



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA Enforcement Committee

*Contact Person: Virginia Herold
(916) 574-7911*

Date: December 12, 2006
Time: 9:30 a.m. – 12:30 p.m.
Place: Radisson Hotel Sacramento
500 Leisure Lane
Sacramento, CA 95815
(916) 922-2020

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 Virginia Herold at (916) 574-7911, 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 to the Drug Enforcement Administration Supporting the Ability of Prescribers to Issue Multiple Prescriptions for Schedule II Controlled Substances at One Time for Future Dispensing
 - b. Proposal to Develop an Ethnic Course for Pharmacists, Modeled After the Experiences of the Medical Board of California In Establishing an Ethics Course for Physicians
2. Presentation by the FDA on the Implementation of the Prescription Drug Marketing Act Provisions Involving Pedigrees
3. Workgroup on E-Pedigree
 - a. Status of the Progress of the EPC-Global Workgroup
 - b. Update by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees, including presentations by:
 - AmerisourceBergen Corporation
 - Cardinal Health, Inc.
 - c. Presentations on Emerging Technology for Electronic Pedigrees
 - d. Question and Answer Session

4. Meeting Dates for 2007

Adjournment

12:30 p.m.

Meeting materials will be on the board's Web site by December 5, 2006

Memorandum

To: Enforcement Committee

Date: December 4, 2006

From: Board of Pharmacy

Subject: DEA Proposed 90-Day Rule for Prescriptions for Schedule II Controlled Substances

At the October Board Meeting, the board directed that staff prepare a letter supporting a proposed shift in DEA policy to allow prescribers to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit. This would allow prescribers to provide patients with three 30-day prescriptions at once, writing "do not fill" until a specified date on the additional prescriptions so that patients do not have to return simply to obtain a new prescription.

This proposal conforms to longstanding board policy to allow a prescriber to write multiple prescriptions for Schedule II drugs, with a "do not fill before" date entered on the additional prescriptions. However, federal interpretation of the federal law prohibited this practice – unless this interpretation is put into effect. (California law provides that a prescription for a Schedule II drug is valid for six months after the date it is written.)

A copy of the board's letter to the DEA is attached.



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

November 3, 2006

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537
Attention: DEA Federal Register Representative/ODL

RE: Docket No. DEA- 287N

Dear Sir or Madam:

Prior to the deadline for public comment of November 6, 2006, I am writing to express the qualified support of the California State Board of Pharmacy for the proposed rulemaking published in the Federal Register on September 6, 2006 (Docket No. DEA-287N). This proposed rule would modify 21 CFR Part 1306 to make clear that the prohibition on refills of Schedule II prescriptions stated by 21 USC § 829 does not prevent or prohibit a prescriber from writing multiple prescriptions for a Schedule II drug for a given patient on a given date, with instructions on the prescriptions indicating the earliest date on which each successive prescription may be filled (e.g., "do not fill before [30 days later/60 days later]").

As the rulemaking notice articulates, and as has long been the position of the California State Board of Pharmacy, this level of flexibility with regard to Schedule II prescribing practices will likely enhance the treatment of, and prevent the interruption of medication for, those patients with chronic pain, Attention Deficit Hyperactivity Disorder (ADHD), or other similar chronic or ongoing conditions being treated with Schedule II medications. The proposed rule better allows prescribers to exercise their professional judgments as to the appropriate interval between patient visits, allowing them where they deem it appropriate to prescribe up to a 90-day supply in three or more separate prescriptions.

The board supports this approach.

However, the board believes that this flexibility to permit prescribers to exercise professional judgment as to the appropriate interval between visits can and ought to be extended further. The board does not see the need to limit this judgment to a maximum of a 90-day supply, and would instead urge that no specific outer limit be placed on the total quantity of Schedule II drugs for which multiple prescriptions with "do not fill before" dates can be written on a given date. It ought to be left to prescribers, in consultation with their patients, to decide the appropriate intervals between visits.

Thank you for this opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "William Powers".

William Powers
President
California Board of Pharmacy

Memorandum

To: Enforcement Committee

Date: December 4, 2006

From: Board of Pharmacy

Subject: Proposal to Develop an Ethics Course for Pharmacists

At the NABP District Meeting in October, Lorie Rice, Associate Dean, External Relations, of the UCSF School of Pharmacy provided a presentation on her experiences in developing an ethics course for physicians. Ms. Rice did this in her role as a board member of the Medical Board of California, following the Medical Board's determination that existing ethics courses available for physicians are inadequate for ethical violations.

A former executive officer of the Board of Pharmacy, Ms. Rice is willing to assist the board in developing a specialized course for pharmacists, similar to that developed for physicians, should this board be interested.

A copy of the Medical Board's regulation requirements specifying an ethics course as a condition of probation is enclosed.

Medical Board of California - Division of Medical Quality
Ethics Course as Condition of Probation
Specific Language of Proposed Regulations

Adopt section 1358.1 in Article 3 of Chapter 2 of Division 13, Title 16 California Code of Regulations, to read as follows:

1358.1. Ethics Course Required as Condition of Probation.

A licensee who is required, as a condition of probation, to complete an ethics course shall take and successfully complete a professionalism program approved by the division that meets the requirements of this section.

(a) **Approved Provider:** The program provider shall be accredited by the Accreditation Council of Continuing Medical Education (ACCME), or by an entity qualified in Section 1337, to sponsor continuing medical education for physicians and surgeons and shall provide satisfactory written evidence that its professionalism program meets all of the requirements of this section.

(b) **Criteria for Acceptability of Program.**

(1) **Duration.** The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment. The provider shall identify the number of continuing medical education hours that will be credited upon successful completion of the program.

(2) **Faculty.** Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or

teaching institution. The provider shall submit with its application a curriculum vitae for each instructor for approval by the division or its designee.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The provider shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The program shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of medicine in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills sets they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact

(6) **Class Size.** A class shall not exceed a maximum of 12 participants.

(7) **Evaluation.** The program shall include an evaluation method that documents that educational objectives have been met—e.g., written examination or written evaluation—and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) **Records.** The provider shall maintain all records pertaining to the program, including a record of the attendance for each

participant, for a minimum of 3 years and shall make those records available for inspection and copying by the division or its designee.

(9) **Program Completion.** The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the division or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

(10) **Change in Course Content or Instructor.** The provider shall report to the division any change in course content or instructor within 30 calendar days after the date of that change.

NOTE: Authority cited: Section 2018, Business and Professions Code.
Reference: Sections 2227, 2228, and 2229, Business and Professions Code.

Memorandum

To: Enforcement Committee

Date: December 4, 2006

From: Board of Pharmacy

Subject: Work Group on E-Pedigree

Bob Celeste of EPCglobal will provide a presentation of where EPCglobal is with respect to its standards setting project, and the next steps in EPCglobal's work.

The FDA will present information on the PDMA implementation of paper pedigrees for drug distribution.

And several corporations have agreed to provide updates on the status of the implementation studies underway for electronic pedigrees.

I am enclosing copies of press releases from two of these firms regarding their pilot studies.



News Release

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AMERISOURCEBERGEN ANNOUNCES INNOVATIVE TRACK AND TRACE PROGRAM FOR THE PHARMACEUTICAL SUPPLY CHANNEL

Prepares California Launch of Unique Pilot Developed in Conjunction with IBM and VeriSign

Valley Forge, PA November 13, 2006-- AmerisourceBergen Corporation (NYSE: ABC) today announced at the NACDS and HDMA RFID Healthcare Industry Adoption Summit being held this week in Washington, DC, an innovative Track and Trace Program that it believes will ultimately benefit the entire pharmaceutical supply channel. AmerisourceBergen has been a leader in protecting the integrity of the pharmaceutical supply channel, first by pledging over one year ago to purchase 100 percent of its pharmaceutical and other products directly from the product manufacturer, and now by launching a unique Track and Trace initiative which will utilize RFID and Electronic Product Code Information System (EPCIS) technology to track and trace products throughout the entire distribution process. AmerisourceBergen plans to formally launch the Track and Trace pilot program at its largest distribution center in California by the end of 2006.

In the pilot, AmerisourceBergen will use IBM's RFID middleware and embedded software on readers to read RFID tags currently used by certain pharmaceutical manufacturers as those products enter the distribution center. The unique product ID from each RFID tag will be electronically stored in IBM's EPCIS, which will be the platform for secure electronic communications back to the product's manufacturer. This secure information exchange will allow AmerisourceBergen and its trading partners to work collaboratively to share transaction information and further secure the supply channel.

As new orders come into the AmerisourceBergen distribution center, the RFID system can monitor product placed in shipping totes as they move through the picking, packing, and shipping processes. As each tote leaves the distribution center the EPCIS software will record

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the time and location of each unit leaving the premises as well as its intended destination so that AmerisourceBergen has a complete record of the history of all RFID tagged drugs.

"The advantage of using the RFID and EPCIS system is that the information regarding the product's journey through the supply chain is stored in a manner that is useful for a number of different applications," said Shay Reid, AmerisourceBergen Vice President for Integrated Solutions. "Once the RFID tags have been read and the data has entered the EPCIS, the system can be queried to build a product pedigree for customers on demand, to provide real time receiving and shipping information to manufacturers as well as to more closely track both inventory and product demand."

"With IBM's extensive experience in designing and deploying RFID solutions, I can say that distributors like ABC will have a great advantage supporting customers through offering unique track and trace data," said Paul Chang, RFID/Pharma Executive, IBM Software Group. "And in an industry that lives depend on, IBM is providing the technology that will lead to a more efficient, safer, and more secure supply chain."

The next step in the pilot program will be to connect AmerisourceBergen's EPCIS directly to other business partner EPCIS systems and to select pharmaceutical manufacturer systems. In the first calendar quarter of 2007, VeriSign will provide services to support the deployment of technology and software necessary to enable AmerisourceBergen to communicate and authenticate transactions with its business partners while also providing the capability to query across multiple EPCIS systems.

Jeff Richards, vice president and general manager of VeriSign Intelligent Supply Chain Services stated, "AmerisourceBergen's innovative pilot will create unprecedented, direct electronic data connectivity to its trading partners. This level of data sharing and connectivity is a critical step towards allowing the pharmaceutical industry to trace the historical path of a particular product through the supply chain, which will add a level of security and efficiency to the pharmaceutical distribution process."

As AmerisourceBergen tests its Track and Trace pilot program, it intends to continue to supply electronic pedigrees in the state of Florida to those wholesale customers that require them under the state's current drug safety laws. Under the pedigree program, customers are charged fees that allow the Company to recover the cost of generating the pedigrees. The Company intends to offer its nationwide wholesale customers the same electronic pedigree program in support of the Prescription Drug Marketing Act (PDMA), which goes into full effect on December 1, 2006. The PDMA rule requires wholesalers who are not "authorized distributors of

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record" to provide a pedigree showing chain-of-ownership back to the manufacturer when selling the drugs to pharmacies.

About AmerisourceBergen

AmerisourceBergen (NYSE:ABC) is one of the world's largest pharmaceutical services companies serving the United States, Canada and selected global markets. Servicing both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel, the Company provides drug distribution and related services designed to reduce costs and improve patient outcomes. AmerisourceBergen's service solutions range from pharmacy automation and pharmaceutical packaging to pharmacy services for skilled nursing and assisted living facilities, reimbursement and pharmaceutical consulting services, and physician education. With more than \$61 billion in annual revenue, AmerisourceBergen is headquartered in Valley Forge, PA, and employs more than 14,000 people. AmerisourceBergen is ranked #27 on the Fortune 500 list. For more information, go to www.amerisourcebergen.com.

Forward Looking Statement

This news release may contain certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. Actual results may vary materially from the expectations contained in the forward-looking statements. The forward-looking statements herein include statements addressing management's views with respect to future financial and operating results and the benefits, efficiencies and savings to be derived from the Company's integration plan to consolidate its distribution network. The following factors, among others, could cause actual results to differ materially from those described in any forward-looking statements: competitive pressures; the loss of one or more key customer or supplier relationships; customer defaults or insolvencies; changes in customer mix; supplier defaults or insolvencies; changes in pharmaceutical manufacturers' pricing and distribution policies or practices; adverse resolution of any contract or other disputes with customers (including departments and agencies of the U.S. Government) or suppliers; regulatory changes; changes in U.S. government policies (including reimbursement changes arising from the Medicare Modernization Act); declines in the amounts of market share rebates offered by pharmaceutical manufacturers to the PharMerica Long-Term Care business, declines in the amounts of rebates that the PharMerica Long-Term Care business can retain, and/or the inability of the business to offset the rebate reductions that have already occurred or any rebate reductions that may occur in the future; any disruption to or other adverse effects upon the PharMerica Long-Term Care business caused by the announcement of the Company's agreement to combine the PharMerica Long-Term Care business with the institutional pharmacy business of Kindred Healthcare, Inc. into a new public company that will be owned 50% by the Company's shareholders (the "PharMerica LTC Transaction"); the inability of the Company to successfully complete the PharMerica LTC Transaction; fluctuations in market interest rates; operational or control issues arising from the Company's outsourcing of information technology activities; the Pharmaceutical Distribution segment's ability to continue to successfully transition its business model to fee-for-service; success of integration, restructuring or systems initiatives; fluctuations in the U.S. dollar – Canadian dollar exchange rate and other foreign exchange rates; economic, business, competitive and/or regulatory developments in Canada, the United Kingdom and elsewhere outside of the United States; acquisition of businesses that do not perform as we expect or that are difficult for us to integrate or control; and other economic, business, competitive, legal, regulatory and/or operational factors affecting the business of the Company generally. Certain additional factors that management believes could cause actual outcomes and results to differ materially from those described in forward-looking statements are set forth (i) in Item 1 (Business) under the heading "Certain Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005 and elsewhere in that report and (ii) in other reports filed by the Company pursuant to the Securities Exchange Act of 1934.

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CardinalHealth

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FOR IMMEDIATE RELEASE

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CARDINAL HEALTH RELEASES RFID PILOT RESULTS

Test data shows promise and gaps of the technology that will affect widespread adoption across pharmaceutical industry

DUBLIN, Ohio, Nov. 14, 2006 — Cardinal Health, Inc., the leading provider of products and services supporting the health-care industry, today announced the results from the first end-to-end test of a technology that could further improve the safety and efficiency of the nation's pharmaceutical supply chain.

The pilot program tested whether ultra-high frequency (UHF) radio frequency identification (RFID) tags could be applied, encoded and read at normal production speeds during packaging and distribution of pharmaceuticals. Verifying the authenticity of medications along each step of the distribution process adds an additional layer of security to lessen the chance of counterfeit pharmaceuticals entering the supply chain. It is also hoped that RFID data could improve efficiencies in the supply chain.

"Cardinal Health's test of RFID under real-world conditions has demonstrated that the technology has real promise to provide an added layer of safety," said Renard Jackson, vice president and general manager of global packaging services for Cardinal Health. "While our pilot demonstrated that using UHF RFID technology at the unit, case and pallet level is feasible for track and trace purposes, a great deal of additional work needs to be undertaken by stakeholders across the industry to address significant challenges including global standards, privacy concerns and the safe handling of biologics. Until those challenges are addressed, direct distribution of medicine continues to be the best near-term approach to maintain the highest levels of security and efficiency in the pharmaceutical supply chain."

RFID Labeling and Online Encoding

Data collected from the pilot suggest that it is feasible for RFID tags to be inlaid into existing FDA-approved pharmaceutical label stock, and the tags can be applied and encoded on packaging lines at normal operational speeds. Online encoding yields were 95 percent to 97 percent, and fine tuning of the process is expected to produce yields that approach 100 percent. The RFID tag application and encoding requires minimal adjustments to current labeling and packaging lines.

RFID Read Rates

Unit-level read rate data varied widely depending on the locations and type of reading stations throughout the supply chain. Highly reliable unit-level read rates in excess of 96 percent were found when reading individual cases one at a time and when reading units mixed with other products in tote containers prepared for delivery to a pharmacy. However, as expected, unit-level read rates were not found to be reliable when attempting to read units within a full pallet of product.

While not 100 percent in all situations, case-level data were found to be more reliable during full pallet reads. The combination of business process changes, and further hardware tuning is expected to improve the reliability of case tag reads to 100 percent, however further tests are needed to prove this hypothesis.

In preparation for delivery to the pharmacy, individual bottles are “picked” and placed in tote containers with other products that did not have RFID tags. The unit-level read rates from the tote containers being read during the quality control phase were acceptable for track and trace. Additional unit-level read rates while the product was in the tote containers were not found to be reliable during subsequent reading stations at the shipping dock of the distribution center and the receiving doors at the pharmacy.

Pilot Program Read Rate Data

Cardinal Health’s RFID pilot program tested many different possible reading stations throughout the supply chain. While the company expected that some reading stations would not achieve acceptable read rates, the lack of hard data in the marketplace led program planners to measure all possible scenarios. Read rate data for item- and case-level tags are included in the chart below.

	Item-Level Read Rates		Case-Level Read Rates	
	Product A	Product B	Product A	Product B
Unit Encoding Yield During Packaging	97.7%	94.8%	NA	NA
Unit to Case Aggregation	96.9%	99.7%	91.8%	100%
Case to Pallet Aggregation*	56.4%	80.8%	100%	99.7%
Shipping Pallet from Packaging Facility*	9.2%	14.3%	82.3%	100%
Receiving Pallet at Distribution Center*	7.8%	9.5%	76.3%	100%
Receiving Case at Distribution Center	92.1%	97.1%	99.4%	100%
Reading Totes at Distribution Center	NA	99.5%	NA	
Shrink Wrap Tote Carts at Distribution Center	NA	64.1%	NA	
Shipping from Distribution Center	NA	46.1%	NA	
Receiving at Pharmacy	NA	85.8%	NA	

RFID Pilot Program Conclusions

Overall data collected by Cardinal Health supports the theory that RFID technology using UHF as a single frequency at the unit, case and pallet levels is feasible for track and trace. However, several challenges remain before it can be adopted industry-wide. Some of those challenges include:

- Technology and process improvements to achieve:
 - Case-level reads in excess of 99 percent at all case reading stations;
 - Unit-level read rates in excess of 99 percent when reading from tote containers at the distribution center and pharmacy locations;
- Allowing unit-level “inference” to become acceptable practice in the normal distribution process at stages where unit-level read rates are unreliable, but case level reads approach 100 percent (*Three stages marked in chart above);
- Barcode technology to be used as complementary and redundant technology to RFID;
- Management of the cost impact to implement and sustain the technology; and
- Improved collaboration across the industry to identify opportunities to significantly improve efficiency.

Pilot Program Background

In conducting the industry's first end-to-end pilot program, Cardinal Health used new technology to place RFID tags on the labels of brand-name solid-dose prescription drugs, then encoded the electronic product code (EPC) standard data at the unit, case and pallet levels during the packaging process. The products were shipped to a Cardinal Health distribution center in Findlay, Ohio, where the data was read and authenticated as products were handled under typical operating conditions. Normal procedures were enhanced with RFID hardware and software from Alien Technology Corporation and IBM along with project management support from VeriSign.

From Findlay, the tagged product was sent to a pharmacy to further test read rates and data flow using the same technology as the distribution center. The product dispensed to patients was not in the RFID packaging.

The company launched the pilot in February and completed the test in the fall. In addition, Cardinal Health is working with Pfizer on a separate RFID pilot to authenticate Viagra[®] shipments at its Findlay facility.

About Cardinal Health

Headquartered in Dublin, Ohio, Cardinal Health, Inc. (NYSE: CAH) is an \$81 billion, global company serving the health-care industry with a broad portfolio of products and services. Through its diverse offerings, Cardinal Health delivers health-care solutions that help customers reduce their costs, improve safety and productivity, and deliver better care to patients. The company manufactures, packages and distributes pharmaceuticals and medical supplies, offers a range of clinical services and develops automation products that improve the management and delivery of supplies and medication for hospitals, physician offices and pharmacies. Ranked No. 19 on the Fortune 500, Cardinal Health employs more than 55,000 people on six continents. More information about the company may be found at www.cardinalhealth.com.

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Except for historical information, all other information in this news release consists of forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied. The most significant of these uncertainties are described in Cardinal Health's Form 10-K, Form 10-Q and Form 8-K reports (including all amendments to those reports) and exhibits to those reports, and include (but are not limited to) the following: competitive pressures in its various lines of business; the loss of one or more key customer or supplier relationships or changes to the terms of those relationships; changes in the distribution patterns or reimbursement rates for health-care products and/or services; the results, consequences, effects or timing of any inquiry or investigation by or settlement discussions with any regulatory authority or any legal and administrative proceedings, including shareholder litigation; difficulties in opening new facilities or fully utilizing existing capacity; the costs, difficulties and uncertainties related to the integration of acquired businesses; and general economic and market conditions. Except to the extent required by applicable law, Cardinal Health undertakes no obligation to update or revise any forward-looking statement.

Memorandum

To: Enforcement Committee

Date: December 1, 2006

From: Board of Pharmacy

Subject: 2007 Enforcement Committee Meetings Scheduled

2007 Enforcement Committee Meetings and the Workgroup on
Implementation of the Electronic Pedigree:

- March 21,
- June 20,
- September 20,
- December 5