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GENERIC PHARMACEUTICAL ASSOCIATION

CHDMA
Healthcare Distribution Management Association

NACDS
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California Pedigree Working Group Industry Response Overview

Presentation to California Board of Pharmacy Enforcement Committee

June 20, 2006

California Pedigree Working Group - Agenda

- Introductions
- Objectives and outcome of effort
- Process for developing response
- The complexities of the pharmaceutical supply chain
- Industry progress to date
- Summary of response
- Formal request to extend implementation date
- Questions

Trade Association Introductions

- **BIO** – The Biotechnology Industry Organization (BIO) is the national trade association for the biotechnology industry, representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

- **GPhA –** The Generic Pharmaceutical Association (GPhA) represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA members manufacture the vast majority of all affordable pharmaceuticals dispensed in the United States. Our products are used in more than one billion prescriptions every year. GPhA's core purpose is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. Toward this end, GPhA advances the interests of our members through initiatives in the scientific, regulatory, federal/state forums and in the public affairs arena.

Trade Association Introductions

- **HDMA – The Healthcare Distribution Management Association (HDMA).** For more than 125 years, HDMA has worked with members to secure a safe, efficient, and reliable healthcare supply chain that is able to provide life-saving health products and services. HDMA members are responsible for ensuring that billions of units of medication are safely delivered to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites in all 50 states in the most efficient manner possible. HDMA members are a vital link in the healthcare system, providing highest-quality solutions that remove costs and empower providers to deliver care more effectively. Through our advocacy activities, HDMA operates at the forefront of healthcare, and ensures that members' perspectives and businesses are understood and addressed in legislative and regulatory arenas. For more information on HDMA, please visit www.HealthcareDistribution.org.

Trade Association Introductions

- **NACDS** – The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. NACDS members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over $700 billion. Other members include almost 1100 suppliers of products and services to the chain drug industry. NACDS international membership has grown to include 95 members from 29 countries. For more information about NACDS, visit www.nacds.org.

- **PhRMA –** The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines. Industry-wide research and investment reached a record $51.3 billion in 2005.

The California Pedigree Working Group has created an industry perspective on pedigree, and a singular response to the Board of Pharmacy

Project Objectives and Outcomes

Objectives

- Provide a response to the request of the California Board of Pharmacy for presentation to the Enforcement Committee Meeting on 6/20/06
- Identify progress to date and what the industry has done over last 2 yrs to tighten supply chain
- Outline current and future steps to advance capabilities and adoption across the supply chain
- Provide industry insight on supply chain complexities and opportunities for the future

Outcome

- Shared point of view on realistic short- and long-term approaches to achieving electronic pedigree compliance
- A collaborative approach with the California Board of Pharmacy

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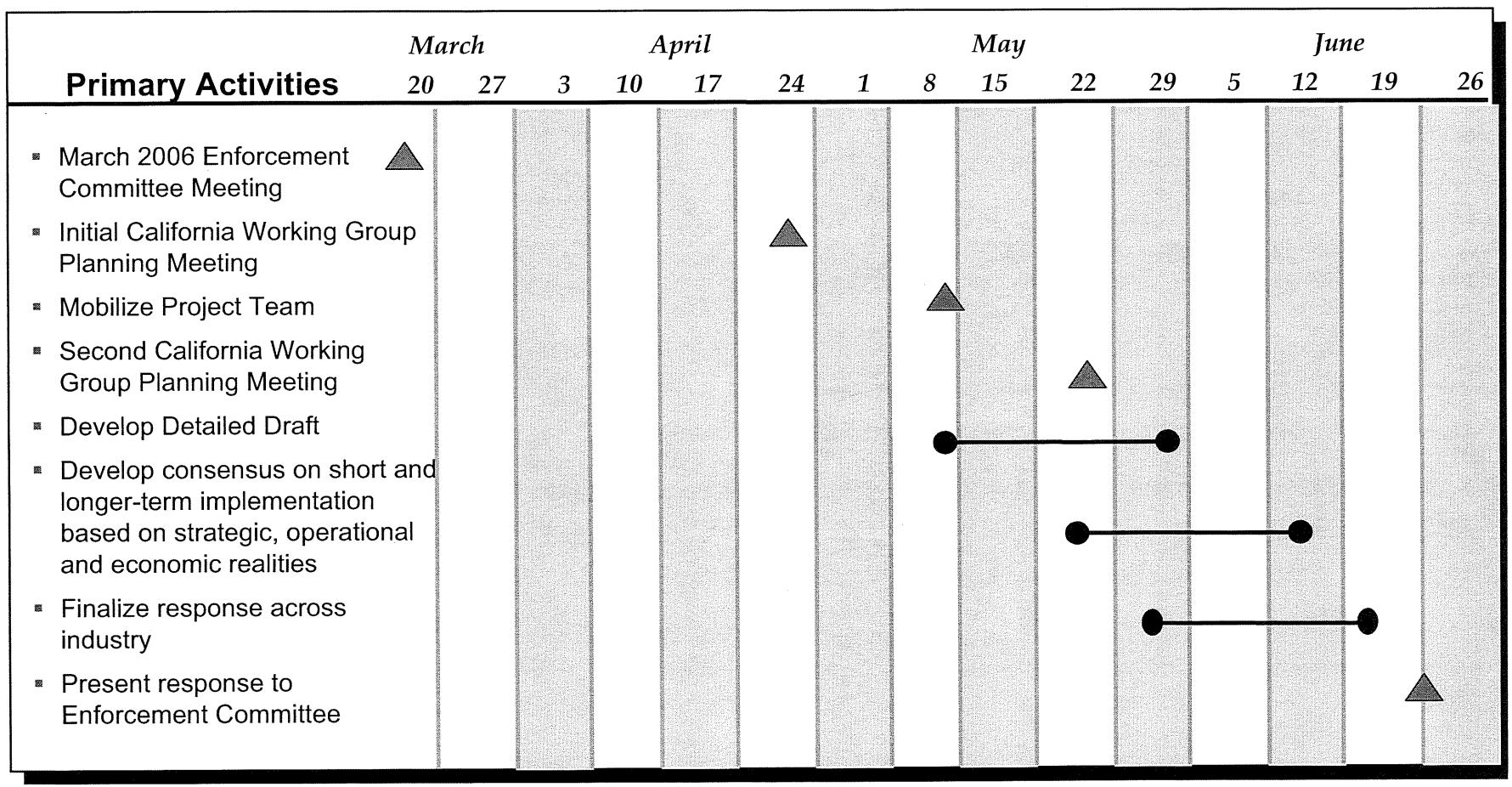
The process for developing an industry consensus on the requirements was a significant undertaking in a short amount of time

California Pedigree Working Group Time Line



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Many of the supply chain trading partners participated heavily and attended one or both of the planning meetings

Manufacturers

- Abbott
- Amgen
- Amylin Pharmaceuticals
- Astrazeneca
- Baxter
- Bayer
- Berlex
- BiogenIdec
- Celgene
- Chiron
- Forest Pharmaceuticals
- Genentech
- GlaxoSmithKiline
- Johnson & Johnson
- Ligand Pharmaceuticals
- Medimmune
- Merck
- Mylan Labs
- Novartis

Manufacturers (continued)

- Pfizer
- Sandoz
- Teva USA
- UCB Pharma
- Wyeth

Trade Associations:

- BIO
- HDMA
- PhRMA
- NACDS
- GPhA
- CPhA – California Pharmacy Association
- FMI California Grocers
- CRA- California Retailers Association
- CHI – California Healthcare Institute

Distributors:

- Amerisource Bergen
- Cardinal Health
- FFF Enterprises
- McKesson
- HD Smith
- PSS World Medical

Community Pharmacies:

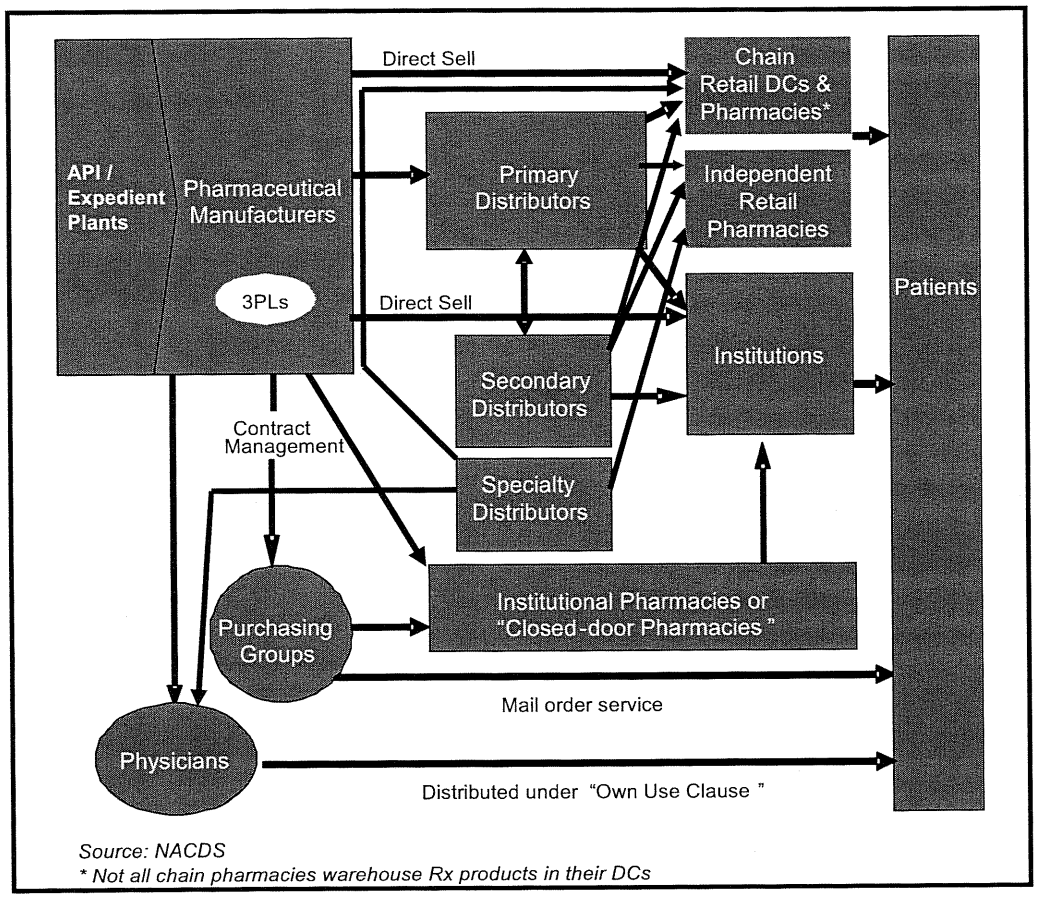
- CVS
- Longs
- Raleys
- Rite-Aid
- Safeway
- Target
- Walgreens
- Wal-Mart

Providers

- Kaiser Permanente

The US Pharmaceutical Supply Chain is a complex web of product and information flows

Supply Chain Dynamics



Source: NACDS
** Not all chain pharmacies warehouse Rx products in their DCs*

California Supply Chain

- In 2005, U.S. pharmaceutical manufacturers sold $20.4B of prescription drugs in California.[1]
- In 2005, there were approximately 287 million prescriptions written by prescribers in California[2]
- There are approximately 4,964 community pharmacies in California, including: approximately 3,122 chain pharmacies and approximately 1,842 independent pharmacies[3]
- There are approximately 13,610 community pharmacists active in the state of California, including 10,826 chain pharmacists with in-state addresses.[4]
- Community pharmacies employ approximately 328,180 full and part-time employees, including[5]:
  - 308,830 chain pharmacy employees
  - 19,350 independent pharmacy employees

Sources:
1) NACDS
2) NACDS
3) HDMA
4) NACDS
5) NACDS

The California Pedigree Working Group has concluded that an extension of the implementation date is required for adequate preparation…

- The challenges are:
  - rapid implementation
  - immature technology
  - complex supply chain
  - lack of industry-accepted standards

- No quick, simple solutions can address the significant volume and complexities of the supply chain or the changing landscape of the pharmaceutical industry

- There are vendors offering proprietary electronic pedigree applications, but our assessment leads us to believe that these would not meet California's goals

- Current solutions do not meet scalability, interoperability and reliability requirements - this process will take considerable time

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...with resolution of specific barriers being priority

- Development of uniform electronic pedigree standards
- Alignment of Supply Chain:
  - Technology reliability and interoperability
  - Data communication, access, and ownership
  - Process changes and impacts
- Consistency between State and Federal requirements

While much progress has been made, we agree more can be done

- Many members have made progress independently to enhance the integrity of the supply chain
- Organizations are now gaining the fundamental insights and understanding they need to develop preliminary electronic pedigree systems that can serve all trading partners and consumers, while complying with California law

Pilots and Research	Standards Setting	Other Developments
A few of the companies who have publicly announced pilots or research toward electronic pedigree (not exclusive or exhaustive): •Pfizer •Purdue Pharma •Wal-Mart •Johnson & Johnson •Ligand Pharmaceuticals •Cardinal Health •FFF Enterprises •McKesson •CVS •Rite-Aid •Safeway •Walgreens	Pedigree Standards process update: • The electronic pedigree specification must first be **ratified** • Once ratification occurs, **test case development and review** is performed (anticipated to take 2-3 months) • Assuming there are no IP issues, **testing** would most likely start in late 1st qtr 2007	• In June 2006, the FDA acknowledged that there are complexities in moving the technology forward • The FDA highlighted that full implementation will be challenging. • FDA has recognized the primary distribution channel as an option, however FDA will require pedigrees for wholesale distributions not conducted by manufacturers or ADRs • Some manufacturers and retailers are requiring implementation of buy-direct requirements in contracts with wholesale distributors • Some manufacturers have adopted anti-counterfeiting security features on their products

The California Pedigree Working Group requests that the Enforcement Committee recommend an extension of the implementation date to allow our progress to continue

- Our members are working together to **ensure that consumers continue to have confidence** in their pharmacies and pharmacists, and the prescription drugs dispensed, while ensuring they have **unimpeded access to products they need**

- We believe that anti-counterfeiting guidance should be considered as **standards are developed and adopted, new distribution processes are developed, and various technologies become more mature**

- An extension of the electronic pedigree implementation date will provide the opportunity to:
  - Develop an **effective, interoperable solution** for California that will enhance security throughout the supply chain
  - Develop a compliance model based on **reasonable and unified steps**, and to create a **non-disruptive and more effective** electronic pedigree system
  - Introduce the **major changes within the supply chain** that the statutory mandates require

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Industry will continue to work towards realistic milestones and identifying other opportunities until a reliable and interoperable electronic pedigree system can be developed

- For an industry-wide electronic pedigree system to be effective, development of common standards, technologies, and processes that are acceptable to stakeholders throughout the supply chain must be completed
- Our members will continue to support the establishment of pedigree standards although, given that the standards process is outside the scope of control of the California Pedigree Working Group, we cannot accurately establish a definitive timeline for standards development and adoption

Realistic milestones:

- Develop standards
- Support technologies
- Support education

Other opportunities:

- Pilot and validate systems and technology
- Consider primary distribution channel regulatory model
- Employ security technologies

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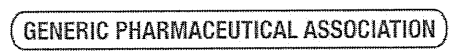

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Questions?