe and secure supply chain. I am not adverse to providing pedigrees; it will help get rid of the criminal element in this industry. However, the requirement to have the pedigree go back to the manufacturer is not realistic, nor is it effective in adding any additional security to the pharmaceutical supply chain.

The PDMA became law on April 22, 1988 and among other things, it established a pedigree requirement for wholesalers and distributors of prescription drugs (Section 503.50(a)(6). A pedigree is nothing more than a document that identifies each and every sale of a prescription drug, beginning with the manufacturer and concluding with the dispenser (doctor, pharmacy, hospital, veterinarian, etc.).

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Unfortunately, Congress has exempted the so called "authorized" distributors (AD) from having to pass pedigrees, which created two distinct categories of drug distributors, an "uneven playing field" in the industry. The word distributor and wholesaler are used interchangeably in this industry.

1. **Authorized (AD),** where the licensed wholesaler buys directly from the pharmaceutical manufacturer.
2. **Unauthorized,** where for a number of reasons the licensed wholesaler cannot purchase directly from the manufacturer and must purchase the same drug from an AD.

Since AD's are exempt from the pedigree requirements and they are currently unwilling to voluntarily provide pedigrees to the unauthorized distributors, the **implementation of the pedigree provision on December 1, 2006 will effectively shut down the 1000's of legitimate, ethical drug wholesalers and distributors.**

The members of the unauthorized wholesale industry are in competition with the members of the authorized wholesale industry and there is no rational basis for favoring authorized wholesalers over non-authorized wholesalers. Almost every reported case of a conviction (or compensatory penalty) for a reported pharmaceutical counterfeiting violation involved an authorized wholesaler, so to single out one category of distributor over the other makes absolutely no sense.

The only way to remedy the situation would be for the unauthorized distributors to buy directly from the manufacturers. However, history shows that this is not an option as most manufacturers have been unwilling to open new distributor accounts. We are precluded from becoming AD's of these manufacturers because of our size and/or volume, or because we don't purchase a wide enough assortment of their product offering.

STAT Pharmaceuticals is an independent specialty wholesaler and as such, many manufacturers choose not to open up direct accounts with distributors its size, and instead, have referred them to one of their "master" distributors (AD's), a practice that hasn't changed for decades. In fact, in the last 3 years, many manufacturers have been closing many of their direct relationships with the small and medium sized distributors which have been customers of theirs for years, without so much as a "by your leave".

Another problem with the current PDMA language is that it states that there is a "normal" supply chain by which all drugs are delivered in the nation today, which is:

Manufacturer (MFR) > Authorized Distributor (AD) > Dispenser

This is erroneous in that for over 30 years, the supply chain in the physician and dental markets has been as follows:

MFR > AD > Physician Distributor (PD) > Dispenser

The office-based physician, podiatrist, dentist, etc. purchases prescription pharmaceuticals in very small quantities compared to that of a retail or hospital pharmacy. The physician medical/surgical supply distributor, at least those that are licensed as a wholesale drug distributor, fills a vital need in the supply chain. It buys pharmaceuticals in much larger quantities, and is willing to provide them in the unit size for sale to the physician. It also buys much of its drugs from the AD's for subsequent sale to the physician.

The national billion dollar drug wholesalers, also known as the **Big 3 (Cardinal Health, McKesson, and Amerisource-Bergen)** have stated that they have no interest in servicing the office-based physicians, which is understandable. That is where companies such as **STAT Pharmaceuticals** provide such a needed service. A case in point is a few years ago when Flu Vaccine was impossible to find, the big wholesalers offered no help to their customers. STAT Pharmaceuticals located vaccine repeatedly and even sent 500 doses to the White House. Small distributors go the extra mile and are valuable.

The effect of exempting authorized wholesalers from the pedigree requirements of the PDMA results in a complete inability on the part of all unauthorized wholesalers to conduct any business at all because they are unable to obtain pedigree information back to the manufacturer from authorized wholesalers. Absent such information, unauthorized wholesalers can not lawfully resell any products and are, therefore, put completely out-of-business.

Example: The Big 3, authorized distributors of XYZ manufacturer, can sell their drugs to a dispenser OR another Licensed distributor. As noted earlier, most physician supply distributors purchase their drugs from the Big 3 because they cannot buy directly from the manufacturers. I interpret this bill as follows: even though I am licensed in CA, and I am licensed in state X that has no pedigree requirements, I still will be unable to sell to my state X customers any product that I don't buy direct from the manufacturer. I can't sell a drug that I legally bought from the big 3 because I'm 1) not an authorized distributor of the manufacturer, 2) the current law as written requires us to provide a pedigree listing all transactions back to the manufacturer and 3) the Big 3 won't provide a pedigree to us.

On June 7, 2001, the FDA submitted its report to Congress. The report advised Congress, among other things, as follows: "The PDMA pedigree exemption for authorized distributors not only puts unauthorized distributors at a disadvantage, but also has the effect of wiping the slate clean each time prescription drugs pass through an authorized distributor." **This is a possible weak link in the supply chain where crooks might introduce counterfeit drugs into the market.**

I believe that given today's prescription drug distribution system, the PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree undermines the purpose of the pedigree by allowing for potential gaps in the distribution history. Small businesses (who can least afford it) in the United States will be burdened with the complex record keeping costs associated with this provision. The billion dollar mega distributors (competitors) who are considered AD's will not have these requirements, and the inherent inefficiencies and costs will further burden small businesses in our ability to remain competitive (assuming we are able to find some way to purchase drugs from an authorized distributor who will provide us with a pedigree).

Questions that need answers include:

1. The legislation in its current form stipulates that the largest AD's are secure sources and they don't need to pass a pedigree when they sell directly to the dispenser. Where is the additional risk of counterfeit drugs being introduced into the supply chain if these secure drugs are first sold to a duly licensed ethical drug distributor, who then sells them to the dispenser and also provides a pedigree listing the transactions back to the AD? In other words, what additional securities will a pedigree listing transactions back to the manufacturer provide? The answer is none, and there is no additional risk to the supply chain.
2. If there is no additional risk, then shouldn't the distributor who buys directly from the Big 3 (AD) also be exempted from passing a pedigree, or at least only required to pass a pedigree listing transactions back to the last secure source (the AD)?

3. Why couldn't a statement be put on each invoice stating that all products were purchased from AD's? This would be the same policy that the Big 3 follow except the word manufacturer that they use would be replaced with the word authorized distributor.

4. Was it the intention of the legislature to make it harder for its constituents to buy from competitive companies that are duly licensed and purchase their products in an ethical manner, thus having to spend more for the same drug after the December 1st pedigree start date than they did in November?

5. Will there be a grace period for inventory that was purchased prior to 12/1/06? If not, what are we to do with the entire inventory that was LEGALLY purchased without a pedigree?

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The following are just some of the negative effects of requiring the "unauthorized distributors" to provide pedigrees back to the manufacturer. Most of these effects would disappear if the pedigree requirement of listing all transactions starting with the manufacturer was changed to listing all transactions starting with the secure authorized distributor, with absolutely NO ADDITIONAL RISK.

1. Implementation of the final rule would leave certain markets for prescription drugs, and ultimately consumers of prescription drugs, significantly underserved.
2. Hospitals will have crisis situations where they will be unable to obtain critical drugs in a timely manner because they will have no options to turn to when their primary wholesaler is out of particular drug.
3. Prices on medications purchased by physicians will increase
4. Reimbursement to physicians will ultimately have to be increased
5. Medical insurance premiums will increase to employers, employees, etc.
6. Tax increases to cover increased Medicare costs will have to be implemented
7. Workmen's Compensation premiums will rise to the employer of all businesses
8. Businesses of all types will have additional expenses to cover
9. Legitimate small businesses (drug distributors) will be forced to close nationwide for NO reason
10. Decreased competition = increased prices
11. Cardinal Health, one of the Big 3, cut off most of their distributor customers in Florida without warning immediately after the July 1 2006 start date of Florida's new pedigree law, which was passed in the dead of night at 11:59pm on the last day of the legislative period. Will history repeat itself?

The correct interpretation of § 503(e)(1)(A) of the FD&C is that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back only to the authorized distributor from which it was obtained.

In summary, **the law as written should be changed to either** (i) the exemption to authorized distributors in § 503(e)(1)(A) of the FD&C is unenforceable and authorized distributors must be required to provide pedigree information tracing the product back to the manufacturer, **or** (ii) the requirement in § 503(e)(1)(A) of the FD&C that a nonexempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back to the manufacturer is unenforceable and that providing pedigree information back to the authorized distributor from which the product was obtained is in full compliance with the statute.

Bill Hubbard, **former FDA associate commissioner** for policy and planning said in an interview with The Pink Sheet (July 10, 2006 edition) that the AD provision creates an "unlevel playing field" in the industry and **suggests Congress should eliminate the provision.**

If the intent of this law is to drive legitimate small & medium sized drug distributors out of business, and to have only the billion dollar mega drug companies supply doctors a vial of lidocaine and a vial of bacteriostatic sodium chloride along with their order of syringes, cotton balls, and pregnancy tests (which they currently do not do), then this legislation does the trick.

Again, **STAT Pharmaceuticals, Inc. supports Congress's move to implement a federal pedigree program**. That said, in an effort to ensure that all drugs and medical products get to all the providers and patients that need them, the definition of 'normal distribution' needs to be thoughtfully revised, or the law needs to be the same for all distributors, with no favoritism shown.
What is needed now is a stay to December 1, 2008 so that the law can be revised in light of the conditions that exist today. Should you choose to let the legislation become law as is and suggest to us that we lobby congress after the fact, there will be a few thousand more pharmaceutical distributors (Small Businesses) that are driven out of business, and the only few left will be the huge corporations who currently control 95% of the business.

For more in depth study on the PDMA, please try any one of the following links.

http://www.rxusa.com/litigation/PDMA%20ACT%20AND%20PEDIGREE%20REQUIREMENTS%20DISCUSSION.pdf

http://www.fda.gov/cber/pdma.htm

http://www.fda.gov/oc/initiatives/counterfeit/cpg.html

http://www.ashp.org/news/ShowArticle.cfm?id=15677

Thank you and your staff for the time and consideration given to this letter.

Sincerely and respectfully,

Gene N. Alley
President & CEO

Prescription Drug Marketing Act (PDMA) and its Pedigree Requirements

Background:

PDMA, acronym for the Prescription Drug Marketing Act, became law on April 22, 1988[1]. The primary objective of this law was to assure safe and effective distribution of prescription drugs and to minimize risks to consumers from taking counterfeit, adulterated, sub-potent or expired drugs[2].

PDMA, among other things, established a "pedigree" requirement for wholesalers and distributors who are not manufacturers or so called authorized distributors.[3] A drug pedigree is nothing more than "a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of each of those transactions and the names and addresses of all parties to those transactions."[4] However, Congress[MSOffice1] excluded the so called authorized wholesalers and distributors from the "pedigree" requirement of PDMA.[5]

Therefore, one of the by products of PDMA was the emergence of two distinct categories of drug wholesalers and distributors: 1) Authorized, where the wholesaler is the "official" distributor of a pharmaceutical manufacturer and 2) Unauthorized, where the wholesaler or distributor purchases from authorized wholesalers.

Since the enactment of the PDMA in 1988, the metamorphosis of drug distribution business has been significant. Back in the eighties, the drug distribution business was fairly linear: Manufacturer → Wholesaler/Distributor → Consumer. Today a drug may go through several transaction cycles before arriving in the hands of a consumer.[6]

Today, secondary wholesalers, the so called unauthorized wholesalers and distributors, account for 5%-10% of the $200 billion wholesale pharmaceutical market.[7] And the transactions often move between authorized and unauthorized wholesalers. The Healthcare Distribution Management Association (HDMA) told the FDA that top drug wholesalers purchase 2%-4% of their products from non-manufacturers.[8] One of the leading drug wholesalers reported that of $16 billion total inventory, approximately $350 million was purchased from non-manufacturers.[9]

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[1] The Prescription Drug Marketing Act Report to Congress June 2001, U.S. Food and Drug Administration.
[2] Ibid
[3] Pharmaceutical Pedigree Requirements, Implementing Electronic "Track and Trace", Gary C. Messplay, J.D. and Colleen Heisey, J.D., *Contract Pharma*, July/August 2006.
[4] Ibid
[5] The Prescription Drug Marketing Act Report to Congress June 2001, U.S. Food and Drug Administration.
[6] Ibid
[7] Ibid
[8] Ibid
[9] Ibid

Section 503(e)(1)(A) of Federal Food, Drug, and Cosmetic Act requires that the pedigree must identify "each prior sales, purchase or trade." The Agency's 1988 guidance letter indicated that the pedigree could start with either the manufacturer or the authorized distributor[10]. This assumption probably was based on the premise of linear distribution channel. Since the issuance of the Agency's 1988 guidance, the unauthorized distributors have construed the Agency's guidance to mean that the pedigree need only go back to the most recent authorized distributor handling the drug[11]. This interpretation is also known as the *status quo.*

However, the language of the current regulation expands the definition of "pedigree" to include "each prior sale, purchase, or trade of such drug" (Section 203.50(a)) and include 'all parties to each transaction...starting with the manufacturer" (Section 203.50(a)(6)).[12]

This interpretation of the statue is incompatible with the *status quo* currently adopted by the non-authorized drug wholesalers and distributors.

Since authorized wholesalers are exempt from the pedigree requirements and, in most cases, are reluctant to provide pedigree documents to whomever they sell pharmaceuticals to, the implementation of the pedigree provision in December 2006 will effectively shutdown the secondary drug wholesaler and distributor market[13].

The only way to circumvent this hurdle is for secondary wholesalers to buy directly from manufacturers. Unfortunately, "big" pharmaceutical companies repudiate this notion.

The Federal Food and Drug Administration had delayed the implementation of the provision of PDMA that requires complete documentation of the custody chain of drugs in the distribution channel five times.[14] Originally the pedigree requirement was scheduled to take effect in December 2000.[15] However, after the publication of the final guidance in 1999, the Agency received numerous public comments. This prompted the agency to delay the implementation date. In February 2004 the Agency again delayed the enforcement of the pedigree provision because the Agency wanted to give the pharmaceutical industry more time to adopt electronic technology (RFID) for tracking drugs through out the distribution channel. The decision was partly based on the premise that the Agency believed that electronic technology for tracking drugs would be wide spread by 2007.[16] The Agency contended that the wide spread adoption of RFID would create the equivalent of an "electronic pedigree", tracking the movements of drugs all throughout the drug distribution channel.[17]

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[10] Ibid
[11] Ibid
[12] Ibid
[13] Ibid
[14] American Society of Health-System Pharmacists; ASHP News: FDA to Enforce Drug Pedigree Rules; www.ashp.org/news
[15] Ibid
[16] Ibid
[17] Ibid

In February 2006, the Agency capitulated to the fact that the 2007 timeline is unattainable.[18] The Agency's Counterfeit Drug Task Force refuses to forecast a new timetable for the possible implementation of electronic track-and-trace technology.[19] The Counterfeit Drug Task Force determined that an electronic pedigree through a track-and-trace method, i.e. an "e-pedigree", would secure the integrity of the drugs in the distribution channel.[20] Paradoxically although the Task Force is unsure of a possible implementation date of the RFID, it nevertheless recommended that the pedigree provision of the PDMA should be implemented effective December 2006.[21] And the Agency decided to adopt the Task Force's recommendation.[22]

The Agency's decision may also have been influenced by states' initiatives to enact distinct pedigree requirements in absence of a federal regulation, potentially burdening the drug distribution channel which could affect consumer access to drugs.[23]

The Task Force also recommended that the Agency issue a draft Compliance Policy Guide to focus the Agency's pedigree enforcement efforts on drugs most vulnerable to counterfeiting and diversion.[24] The Agency has already published a Compliance Policy Guide relating to the enforcement of the pedigree provision of the PDMA. The guideline seems to indicate that the agency is likely to take a risk-based approach to utilize its enforcement authority.[25]

Radio Frequency Identification (RFID) Device:

A Radio Frequency Identification device is a small electronic identification chip attached to drugs products.[26] The chip contains data in the form of electronic product code (EPC). This product information is transmitted via wireless to "readers".[27] The information is then gathered, analyzed, and stored in a database, providing an electronic blueprint of a drug's movement from point-of-origin to destination.[28]

The Agency is a strong proponent of the widespread use of Radio Frequency Identification devices: "FDA continues to believe that RFID is the "most promising" technology for tracking and tracing drugs in the supply chain, said Randall Lutter, FDA's associate commissioner for policy and planning."[29] However, the Agency's earlier

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[18] Ibid
[19] Ibid
[20] Pharmaceutical Pedigree Requirements, Implementing Electronic "Track and Trace", Gary C. Messplay, J.D. and Colleen Heisey, J.D., *Contract Pharma*, July/August 2006.
[21] Ibid
[22] Ibid
[23] eSource: Regulatory
[24] Pharmaceutical Pedigree Requirements, Implementing Electronic "Track and Trace", Gary C. Messplay, J.D. and Colleen Heisey, J.D., *Contract Pharma*, July/August 2006.
[25] Ibid
[26] eSource: Regulatory
[27] Ibid
[28] Ibid
[29] American Society of Health-System Pharmacists; ASHP News: FDA to Enforce Drug Pedigree Rules; www.ashp.org/news

prediction of widespread use of Radio Frequency Identification devices by year 2007 seems unrealistic. Several issues are blamed for the slow acceptance of Radio Frequency Identification devices by the pharmaceutical industry[30]:

1. The limitations of RFID
2. The uniform adoption of RFID
3. The cost
4. The unknown effect of RFID on biologics
5. Privacy issues

In spite of the above outlined concerns, the Agency's exuberance on Radio Frequency Identification devices continue to remain high: " We're hoping that the industry will continue to move forward with some speed to get the e-pedigree in place as quickly as possible,''commented Steve Niedelman, assistant commissioner for regulatory affairs at FDA.[31]

<u>The Impact of the Implementation of Pedigree Provision of PDMA:</u>

1. ***Uneven Playing Field among Drug Wholesalers and Distributors:***

   a. Congress exempted authorized distributors from the pedigree requirements of PDMA.[32] Due to this, most authorized distributors do not maintain or pass on pedigree, creating enormous problems for unauthorized distributors wishing to purchase from authorized distributors for resale. Once PDMA is implemented in December 2006, it will be illegal to resale prescription drugs without a pedigree.[33] This would have an adverse effect on consumers' access to pharmaceuticals and the price they pay for them.

   b. When PDMA was enacted, the drug distribution channel was linear (explained above). Today the drug distribution channel for the delivery of pharmaceuticals in the hands of consumer is much more involved than before. Therefore, authorized distributors should also be required to provide and maintain pedigree.

   c. The Agency has expressed its concerns relating to the pedigree exemption provision of authorized distributors under PDMA.[34]

   d. The only way the secondary wholesalers and distributors can legally operate after December 2006 is to purchase pharmaceuticals directly from

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[30] eSource: Regulatory
[31] American Society of Health-System Pharmacists; ASHP News: FDA to Enforce Drug Pedigree Rules; www.ashp.org/news
[32] The Prescription Drug Marketing Act Report to Congress June 2001, U.S. Food and Drug Administration.
[33] Ibid
[34] Ibid

manufacturers. Unfortunately, most "big" pharmaceutical companies refuse to open new distributors.

e. Bill Hubbard, former FDA associate commissioner for policy and planning said in an interview with Pink Sheet that the ADR provision creates an "unlevel playing filed" in the industry and Congress should eliminate the provision.[35]

2. ***Potential for Oligopoly Condition in the Drug Distribution Channel:***

a. The big-three wholesalers already control 95% of the drug wholesaler market. The implementation of the pedigree provision is likely to force many secondary wholesalers and distributors out of business. This would mean that the big-three wholesalers will gain even more control of the drug wholesaling market than today. As one would expect, reduced competition would increase the price paid by consumers for pharmaceuticals.

b. Independent drug stores are most susceptible to this potential emerging market condition. The inability of the secondary wholesalers to provide pedigree could force the independent drug stores to buy branded drugs from the big-three wholesalers perhaps at a higher price than previously possible from secondary wholesalers.

c. Since independent drug stores most likely will pass on the increased cost to consumers, this will ultimately add to the already spiraling prescription drug cost.

d. The pharmacies unable to pass on the increased cost to remain price competitive will experience shrinking gross margin. This could push many pharmacies to the brink of closing.

e. If the big-three wholesalers enhance their market dominance, the cost of generic pharmaceuticals to independent drug stores will increase. Generic pharmaceuticals are already a major profit opportunity for big-three wholesalers, yielding between 15%-30% gross margin. To maximize their profit opportunity, it is not uncommon to find that the big-three wholesalers often impose a purchase target for generic pharmaceuticals. Failing to meet this pre-determined target could translate into higher acquisition cost of brands, and in some cases, could mean termination of purchasing relationship.

f. Selling of generic pharmaceuticals by secondary wholesalers at a margin lower than the big-three wholesalers is keeping the price of generic pharmaceuticals for independent drug stores in check. If the secondary

[35] The Pink Sheet, July 10, 2006

wholesaler market is eclipsed, independent drugstores and consumers are likely to pay higher price for generic pharmaceuticals.

g. The Healthcare Distribution Management Association (HDMA), which had a great deal of influence with the Agency and Congress in crafting the pedigree provision of PDMA, is essentially the voice of authorized distributors. The association perhaps to limit the voice of unauthorized distributors and wholesalers has recently created a different classification for this group: non-authorized distributors, or "associate membership", as opposed to 'full membership[MSOffice2]'.

h. We believe the FDA"s June 9th comment, released when the task force decided to lift the stay of the PDMA, that "they have not heard the concerns raised in the past regarding the impact on small wholesalers" is a function of HDMA taking the voice away from the secondaries/ "associate members", thus making the 'full members' voice, the only one heard.

3. ***The Loop-holes for the Entry of Counterfeit Drugs into the Distribution Channel Continues***

a. The exemption of authorized distributors from the pedigree requirement compromises the very goal of PDMA: To avoid the unacceptable risk of counterfeit and adulterated drugs from being taken by consumers.[36] This exemption perhaps allows an unscrupulous wholesaler or distributor **(or individuals within that company)** to sell a counterfeit drug without giving any pedigree, just because they are an 'A/D', authorized distributor, and are not required to maintain or pass on a pedigree when the drugs are resold. Therefore, the PDMA, if implemented in its current form, will not provide the American consumer 100% protection against counterfeit, adulterated, or diverted drugs.

4. ***The Pedigree Exemption is Tantamount to "Wiping the Slate Clean" Each Time Drugs Pass through Authorized Distributors***

a. The PDMA pedigree exemption is not only bad for unauthorized distributors, but also has the effect of "wiping the slate clean" each time drugs touch the authorized distributors' dock. This keeps the door open for counterfeit, sub-potent, and misbranded drug back into the distribution channel, compromising health of consumers.[37]

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[36] Ibid
[37] Ibid

5. ***Universal Pedigree Requirement is an Additional Deterrent against Marketing Counterfeit Drugs***

   a. While there is no bullet-proof protection against the entry of counterfeit drugs into the distribution channel, universal pedigree requirement would make it difficult for someone planning to introduce counterfeit or diverted drug into the distribution channel.

In summary, the enforcement of the PDMA in its current form will not guarantee that drugs purchased by consumers are safe and effective, however it will cause the secondary wholesale and distributor class of trade to become defunct. The law, as it remains, will significantly burden the drug distribution channel, and negatively impact both access and price, of prescription drugs, especially generics. The Authorized Distributor exemption should be removed from the FDA regulations.

Attachment 10

Meeting Summary of the Enforcement Committee and the Work Group on E-Pedigree September 28, 2006

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee and Work Group on E-Pedigree

Summary of the Meeting of September 28, 2006

Radisson Hotel
500 Leisure Lane
Sacramento, CA 95815

9:30 -12:30

Present: Stan Goldenberg, Board Member and Acting Chair
Rob Swart, PharmD, Board Member
Ruth Conroy, PharmD, Board Member

Absent: Bill Powers, Board President

Also Present: Virginia Harold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Karen Cates, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Tim Daze, Board Member

Call to Order:

Acting Chairperson Stan Goldenberg called the meeting to order at 9:35.

The individuals present introduced themselves

Formulary of Drugs Under Development by the Bureau of Naturopathic Medicine for Naturopathic Doctors

Gloria St. John, Executive Director of the California Naturopathic Doctors Association, provided information about California's regulation of naturopathic doctors, a relatively new licensing program enacted by SB 903 (Burton) in 2003. Today there are about 200 naturopathic doctors licensed in California by the Bureau of Naturopathic Medicine, a bureau in the Department of Consumer Affairs. Naturopathic doctors must earn 60 hours of continuing education to renew their licenses every two years, of which at least 20 hours must be in pharmacotherapeutics. She added that naturopathic medicine is a

form of primary care that is an art, science, philosophy and practice involving diagnosis, treatment and prevention of illness.

Naturopathic doctors are allowed to prescribe hormone and epinephrine for anaphylaxis independently and to prescribe Schedule III through IV drugs under protocol with an MD. To furnish and order drugs, NDs must obtain a furnishing number from the bureau, which requires completion of a 48-hour course in pharmacology.

Naturopathic doctors can administer, order and prescribe food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and non prescription drugs, consistent with the following routes of administration: oral, nasal auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular. The bureau states that NDs may use ocular and intravenous routes of administration only if they are clinically competent to do so.

Senate Bill 907 specified that the Bureau of Naturopathic Medicine establish a Naturopathic Formulary Committee to determine the formulary from which naturopathic doctors will prescribe. The committee is comprised of an equal number of physicians, pharmacists, and naturopathic doctors. The committee makes recommendations regarding the prescribing, ordering and furnishing authority of an ND and the required supervision and protocols for these functions. The formulary is to be submitted to the Legislature by January 1, 2007 regarding the prescribing and furnishing authority of an ND, and the required supervision and protocols for the use of IV and ocular routes of prescription drug administration.

Ms. St. John stated that 13 states license NDs, and nine of these states allow NDs to prescribe independently with no MD oversight. No state reports disciplining NDs for prescribing. The committee concluded that there are only a limited number of MDs who possess the training and philosophy needed to supervise NDs. Moreover, the few MDs who do qualify have difficulty obtaining adequate malpractice coverage. Based upon these factors, the committee believes that MD supervision of NDs is untenable.

The Naturopathic Formulary Committee recommends:

- Inclusion Formulary: Pursue changes to California law to allow NDs to be able to independently prescribe without MD supervision from the committee-recommended formulary.
- IV Therapy: NDs should be able to practice without MD supervision after completing specific CE comprised of a 25-hour course, with 14 hours of practicum, and a refresher course every five years. Upon completion, NDs will be able to independently administer drugs listed in the IV formulary via the IV route.
- Chelation Therapy: Any ND who performs this therapy (used to detoxify for heavy metal exposures) must complete a 12-hour CE course in addition to the IV therapy course.

Ms. St. John distributed a proposed formulary to the Enforcement Committee. She indicated that she would be happy to make a similar presentation to the full board.

After some discussion, Chairperson Goldenberg invited Ms. St. John to present this information to the board at its October Board Meeting.

Plan B Emergency Contraception Becomes Over-the-Counter for Patients 18 and Older

In mid-August, the FDA reclassified Plan B from prescription status to over-the counter status for emergency contraception for patients aged 18 and older. For patients 18 years and younger, Plan B remains a prescription drug.

In California existing law contains provisions that allow a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of drugs, including Plan B (California Business and Professions Code section 4052, and California Code of Regulations section 1746).

The committee reviewed a number of questions and answers developed by staff to explain implementation of the law in California.

Although OTC, Plan B may be sold only by pharmacies and must be kept behind the pharmacy counter. Anyone, a pharmacist, pharmacist intern, pharmacy technician or clerk may sell the drug. Individuals who are 18 and order may purchase the drug. No records of these sales are required.

If the patient is less than 18, then the pharmacist, if qualified, may write a prescription for Plan B or any other medication authorized in the state protocol for emergency contraception or in the protocol established with a physician. In this case, the emergency contraception drug is a prescription drug, and all requirements for dispensing prescription drugs apply, including consultation by the pharmacist.

Also, other drugs listed in the state protocol for emergency contraception remain prescription drugs, not over-the-counter, regardless of the age of the patient or purchaser.

Several changes were suggested to the questions and answers.

Once finalized, the questions and answers will be added to the board's Web site.

Work Group on E-Pedigree

Supervising Inspector Nurse provided a Power Point presentation on changes to California's e-pedigree requirements that were amended into SB 1476. At the time of this meeting, the Governor had not yet acted on this bill to sign, veto or let become law without his signature on this bill.

Senate Bill 1476 would delay implementation of e-pedigree requirements in California until 2009, with the board having the ability to delay implementation until January 1, 2011.

The board drafted additional amendments into SB 1476 that would clarify that the e-pedigree system must interoperable through all levels in the distribution system, that serialization is needed to product container, that the board must be notified if counterfeit drugs or fraudulent pedigrees are suspected, that drugs returned to a wholesaler must maintain the same pedigree, that repackagers must maintain the pedigree into repackaged items, and that drug samples do not require pedigrees.

Chairperson Goldenberg emphasized that the e-pedigree work group meetings over the next few years will be crucial to being able to develop necessary regulations and move forward timely with implementation of these requirements that are necessary to ensure a safe distribution system for patients.

EPCglobal provided a PowerPoint Presentation about industry's progress in developing unified standards for electronic pedigrees. There continues to be progress in development, and testing on a "last call working draft" version of a standard is underway. The purpose of this standard is to ensure that different entities in the supply chain can all access the pedigree and interpret it in the same manner.

Among the issues to be resolved include decommissioning of a chip to protect patient privacy, item level tagging – whether high frequency or ultrahigh frequency would be best. It may the third quarter of 2007 before the standard for item tagging is ready. Mike Rose of Johnson and Johnson stated that 2-d bar codes are being examined as well.

EPCglobal reported on a pilot study conducted; recently six companies were given seven of the most challenging scenarios and test data to create pedigrees against. A total of 42 pedigrees were tested. Their pedigrees were compared, line-by-line, with the expected outcome from the standard. There were no changes to the standard.

Concern was expressed by Board Member Daze about the proposed delay of electronic pedigree requirements until 2009, and whether patient safety is being adequately considered.

McKesson provided a brief overview of the "On Track" pilot program underway which is seeking answers among various entities in the supply chain to e-pedigree issues such as data sharing, track and trace visibility, tag data components, tag frequency and reading ranges, and changes needed in current business processes. Generation 1 will be completed in December 2006, when a generation 2 study will begin.

Johnson and Johnson stated that they are working to implement the e-pedigree requirements but they believe implementation is still 4-5 years away. The infrastructure is not ready, and that not all products really need electronic pedigrees.

During 2006-08, Johnson and Johnson will be working on building the structure to use e-pedigrees, and test 3-5 products using both RFID and 2-D bar code technology.

In 2010, the standards will be deployed, and they believe that 50 percent of their products will be tagged by 2011. But implementation cannot be fully achieved until 2011-2012.

The company emphasized the importance of interoperability – of one standard used by everyone, and indicated that regulations to require a specific standard may be required.

The California Retailers Association stated that one standard is needed because pharmacies are at the end of the process and cannot function with multiple electronic pedigree systems, each requiring unique equipment. At this stage, the CRA cannot offer a timeline for implementation because they are waiting for the drug manufacturers and wholesalers to refine the standards. The CRA also emphasized that they are participating in the On Track and EPCglobal standards setting and pilot tests of electronic pedigrees.

Stat Pharmaceuticals provided information about its operations as a secondary wholesaler, and the association of secondary wholesalers the company is part of, which is not a part of the EPCglobal group. Gene Alley stated the difficulty that the FDA's authorized distributor and paper pedigree standards that will go into effect in December 2006 will have on such companies as his. He added that by exempting authorized distributors from pedigree requirements but requiring secondary wholesalers to obtain pedigrees from the authorized wholesalers, especially since the authorized distributors will not provide pedigrees, will force companies such as his out of business. Chairperson Goldenberg asked that he come to the October Board Meeting to provide a presentation.

Adjournment:

There being no additional business, Chairperson Goldenberg adjourned the meeting at 12:30.

Attachment 11

Enforcement Data
July 1- October 1, 2006

Board of Pharmacy Enforcement Statistics
Fiscal Year 2006/2007

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 06/07
Complaints/Investigations					
Initiated	378				378
Closed	412				412
Pending (at the end of quarter)	671				671
Cases Assigned & Pending (by Team)					
Compliance Team	103				103
Drug Diversion/Fraud	106				106
Mediation Team	85				85
Probation/PRP	56				56
Enforcement	94				94
Application Investigations					
Initiated	68				68
Closed					
Approved	3				3
Denied	2				2
Total*	6				6
Pending (at the end of quarter)	98				98
Citation & Fine					
Issued	141				141
Citations Closed	172				172
Total Fines Collected	$75,815.00				$75,815.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2006/2007

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 06/07
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	35				35
Pleadings Filed	24				24
Pending					
Pre-accusation	59				59
Post Accusation	86				86
Total	149				149
Closed**					
Revocation					
Pharmacist	1				1
Pharmacy	1				1
Other	9				9
Revocation,stayed; suspension/probation					
Pharmacist	1				1
Pharmacy					0
Other					0
Revocation,stayed; probation					
Pharmacist	1				1
Pharmacy					0
Other					0
Suspension, stayed; probation					
Pharmacist					0
Pharmacy					0
Other					0
Surrender/Voluntary Surrender					
Pharmacist	3				3
Pharmacy					0
Other	1				1
Public Reproval/Reprimand					
Pharmacist					0
Pharmacy					0
Other					0
Cost Recovery Requested	$40,239.00				$40,239.00
Cost Recovery Collected	$21,104.66				$21,104.66

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2006/2007

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 06/07
Probation Statistics					
Licenses on Probation					
Pharmacist	93				93
Pharmacy	5				5
Other	14				14
Probation Office Conferences	9				9
Probation Site Inspections	92				92
Probationers Referred to AG for non-compliance	3				3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 09/30/06)

Program Statistics					
In lieu of discipline	0				0
In addition to probation	2				2
Closed, successful	1				1
Closed, non-compliant	1				1
Closed, other	0				0
Total Board mandated Participants	50				50
Total Self-Referred Participants*	26				26
Treatment Contracts Reviewed	43				43

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of September 30, 2006.

Citation and Fine Statistics
July 1, 2006 – September 30, 2006

160 citations have been issued fiscal year 06/07

Total dollar amount of fines issued $ 402,775.00

Total dollar amount of fines collected $ 23,550.00*

*This amount only reflects payment of the citations issued this fiscal year.
Citations issued prior to this fiscal year have also been paid during this quarter.

Average number of days from date citation is issued to date citation is closed
INSUFFICIENT DATA

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
140	34	6	41	14	12	6	5	2

Miscellaneous Citation Breakdown by license type

Wholesalers	Designated Reps	Clinics	Hypo permits	Hospital pharmacy	Unlicensed Premises	Unlicensed person	VET
4	5	1	0	3	5	1	1

Top Ten Violations for the first quarter of 2006/2007 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	22%	1716 - Variation from prescription	14%	1715 - Self-Assessment of a Pharmacy by the Pharmacist-In-Charge	8%
4322 - Fraudulent licensure	6%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security Standards and Security,	14%	All remaining violations cited	4%
4339 – Actions to enjoin	6%	1716/1761 - Variation from Rx / Erroneous Rx	6%		
1711(d) - Quality Assurance Programs, Investigation and findings	5%	1711(d) - Quality Assurance Programs, Investigation and findings	3%		
1716/1761(a) - Variation from Prescription/Erroneous or Uncertain Prescription	5%	4115(e) - Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios, Technician license required	3%		
1714(d) - Operational Standards and Security, pharmacist responsible	3%	1716/1761 - Variation from Prescription/Erroneous or Uncertain Prescription	2%		
1716/1761 - Variation from Rx / Erroneous Rx	3%	1715((b) - Self-Assessment of a Pharmacy by the Pharmacist-In-Charge, New permit or change in Pharmacist-In-Charge	2%		
4059(a) - Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions, Prescription required	3%	All remaining violations cited	1%		
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory, Records open to inspection, current inventory	3%				
4342 - Actions by Board to Prevent Sales of Preparations or Drugs Lacking Quality or Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales	3%				

Contested Citations Office Conference

(These statistics also include contested Letters of Abatement)

There were six office conferences held

Number of requests	65

Number scheduled	39

Number appeared	36

Number Postponed	4*

***Please note these are added back into the number of requests and scheduled case totals above.**

Total number of requests withdrawn	2
Failed to appear	6

Office Conference results

Total number of citations affirmed	21

Decision	Total citations	Total dollar amount reduced
Modified	10	$74,625.00
Dismissed	13	$1,000.00
Reduced to letter of admonishment	0	$0.00

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months
Measure:	Percentage of cases closed

Tasks:

1. Mediate all complaints within 90 days (for cases closed during quarter)

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	141	113 (81%)	5 (3%)	11 (8%)	12 (8%)	50

2. Investigate all cases within 120 days (for cases closed during quarter)

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	271	165 (61%)	30 (11%)	49 (18%)	27 (10%)	87

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed, no additional action	210	166	14	15	15
Cite and/or fine letter of admonishment	167	82	50	25	10
Attorney General's Office	35	11	7	10	7

Objective 1.2	Manage enforcement activities for achievement of performance expectations.
Measure:	Percentage compliance with program requirements.

Tasks:

1. Administer the Pharmacists Recovery Program.

	Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program
Qtr 1	26	50	1	1

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	107			
Sites	5			
Tolled	27			
Inspections Conducted	92			
Successfully Completed	1			
Petitions to Revoke Filed	3			

3. Issue all citations and fines within 30 days

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	140	41	61	21	17	51
		(29%)	(43%)	(15%)	(12%)	

4. Issue letters of admonishment within 30 days

	N	30 days	60 days	90 days	> 90 days	Average
Qtr 1	33	30	1	2	0	12
		(91%)	(3%)	(6%)	(0%)	

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	2

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	N
Qtr 1	1	0	2	3

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.
Measure:	Percentage of administrative cases closed within 1 year

	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
22	6	11	3	1	1	456 days
	(27.3 %)	(50 %)	(13.6%)	(4.6%)	(4.6%)	

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

	Number of Inspections	Aggregate Inspections This Cycle	Percent Complete
Qtr 1	634	2,735	37%

2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.

	Number of Inspections	Number Inspected Late
Qtr 1	77	1

3. Initiate investigations based upon violations discovered during routine inspections.

	Number of Inspections	Number of Investigations Opened	Percent Opened
Qtr 1	634	33	5%

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011
Measure:	The number of issues
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California.

Sept. 28, 2006: *Board convenes third workgroup on implementation of e-pedigree meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.*

Sept. 30, 2006: *Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.*

Oct. 6, 2006: *FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.*

2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.

Sept. 2006: *Final phase-in of federal requirements takes effect on 9/30. Board newsletter provides information for licensees.*

3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.

Sept. 2006: *DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.*

Oct. 2006: *Board considers proposed rule.*