California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee
And Work Group On E-Pedigree

Contact Person: Virginia Herold
(916) 574-7911

Date: March 21, 2007
Time: 9:30 a.m. – 12:30 p.m.
Place: Red Lion Hotel Sacramento
1401 Arden Way
Sacramento, CA 95815
(916) 922-8041

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Gloria Schultz at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 9:30 a.m.

1. Enforcement Committee
   a. Letter of Concern to CMS regarding the Federal Deficient Reduction Act's Use of Average Manufacturers' Cost as Reimbursement Base for Medications for Medicaid Patients
   b. Proposal to Develop an Ethics Course for Pharmacists, Modeled After the Experiences of the Medical Board of California In Establishing an Ethics Course for Physicians
   c. Proposed Modified Disciplinary Guidelines for the Board of Pharmacy
   d. Strategic Plan Update for 2007-08

2. Comments by the FDA on the Implementation of the Prescription Drug Marketing Act Provisions Involving Pedigrees 10:00 a.m.

3. Workgroup on E-Pedigree
   a. Status of the Progress of the EPCglobal Workgroup and Standards for Electronic Pedigrees
   b. Summary of Meeting with EPCglobal of March 8, 2007
   c. Update by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees
   d. Question and Answer Session

Adjournment 12:30 p.m.

Meeting materials will be on the board's Web site by March 16, 2007

Agenda Item 1(a)
Letter to CMS

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

March 14, 2007

To: Enforcement Committee

Subject: Letter of Concern to Regarding the Federal Deficit Reduction Act's Use of Average Manufacturers' Price as the Reimbursement Base for Medicaid

At the January 31, 2007 Board Meeting, the board voted to submit comments to CMS in response to their proposal to base Medicaid reimbursement upon average manufacturer price. The board's concern was that this policy could lead to pharmacies withdrawing from the program if reimbursement costs are less than their acquisition costs for the medicine. As a result, patient access to pharmacies and medicine, especially in inner city and rural locations may become imperiled.

A copy of this letter follows.

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STATE AND CONSUMER SERVICES AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

February 16, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: File Code CMS-2238-P

Dear Sir or Madam:

The California State Board of Pharmacy (Board) appreciates this opportunity to submit comments on the proposed rulemaking in 42 CFR Part 447 (File Code CMS-2238-P), the purpose of which is to implement provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. While the Board is pleased that an attempt is being made to clarify this difficult subject area, and recognizes the constraints and mandates placed on CMS by the provisions of the DRA, the Board is concerned that the proposed rules, as written, may result in significant barriers to access necessary medication(s) by California residents who are recipients of Medicaid, particularly in rural and inner city locations.

The primary mandate of the Board is protection of the health and safety of the public in California. In the realm of drug distribution and treatment, this includes helping to ensure a safe, reliable, drug supply, and timely access to medications necessary for treatment.

When such access is impaired, particularly in vulnerable populations such as is often the case for recipients of Medicaid, public health and safety are also impacted. Furthermore, where the concern is overall health system cost savings, any such impairment of access to drugs, particularly among vulnerable populations, may lead to greater overall costs due to increased Emergency Room visits, hospitalizations, or aggravation of preexisting conditions due to an interruption of drug therapy.

We are concerned that the proposed rules may have this detrimental effect on access. We have heard from numerous stakeholders in the pharmaceutical industry, especially but not exclusively community pharmacies both large and small, that the proposed rules would make it economically infeasible for them to continue participating in Medicaid and/or providing drugs to Medicaid recipients in California. They have concluded that

the proposed rules would result in reimbursement and dispensing rates significantly below the lowest prices at which they can purchase the drugs to be dispensed.

Stakeholders in the industry will certainly express to CMS their specific concerns about the text of the proposed rulemaking more comprehensively than the Board, but as articulated to the Board, the difficulties with the current rules include: despite an acknowledgment of flaws in AMP data as a predictor of actual costs-to-dispense, CMS intends to rely on (and to publicly release) that data before resolving its uncertainties and unreliability; the given definition of AMP does not accurately reflect actual acquisition costs by pharmacies; the proposed rules for generics reimbursement will significantly undercount the actual costs of purchasing such drugs, by up to an average of 36 percent;[1] and without any direction to states to increase dispensing fees (particularly for generics), the average dispensing fee payment of $4.50 is significantly below the actual costs-of-dispensing for pharmacies nationwide which has been cited to be between $10.00 and $12.00.[2] The overall message that has been delivered is that the new rules may very well result in a reduction or even elimination of the retail sites that are willing or fiscally able to dispense drugs to Medicaid recipients.

In his May 12, 2006 letter to Secretary Leavitt, Senator Charles Grassley also expressed a similar concern that states must be encouraged or required to reconsider their dispensing fees paid to pharmacies to compensate for presumably lowered drug costs under the new AMP-based calculation protocol. As Senator Grassley said:

> I expect states will very soon begin shifting to a pharmacy payment methodology based on the newly published interim AMP data. CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs. *States may have been working under an assumption borne out in numerous reports of the Office of the Inspector General that pharmacies were being reimbursed well beyond the acquisition cost of the drugs and so dispensing fees were set at levels below the actual cost of the dispensing of a drug. States should carefully consider data regarding the cost of dispensing in determining dispensing fees at the same time they change their reimbursements for acquisition cost to be more consistent with the actual cost of acquisition.*

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[1] See *Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO Report No. GAO-07-239R (December 22, 2006).

[2] See *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared by Grant Thornton LLP for The Coalition for Community Pharmacy Action (January 2007).

The Board agrees that in order to ensure appropriate access to prescription drugs for those residents of California who are recipients of Medicaid, the final result of this rulemaking must be that a combination of reimbursement and dispensing fees paid equals or exceeds the actual cost(s) of drug dispensing. Otherwise, access will be rapidly diminished.

Thank you for this opportunity to provide comments.

Sincerely,

WILLIAM POWERS
Board President

Agenda Item 1(b)

Development of an Ethics Course for Pharmacists

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

March 14, 2007

To: Enforcement Committee

Subject: Proposal to Develop an Ethics Course for Pharmacists, Modeled After the Experiences of the Medical Board of California in Establishing an Ethics Course for Physicians

At the January 31, 2007 Board Meeting, the board directed that a small work group be formed to perform an in-depth review of a proposal to develop an ethics course for pharmacists which could be used as a possible term in disciplinary decisions. Some of the topics the board directed to this work group for review include: recommendation of the types of violations that could warrant a probation condition of completing an ethics course, consideration of the experiences of the Medical Board, and generally, to look at the proposal and components more fully.

The board directed that a report of this review be provided at the October 2007 Board Meeting.

The work group will be formed shortly. Reports will be provided at the June 20 and September 20 Enforcement Committee meetings.

Agenda Item 1(c)

Modifications to the Board's Disciplinary Guidelines

Document unavailable – Enforcement Guidelines will be discussed at the June 20, 2007 Enforcement Committee Meeting.

Agenda Item 1(d)

Enforcement Committee Strategic Plan Update

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March 14, 2007

To: Enforcement Committee

Subject: Update of the Enforcement Committee's Strategic Plan 2007-08

Last July, the board finalized its strategic plan for 2006-2011. However, each year in the spring, the board revises its plan to keep it current. It is time to start this review for 2007-08.

At this meeting, the Enforcement Committee will have the opportunity to revise its strategic plan, if warranted.

At the April Board Meeting, the board will review any modifications to the strategic plan recommended by each committee for development of the 2007-08 strategic plan (completing the annual updating process).

The last activity update of the Enforcement Committee's strategic plan follows this page.

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
Qtr 2	72	67 (94%)	0 (0%)	4 (5%)	1 (1%)	17

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

	N	< 120 days	< 180 days	< 270 days	Longer	Average Days
Qtr 1	271	195 (72%)	49 (18%)	25 (9%)	2 (1%)	87
Qtr 2	173	146 (84%)	15 (9%)	12 (7%)	0 (0%)	79

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
Qtr 2	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action	104	94	6	3	1
Cite and/or fine letter of admonishment	128	33	84	6	5
Attorney General's Office	12	2	4	3	3

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
Qtr 2	30	54	0	4

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	107	100		
Sites	5	6		
Tolled	27	27		
Inspections Conducted	92	41		
Successfully Completed	1	1		
Petitions to Revoke Filed	3	0		

3. Issue all citations and fines within 30 days

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	140	41 (29%)	61 (43%)	21 (15%)	17 (12%)	51
Qtr 2	118	14 (12%)	22 (18%)	41 (35%)	41 (35%)	84

4. Issue letters of admonishment within 30 days

	N	30 days	60 days	90 days	> 90 days	Average
Qtr 1	33	30 (91%)	1 (3%)	2 (6%)	0 (0%)	12
Qtr 2	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	18

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
Qtr 2	0	0	1

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
Qtr 2	0	0	0	0

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

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	22	6	11	3	1	1	456 days
		(27.3 %)	(50 %)	(13.6%)	(4.6%)	(4.6%)	
Qtr 2	37	13	11	7	2	4	568 days
		(35.1%)	(29.7%)	(18.9%)	(5.4%)	(10.8%)	

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%
Qtr2	587	3,042	41%

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

	Number of Inspections	Number Inspected Late
Qtr 1	77	1
Qtr2	50	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%
Qtr2	587	25	4%

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.* *Dec. 2006:* *Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.* *Jan. 2007:* *EPCglobal finalizes electronic messaging standards for electronic pedigrees.* 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.* *Oct. 2006:* *Board adds Consumer friendly materials regarding sales of these drugs to its Website.* 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.* *Nov. 2006:* *Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.*

California State Board of Pharmacy Citation and Fine Statistics July 1, 2006 – March 14, 2007

561 citations have been issued so far this fiscal year

Total dollar amount of fines issued since July 1, 2006
$ 1,112,925.00

Total dollar amount of fines collected
$ 224,251.70*

*This amount also reflects payment of the citations issued before July 1, 2006.

The average number of days from date case is opened until a citation is issued is **120**

Average number of days from date citation is issued to date citation is closed is **45**

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
561	94	14	138	68	80	23	16	2

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
27	19	2	0	4	6	48	17	3

*Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

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

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	45%	1716 - Variation from prescription	26%	1716 - Variation from prescription	9%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	9%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	14%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	9%
4322 - Misdemeanor or infraction: false representation to secure license for self or others; false representation of licensure	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	7%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	9%
4339 - Non-pharmacist acting as manager, compounding, dispensing, or furnishing drugs	4%	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	5%	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	8%
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%	1764/56.10et seq.- Unauthorized disclosure of prescription and medical information	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
1707.3 – Duty to review drug therapy	3%	1714(c)- Operational standards and security; the pharmacy must be maintained in a sanitary condition	3%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	5%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	3%	1716/1761 - Variation from Rx / Erroneous Rx	3%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	5%
4059(a)- Furnishing dangerous drugs without a prescription	3%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	2%	1304.11- Inventory requirements	4%
1764/56.10et seq.- Unauthorized disclosure of prescription and medical information	2%	4081(a)- Records of dangerous drugs kept open for inspection	2%	1707.2- Duty to consult	4%
4081(a)- Records of dangerous drugs kept open for inspection	2%	4115(e) - Pharmacy technician license required	2%	1711- Quality assurance programs	3%

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were thirteen office conferences held so far this fiscal year

Number of requests	170
Number appeared	104*

Number scheduled	170
Number Postponed	40**

*Please note on three occasions unscheduled citations were heard with a related case at office conference.
**Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	26
Failed to appear	4

Office Conference results held between July 1, 2006 and February 22, 2007

Total number of citations affirmed	54

Decision	Total citations	Total dollar amount reduced
Modified	26	$9,725.00
Dismissed	18	$4,625.00
Reduced to Letter of Admonishment	1	$0.00

Please note due to additional investigation being required,
Three cases from SOC, are pending a decision

Agenda Item 2

FDA's Update on the PDMA

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March 14, 2007

To: Enforcement Committee

Subject: Update by the FDA on the Prescription Drug Marketing Act

In June 2006, the FDA indicated that it would be implementing PDMA pedigree requirements for transactions outside the authorized distribution channel beginning in December 2006.

However, just before the December 2006 implementation a U.S. District Court Judge in the Eastern District of NY issued a written order granting a preliminary injunction enjoining FDA from implementing 21 CFR 203.50(a), which specifies the type of information that must appear in the pedigree.

The FDA has placed on its Web site the following information regarding pedigree requirements given this order.

At this meeting, Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs, FDA, Office of the Commissioner/Office of Policy will provide a brief update.

ADDENDUM to FDA's *Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers* Related to the Preliminary Injunction ordered 12/5/06 in *RXUSA Wholesalers, Inc. v. HHS*

12.15.06

A. What is affected by the preliminary injunction?

- 21 CFR § 203.50(a). The court order enjoins FDA from implementing 21 CFR § 203.50(a). 21 CFR § 203.50(a)(6), states that information regarding "each prior transaction involving the drug, starting with the manufacture" be included in the pedigree. However, while the preliminary injunction is in effect, pedigrees shall include information regarding prior transactions going back to the manufacturer *or* the last ADR that sold, purchased, or traded the prescription drugs. FDA encourages wholesalers to include information regarding each prior transaction going back to the manufacturer when that information is available.

- 21 CFR § 203.50(a)(1)-(5). The court order also enjoins FDA from implementing the language in 21 CFR § 203.50 that requires pedigrees to include lot and control numbers, dosage, container size, and number of containers. As described in more detail below, however, the preliminary injunction does not affect the statutory requirement that pedigrees contain the dates of all listed transactions and the names and addresses of all parties involved in those transactions. In addition, since the court did not enjoin implementation of 21 CFR § 203.3(u), a written agreement between a manufacturer and a wholesaler may limit ADR status to a particular lot number(s), dosage, or the number or size of the containers of prescription drugs. We also note that, without the lot number on the pedigree, it would be extremely difficult to track the inventory that matches the pedigree if the inventory is further sold, purchased or traded. Therefore, FDA recommends that the lot or control number, dosage, and the number and size of the prescription drug containers be included on the pedigree even though it is not required while the preliminary injunction is in effect.

- Pedigrees for all current and future inventory are affected by the preliminary injunction as long is it remains in effect.

B. What is not affected by the preliminary injunction?

Pedigrees still must be passed by non-authorized distributors of record (non-ADR) prior to each wholesale distribution. In addition, the court does not mention other pedigree-related regulations or other agency-issued documents relating to the pedigree requirement. Accordingly, those regulations and documents, some of which are described below, are not affected by the preliminary injunction.

- 21 CFR § 203.3(u). This regulation, which went into effect on December 1, 2006, defines "ongoing relationship" for the purposes of determining who qualifies as an authorized distributor of record (ADR.) As of December 1, 2006, only those

wholesale distributors who have an ongoing relationship (including a written agreement) with the manufacturer, as that term is defined by this regulation, are exempt from the pedigree requirement.

- Compliance Policy Guide (CPG) 160.900, which issued in November 2006, remains in effect until December 1, 2007. The CPG describes how FDA intends to prioritize its enforcement efforts regarding the pedigree requirements in the first year after the effective date of 21 CFR §§ 203.3(u) and 203.50. However, FDA will not enforce 203.50(a) as long as the preliminary injunction remains in effect.

- All other definitions in 21 CFR Part 203 that relate to the pedigree requirement, including but not limited to, the definitions of manufacturer and wholesale distribution, have been in effect since December 2000 and remain in effect despite the injunction.

- The names and addresses of all parties to the transaction and the date of the transactions are required by the statute and must be included in the pedigree.

- 21 CFR § 203.50(b). This regulation, which went into effect on December 1, 2006, requires all wholesale distributors (both ADRs and non-ADRs) involved in the distribution of a prescription drug to retain a copy of the pedigree for three years. Accordingly, all wholesale distributors that provide or receive pedigrees after December 1, 2006, must retain copies of the pedigrees for three years.

- 21 CFR § 203.50(c). This regulation, which also went into effect on December 1, 2006, provides that a manufacturer that subjects a drug to additional manufacturing processes is not required to provide a pedigree identifying previous sales of the drug or its components.

- 21 CFR § 203.50(d). This regulation also went into effect on December 1, 2006, and requires manufacturers to maintain a current written list of all ADRs, to specify whether each ADR is authorized to distribute all of the manufacturer's drug products or only particular products, to update its list of ADRs on a continuing basis, and to make its list of ADRs available for public inspection or copying. Accordingly, as of December 1, 2006, all manufacturers should have available for public inspection a current list of ADRs that indicates which drug products the ADR is authorized to distribute.

- 21 CFR § 203.60. This regulation sets forth certain requirements with respect to the use of electronic records and signatures, record retention, and the availability of records for review and reproduction by FDA and other federal, state, and local regulatory and law enforcement officials. This regulation has been in effect since December 2000 and remains in effect despite the injunction.

C. Since the court's order only applies to 21 CFR § 203.50(a), does this mean that the statutory requirement that non-ADRs provide pedigrees that include "each prior sale, purchase, or trade" of the drugs is still in effect?

- Yes. The court order does not enjoin FDA from enforcing the statute. The court order affects only the regulations at 21 CFR § 203.50(a). It has been FDA's long-standing position, consistent with the language of the PDMA and its legislative history, that, 21 CFR § 203.50 notwithstanding, the statute itself requires non-ADRs to provide pedigrees that documents each prior transaction going back to the manufacturer. FDA recognizes, however, that confusion regarding the pedigree requirement could cause disruptions or delays in the nation's drug distribution system. Accordingly, as long as the court order remains in effect, FDA intends to exercise enforcement discretion, as described below. To this end, FDA does not intend to enforce the statute insofar as it requires pedigrees to contain information regarding each transaction going back to the manufacturer. Rather, FDA intends to permit non-ADRs to provide pedigrees that include information regarding transactions going back to the manufacturer *or* the last ADR that handled the prescription drugs. FDA, however, encourages all wholesalers to provide complete pedigrees documenting each prior transaction involving the prescription drug when that information is available.

D. How will FDA apply the court's order outside of the Eastern District of New York (EDNY) and to wholesale distributors that are not plaintiffs in the lawsuit?

- FDA believes that limiting application of the preliminary injunction to either the named plaintiffs or the EDNY could lead to confusion and possible disruptions or delays in the nation's drug distribution system and could provide undue advantage to certain wholesale distributors. Accordingly, to the extent that it could be argued that the injunction should be limited in scope, FDA intends to exercise enforcement discretion in a manner that is consistent with the court's opinion. To this end, as long as the court's order is in effect, FDA does not intend to initiate any enforcement actions against any wholesalers solely for (1) failing to include lot numbers, dosage, container size, or number of containers on a pedigree; or (2) failing to provide a pedigree that goes back to the manufacturer so long as the pedigree otherwise identifies the last authorized distributor of record that handled the drugs.

E. How does the court's order impact what FDA said in the Guidance to Industry: PDMA Pedigree Requirements – Questions and Answers (http://www.fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf)?

- To the extent that Questions 2, 9, 10, 11, 14, 24, 29, and 33 refer to 21 CFR § 203.50(a), as long as the preliminary injunction is in effect, such references are limited to the scope of the court's order. For example, if the question states that a pedigree include information about each prior transaction going back to the

manufacturer, then the answer would be limited to including information going back to the manufacturer *or* the last ADR that handled the drugs.

Agenda Item 3

Workgroup on E-Pedigree

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March 14, 2007

To: Enforcement Committee

Subject: Work Group on Electronic Pedigree

1. EPCglobal Ratifies Its Pedigree Standard

Since the last meeting, EPCglobal has released its Ratified Pedigree Standard (January 2007). A copy of the press release follows this page (which contains the email address for downloading a copy of the standard – 138 pages).

An overview of this standard will be provided in a presentation by EPCglobal at this meeting.

The ratification of this standard is a major milestone!

2. EPCglobal Conducts Hospital Summit

On February 20, EPCglobal held a "summit" for California hospitals to initiate awareness of the electronic pedigree requirements and to engage hospitals in what their supply chain partners are doing. Speakers included individuals from hospitals, regulators, and manufacturers (pharmaceuticals, medical devices, biologics, blood products, distributors and vendors). Additional hospital summits are planned by EPCglobal for Boston and Chicago.

Hospitals have also been invited to attend the board's quarterly Work Group on Electronic Pedigree meetings.

3. California Board of Pharmacy Review of Pedigree Standard

On March 8, 2007, Board Members Bill Powers and Stan Goldenberg and board staff met with nine EPCglobal representatives to review the EPCglobal Standards and assure the components met California's legal requirements.

This was a lengthy meeting and a summary of the meeting is provided in this tab section.

The board believes the standard meets California's electronic pedigree requirements. However, additional work and amplification need to be done by industry and by the board. In some cases regulations may be necessary to provide the necessary specification.

FOR IMMEDIATE RELEASE

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EPCglobal Inc Ratifies Electronic Pedigree Standard

Provides Platform for Compliance for Pedigree Laws Requiring a Document-Based Approach

BRUSSELS, Belgium – January 11, 2007 – GS1 EPCglobal, the not-for-profit standards organization dedicated to driving global adoption of the Electronic Product Code (EPC) for supply chain excellence, today announced the ratification of the Electronic Pedigree Document specification.

The new standard was developed to help companies that are serializing products using EPC technology to comply with pedigree regulations, such as ones recently enacted in multiple states within the United States. The initial focus of the EPCglobal Electronic Pedigree Document standard was the Florida Drug Pedigree Act, but it was designed to be usable as a platform to support a wide variety of pedigree process applications.

The EPCglobal standard includes an ePedigree document schema as well as an ePedigree envelope schema that companies can use as a way of holding multiple ePedigrees together in a single document for electronic transmission. Industries currently using paper-based pedigree documents will find this standard a useful tool in the fight against product counterfeiting and for brand protection. The new standard will enable technology providers to create solutions that can provide document interoperability across the supply chain, from manufacturers to wholesalers to retailers.

"This effort marks an important step in ensuring trading partners have an interoperable way to exchange document-based pedigrees for pharmaceuticals and other products," said Chris Adcock, president of EPCglobal Inc. "We extend our thanks to the pharmaceutical supply chain professionals and solution providers who collaborated to develop and test the Electronic Pedigree Document standard. With this standard in place, supply chain participants can begin to comply with document-based pedigree regulations, like the Florida Drug Pedigree Act, without fear of serious interoperability issues."

Looking to the future, the EPCglobal Healthcare and Life Sciences (HLS) Industry Action Group has begun work to define the requirements to develop a full track and trace system based on the EPCIS (EPC Information Services) standard, which is expected in the first quarter of 2007. A full track and trace approach would enable the pedigree information to be shared upstream and downstream, as opposed to the limitation of simply passing it from trading partner to trading partner in one direction only. Track and trace has significant value for protecting the integrity of the supply chain and is seen as a more universal approach that can be applied globally and across multiple industries. Refinement and definition of this alternative approach is anticipated in 2007.

About EPCglobal Inc

EPCglobal Inc supports the global adoption of the Electronic Product Code as a global standard to enable accurate information and visibility about products in the supply chain. More information about EPCglobal Inc can be found at http://www.epcglobalinc.org.

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Meeting Summary
March 8, 2007

California Board of Pharmacy Review of EPCglobal's Electronic Pedigree Standard

1625 N. Market Boulevard
Sacramento, CA 95834
9 a.m. – 3 p.m.

Present: Bill Powers, Board President
Stan Goldenberg, RPh, Board Member
Virginia Herold, Executive Officer
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General,

From EPCglobal:
Ron Bone, CoChair, EPCglobal Healthcare & Life Sciences Industry Action Group
Mike Rose, CoChair, EPCglobal Healthcare & Life Sciences Industry Action Group
Dirk Rodgers, CoChair, Pedigree Working Group
Eric Douglass, EPCglobal Retail Representative
Grant Hodgkins, CoChair, EPCglobal Adoption Group
John Howells, CoChair, EPCglobal Track & Trace Group
Bryan Bond, substituting for Public Policy, Adoption Member
Tom Pizutto, Industry Member
Robert Celeste, Director, Healthcare, EPCglobal North America

The meeting started with a detailed review of the pedigree standard, and the information that is appended to the pedigree at each step in transactions involving a change in ownership as a drug moves from a manufacturer to a pharmacy. The discussion included the electronic pedigree format, the initial pedigree components and how shippers and receivers annotate to the pedigree. Mixed into this discussion were descriptions about how various segments of the distribution channel would append the pedigree. A detailed list of discussion points used to frame the meeting is provided as Attachment A.

Specific Discussion Items:

1. The California pedigree law requires that a single pedigree include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another NDC number.

   A question was raised about how to handle bulk repackaging; for instance, where tablets from several/numerous bulk containers, cases, lots, etc. are mixed together and repackaged, separating tablets from their original containers/lots (and original pedigrees).

   One suggestion was to modify business practices so that all such "source" tablets are from the same manufacturer lot/shipment.

2. The California pedigree law requires that the pedigree track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the drug.

   A question was raised about how to handle "unit dose" packaging (e.g., individual-dose packaging used in hospitals or physician's offices), which may present additional challenges for attachment of data elements sufficient to generate a pedigree serialized to this level.

3. The California pedigree law requires that the pedigree include, among other things, a certification as to accuracy of the pedigree from the source of the dangerous drug, and identifying information/signatures from responsible parties at both the delivering and receiving entities, verifying shipment. The EPCglobal standard incorporates the requirement that both the sender and receiver enter an electronic signature to verify shipment and receipt.

   A question was raised about the timing of the signature and verification of shipment upon receipt, i.e., whether that signature (and/or the verification of the drugs received to the pedigree) requires that the entire shipment be verified down to the serialized bottle or other immediate container before delivery is accepted, or if the recipient may "infer" accuracy of the shipment based on verification at the lot, case, pallet, or other aggregate level, subject to subsequent verification of the shipment down to the serialization level.

4. The California pedigree law does not presently allow for or define circumstances under which a pedigree may be "voided" or the RFID tags (if used) "turned off"/decommissioned.

   Questions were raised about what to do, for instance, when drugs subject to a pedigree are destroyed (or returned for destruction), or if there is a material inaccuracy in the pedigree itself.

5. The California pedigree law requires that every change in ownership be recorded on the pedigree. The pedigree is part of the records of acquisition and disposition of a drug, so must travel with the drug even where no change in ownership has taken place.
   A question was raised about how to handle "drop shipments" directly from manufacturers to pharmacies, where the pharmacy places the order directly with the manufacturer, and the drug(s) are shipped (at least some of the time on an emergency or expedited timeline) directly to the pharmacy, but for business/billing reasons the economics of the transaction are handled through a wholesaler (i.e., the wholesaler bills the pharmacy, and pays the manufacturer). In these cases, the wholesaler never takes possession of the drugs, which are delivered directly from manufacturer to pharmacy.

6. The California pedigree law requires that every change in ownership be recorded on the pedigree; it specifically requires that any return of a drug to a wholesaler or manufacturer be documented on the same/single pedigree.

   A question was raised about whether it would be possible (for marketing/business reasons) to "restart" the pedigree: when a returned drug has been thoroughly tested/authenticated by the manufacturer, and is shipped back out under circumstances identical to its initial shipment, could the manufacturer create a new pedigree (i.e., be "exempt" from the single pedigree requirement)?

ATTACHMENT A

California Board of Pharmacy
Review of EPCglobal Pedigree Messaging Standard

1. **Electronic Pedigree Format**
   The basic components of a pedigree are shown. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).

2. **Initial Pedigree Components**
   The diagrams illustrate the different forms the innermost content of the pedigree may take before the content is nested in the first shippedPedigree layer. These components do not represent complete shipped and received pedigrees. In order to represent a complete pedigree, the innermost content is embedded in a shippedPedigree and digitally signed with a Signature element.
   a. **Innermost content for a manufacturer pedigree** (initiated by manufacturer, before a wholesale distribution)
   b. **Innermost content for a wholesaler pedigree** (initiated by first wholesaler, includes transaction information for first wholesale distribution)
   c. **Innermost content for a wholesaler pedigree with attachment** (initiated by wholesaler, includes ASN data as attachment to facilitate manual authentication by downstream trading partners)
   d. **Innermost content for a wholesaler pedigree with scanned source pedigree** (initiated by wholesaler, includes previous pedigree which may reflect one or more previous distributions)
   e. **Innermost content for a repacker pedigree** (initiated by repacker, repacked item contains two source pedigrees)
   f. **Innermost content for a kit pedigree where the kit has an assigned NDC** (initiated by kit manufacturer, kit contains two pedigrees)

3. **Shipped and Received Pedigree Components**
   The diagrams illustrate the different forms a complete pedigree may take when pedigrees are exchanged between trading partners.
   a. **Signed manufacturer pedigree** (initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)
   b. **Signed wholesaler pedigree** (initiated by wholesaler, after the wholesale distribution, signed by both wholesaler and retailer DC)
   c. **Signed repacker pedigree** (initiated by repacker, after wholesale distribution, signed by both repacker and wholesaler recipient)
   d. **Signed kit pedigree** (kit has NDC, initiated by kit manufacturer, after wholesale distribution, signed by both kit manufacturer and wholesaler recipient)
   e. **Pedigree with two signed transactions** (initiated by manufacturer, received and signed inbound by wholesaler recipient, signed outbound by wholesaler upon shipment to pharmacy, received and signed inbound by pharmacy recipient)

f. **Pedigree without inbound receipt signature** (initiated by manufacturer, received but not signed inbound by wholesaler recipient, signed outbound by wholesaler upon shipment to pharmacy)
g. **Pedigree without inbound receipt information or signature** (initiated by manufacturer, signed outbound by wholesaler upon shipment to pharmacy)
h. **Pedigree with partial receipt** (initiated by manufacturer, updated with partial receipt information and signed inbound by wholesaler recipient for first receipt, and then generation of another received pedigree with remaining receipt information and signature for second receipt)
i. **Pedigree with return transaction** (initiated by manufacturer, received and signed inbound by wholesaler, return transaction applied by wholesaler for manufacturer return and signed outbound, received and signed inbound by manufacturer)
j. **Pedigree with return transaction applied by wholesaler on behalf of pharmacy** (initiated by wholesaler, signed outbound by wholesaler for shipment to pharmacy, return transaction applied by wholesaler for pharmacy return, signed outbound by wholesaler for subsequent sale)

4. Non-Normative Usage Guidelines for Creating and Appending Information to Pedigrees

This section explains how to use the Pedigree element and its sub elements to create pedigrees and append transactional and signature information to them. All content in this section is non-normative.

a. **Pedigree Flow Initiated by Manufacturer** (The pedigree flow is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree.)
b. **Pedigree Flow Initiated by Wholesaler** (The pedigree flow is described for a sale from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.)
c. **Pedigree Flow Initiated by Wholesaler from Paper Pedigree** (The pedigree flow is described for a sale from a wholesaler to a retail pharmacy DC, when the prior pedigree was in paper form and the receiving information was applied to the paper pedigree, and the wholesaler converts the pedigree to electronic form prior to the sale to the retail pharmacy DC.)
d. **Pedigree Flow Initiated by Repacker** (The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. A repack pedigree may or may not contain the pedigrees for the source products used to create the repack products, depending on the regulatory requirements of a given pedigree law. The usage guideline describes how to construct the pedigree for both scenarios, when the source pedigrees are required and when they are not required. The usage guideline also describes how to include the source pedigree when the source pedigree is an electronic pedigree created or received, or

a pedigree received in an alternate form, such as a scanned paper pedigree.)

e. **Pedigree Flow for a Kit** (A kit is a packaged product that can contain one more prescription drugs. Kits containing prescription drugs may or may not have an NDC assigned to the kit itself. This usage guideline describes the process for creating a kit that has an assigned NDC. If the kit does not have an assigned NDC, one of two options can be utilized:)
f. **Partial Receipt of Products against Pedigree** (The partial receipt of product against pedigree is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler receives the products in two partial shipments and updates each partial receipt against the original pedigree, resulting in a new received pedigree for each partial receipt.)
g. **Pedigree Receipt without Applying Receiving Signature** (The flow for the receipt of a pedigree without signing the pedigree on inbound receipt is described. The pedigree is subsequently signed on the next outbound transaction.)
h. **Pedigree Flow for Pedigree with Two Transactions** (The pedigree flow is described for a sale from a manufacturer to a wholesaler and then the wholesaler to a pharmacy.)
i. **Pedigree Flow for Pedigree with Return Transaction** (The pedigree flow is described for a sale from a manufacturer to a wholesaler and then with a return from the wholesaler back to the manufacturer. The party making the return applies the return transaction to the pedigree.)
j. **Pedigree Flow for Wholesaler Applied Return Transaction to Pedigree** (The pedigree flow is described for a sale from a wholesaler to a pharmacy, and then a return from the pharmacy back to the wholesaler with the wholesaler updating the pedigree with the return transaction.)
k. **Pedigree Flow for a Manufacturer-initiated Drop Ship** (The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer initiates the start of the drop ship pedigree documenting the sales transaction from the manufacturer to the wholesaler with the shipping information indicating the direct shipment to the pharmacy. The wholesaler adds only the second part of the drop ship transaction to the pedigree documenting the sales transaction from the wholesaler to the pharmacy.)
l. **Pedigree Flow for a Wholesaler-initiated Drop Ship** (The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer does not provide the wholesaler with a pedigree and the wholesaler documents both parts of the drop ship transaction on the pedigree (assuming the wholesaler has access to this information).)

5. **Usage Guidelines for Voiding and Altering Pedigrees**
Some pedigree regulations (see US State of Florida Regulations) allow pedigrees to be altered or voided after they are transferred to downstream trading partners. These regulations contain specific requirements around this type of activity. The current revision of the EPCglobal Pedigree Standard does not contain a mechanism to automate the notification of trading partners when a void or alteration occurs. However, some non-binding best practices are provided as recommendations to assist the industry in handling pedigree alterations and voids until a later revision of this standard may include a way to automate these activities.

6. **Pedigree Scenarios**
   a. **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.

   b. **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.

   c. **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.

   d. **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

   e. **Scenario 5:** This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.

   f. **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.

   g. **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.

h. **Scenario 8:** This scenario depicts the ability for a company to identify the location of all the units of a particular NDC/lot or a particular EPC at downstream trading partners that they have sold product to in order to support faster recalls.

i. **Scenario 9:** This scenario depicts the ability for a company to see the aggregate inventory levels and product movement of all of a particular NDC/lot at downstream trading partners that they have sold product to in order to support more effective forecasting & replenishment.