

HDMA Weekly Digest



▶ A Newsletter for HDMA Members

November 16, 2010

In This Issue

- ▶ [Track-and-Trace Technology Seminar Highlights](#)
[Registration Now Open for HDMA's 2011 Business & Leadership Conference — the Distribution Industry's Signature Annual Conference!](#)
- ▶ [2010 Specialty Pharmaceuticals: Facts, Figures and Trends Highlights Key Trends on Fastest-Growing Sector of the Healthcare Industry](#)
- ▶ [From the Hill: Congress Returns This Week; Senators Urge HHS Leadership on Sunshine Implementation](#)
- ▶ [Fiscal Commission Releases Draft Proposal](#)
- ▶ [FDA Updates RxUSA v. HHS/FDA Backgrounder](#)
- ▶ [The HDMA Directory: Your Connection to Supply Chain Partners](#)
- ▶ [Regulatory Update: FDA Reopens PDUFA Comment Period, Releases Draft Guidance on "Dear Health Care Provider" Letters; OSHA to Hold Public Hearing on Fall Protection Systems Proposed Rule](#)
- ▶ [From the States: New Mexico Proposes Adding Tramadol as a Schedule IV Controlled Substance](#)
- ▶ [NAMD Becomes Independent Affiliate of NGA](#)
- ▶ [CMS Issues Final Rule to Withdraw Rx Reimbursement Provisions Under the Deficit Reduction Act](#)
- ▶ [CMS Releases Proposed Rule Implementing Healthcare Reform Changes to Medicare Advantage and Part D](#)

HDMA 2011

DISTRIBUTION MANAGEMENT CONFERENCE
AND TECHNOLOGY EXPO

Sunday, March 6–Wednesday, March 9, 2011
Tampa Marriott Waterside Hotel, Tampa, Fla.

Track-and-Trace Technology Seminar Highlights

Last week more than 100 healthcare distribution industry leaders convened just outside of Washington, D.C. for HDMA's *Track-and-Trace Technology* seminar. In its second year, the seminar explored important legislative, regulatory and industry updates surrounding the use of track-and-trace technologies in the healthcare supply chain.

The seminar opened on Monday, November 8 with a business session outlining serialization's impact on packaging operations and the technology architecture required to support serialization data, presented by David DeJean, Vice President of Professional Services at Systech International™.

Headlines

[AMCC, Walgreens Drive Awareness Around Expired Medicines in the Home](#)

Drug Store News,
November 10, 2010

[AmerisourceBergen Promotes Collis to COO](#)

Chain Drug Review,
November 12, 2010

[Big Pharma Gearing Up](#)



Dr. Ilisa B.G. Bernstein updates seminar attendees on the FDA's supply chain safety and security initiatives.

The next day, Dr. Ilisa B.G. Bernstein, Deputy Director (Acting), Office of Compliance Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, discussed a number of FDA's supply chain initiatives supporting the use of technology to help further secure the drug supply and enhance patient safety. Dr. Bernstein indicated that she will be working in a new CDER drug integrity and security program and reiterated FDA's support of a universal and uniform federal pedigree.

Dr. Bernstein's presentation was followed by HDMA Vice President for Government Affairs Liz Gallenagh. Gallenagh updated attendees on current legislative and regulatory developments at the federal and state levels, including what lies ahead in California. The program also provided insight into the work distributors and manufacturers have been doing to prepare for 2015.

Attendees were able to examine case studies from both manufacturers and distributors. Speakers included Michelle Keller, Senior Manager, Marketing, TEVA Pharmaceuticals USA; Kevan MacKenzie, Senior Solutions Analyst, McKesson Corporation; and Julie Kuhn, Director, Operations, Cardinal Health, Inc.

Other seminar highlights included a presentation by Brian Lee, Technical Services Manager – Packaging Technologies, Merck, who compared global and U.S. serialization requirements and the likelihood of mass serialization in Europe over the next 3 to 5 years.

Jim Bracken, CEO, GS1 Ireland, also provided valuable perspectives on serialization in Europe. Bracken shared information on the Clinical Laboratory Automated Stockroom System (known as the CLASS Project), which was formed to address the need to achieve visibility of product movements across the entire medical device supply chain by implementing GS1/EPC open global standards and EPC Gen 2 tags.

Beyond the seminar's many thought-provoking presentations, the program also offered attendees an opportunity to engage in a variety of interactive roundtable discussions. Topics addressed included the standards gap, the benefits of serialization, data exchange, barriers to implementation, the Global Data Synchronization Network™ (GDSN) and inference.

HDMA is grateful to **Axway, Inc.** and **Stericycle ExpertRETURN**, whose support helped make the 2010 *Track-and-Trace Technology* seminar possible. Stay tuned to [HDMA's website](#) for the latest education updates and the 2011 seminar dates to be announced later this year.

[top of page ^](#)

Registration Now Open for HDMA's 2011 Business & Leadership Conference — the Distribution Industry's Signature Annual Conference!

Registration is officially open for [HDMA's 2011 Business & Leadership Conference](#)! This year's conference will take place Sunday, June 5 through Wednesday, June 8 at the JW Marriott Desert Ridge in Phoenix.

The Business & Leadership Conference is the healthcare distribution industry's signature annual conference, bringing together high-level executives, thought leaders and influential managers from across the healthcare supply chain. Exclusive to HDMA member companies and developed by and for healthcare supply chain leaders and innovators, the Conference provides:

- A forum for strategic business discussions on the most pressing industry issues;
- Unmatched opportunities to network with your peers and trading partners; and

[to Face the Patent Cliff](#)
The Philadelphia Inquirer,
November 12, 2010

[FDA Seen Tougher on Drug Risks Post-Avandia](#)
Reuters, November 12, 2010

[Republicans are Spoiling for a Healthcare Fight](#)
Los Angeles Times,
November 15, 2010

Featured Event

[HDMA 2011 Distribution Management Conference and Technology Expo](#)

March 6–9, 2011
Tampa Marriott Waterside Hotel,
Tampa, Fla.
[Register Now >](#)

[All HDMA events >](#)

Publications of Interest

[2010 Specialty Pharmaceuticals: Facts, Figures and Trends](#)

[All HDMA publications >](#)

- Two and a half days of productive business appointments, saving your company time and money by meeting one-on-one with your valued business partners — all in one place and at one time.

The conference also will provide an opportunity to recognize innovation, leadership and lifetime achievement with the DIANA and Nexus Awards, presented to HDMA members during an evening of industry celebration.

[Register now](#) for the essential event for every HDMA member. For more information, contact [HDMA's Meetings & Conferences Department](#) at (703) 885-0278.

[top of page ^](#)

2010 Specialty Pharmaceuticals: Facts, Figures and Trends **Highlights Key Trends on Fastest-Growing Sector of the** **Healthcare Industry**

The U.S. specialty industry continues to experience unprecedented growth, reaching \$64 billion last year — or nearly half of the global market for specialty pharmaceuticals. Do you have the latest metrics to understand and explore this evolving market segment? Recently released by the Center for Healthcare Supply Chain Research, *2010 Specialty Pharmaceuticals: Facts, Figures and Trends* provides insight into dozens of performance trends on the specialty pharmaceutical segment of the healthcare industry.

Unlike any other benchmarking publication currently available, *Specialty Pharmaceuticals* presents primary survey data from both manufacturers and distributors of specialty pharmaceuticals, exploring such trends as market characteristics, distributor and manufacturer performance on finance, operations and handling and more. The publication also spotlights medications in the pipeline, cold chain practices and special handling needs, as well as trends within therapeutic areas to provide insight on growing fields of interest.

Valuable data found only in the latest edition of *Specialty Pharmaceuticals* include:

- Oncology continues to represent the most rapidly growing therapeutic area in the specialty segment, with 100 percent of distributor respondents reportedly specializing in this field. Oncology products account for 59 percent of distributors' annual sales volume (weighted average by sales), increasing from 56 percent in 2009.
- The average specialty pharmaceutical product spends approximately 20 days in the supply chain from the time the product is ordered to the time it arrives at the customer — nearly five days less than last year.
- Specialty pharmaceuticals largely require cold chain storage and shipping compared to their traditional counterparts. On average 40 percent of specialty distributor warehouse space is dedicated to refrigeration.
- Specialty products account for 49 percent of all pharmaceuticals that require Risk Evaluation and Mitigation Strategies (REMS).

Whether you're seeking to gain insights to break into this growing market or benchmark your performance against your peers, this is valuable research you won't find anywhere else.

Purchase your copy of *2010 Specialty Pharmaceuticals: Facts, Figures and Trends* for \$185 by visiting the [HDMA Marketplace](#). Bulk discounts are available. For more information, contact [Kayla Sutton](#) at (703) 885-0285.

From the Hill: Congress Returns This Week; Senators Urge HHS Leadership on Sunshine Implementation

Congress Returns this Week

The House and Senate returned to Capitol Hill this week to conduct leadership elections following the midterm races. Members will be voting for the Speaker and Minority Leader in the House, the Majority and Minority Leader in the Senate and committee chairmanships in both chambers. Committee assignments for legislators could be determined in December.

Additionally, two Senate committees will convene hearings of interest to HDMA members this week:

- The Senate Committee on Finance will hold a hearing entitled “Strengthening Medicare and Medicaid: Taking Steps to Modernize America’s Health Care System” on Wednesday, November 17 at 10:00 a.m. in 215 Dirksen Senate Office Building. Dr. Donald Berwick, Administrator of the Centers for Medicare & Medicaid Services, will testify.
- The Senate Health, Education, Labor and Pensions Committee will hold a hearing to consider HR 5710, the *National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010* on Wednesday, November 17. Time and location of the hearing are yet to be determined.

Please keep in mind that dates and times are subject to change.

For more information, contact [Jewelyn Wellborn](#).

Senators Urge HHS Leadership on Sunshine Implementation

Senators Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.) sent a letter to HHS Secretary Kathleen Sebelius on the implementation of the sunshine (or gift disclosure) provisions within the *Patient Protection and Affordable Care Act*. The senators sponsored the *Physician Payment Sunshine Act*, which became law as part of the healthcare overhaul enacted this year. The sunshine provisions require drug and medical device manufacturers to disclose to HHS anything of value provided to physicians, including payments, gifts, honoraria or travel above certain minimum thresholds.

For more information, contact [Kristen Freitas](#).

Fiscal Commission Releases Draft Proposal

Last week the co-chairs of the [National Commission on Fiscal Responsibility and Reform](#) released a [draft proposal](#) with suggestions for “identifying policies to improve the fiscal situation in the medium term and to achieve fiscal sustainability over the long run.”

At least two of the proposals may be of interest to distributors. The first is a broad recommendation related to the physician payment fix and general healthcare payment reforms (see pages 8 and 31). The proposal also includes a recommendation to eliminate the LIFO accounting method (see page 27), and other recommendations related to corporate tax reform.

HDMA is currently reviewing the document in its entirety and will provide additional information as it becomes available.

For more information, contact [Kristen Freitas](#).

[top of page ^](#)

FDA Updates RxUSA v. HHS/FDA Backgrounder

FDA has updated its “BACKGROUND re: RxUSA Wholesale, Inc. v. HHS” to reflect the recent decision by United States District Judge Joanna Seybert granting a motion permitting the parties to have through June 30, 2011 to reopen RxUSA Wholesale, Inc. v. HHS (see related [Weekly Digest story](#) of October 19). The case remains administratively closed until then, and the preliminary injunction issued by the District Court in 2006 remains in effect. The Agency intends, therefore, to exercise enforcement discretion in a manner that is consistent with the court's opinion. The [updated backgrounder](#) can be viewed online.

For more information, contact [Anita Ducca](#).

[top of page ^](#)

The HDMA Directory: Your Connection to Supply Chain Partners

Do you need to reconnect with a trading partner? Maintain your connections anytime, anywhere by accessing the [HDMA Directory](#). Conveniently located on HDMA's website, the *Directory* is your link to supply chain partners, connecting you with the most influential healthcare product manufacturers, distributors and service providers. Best of all, it's free to all HDMA members!

Industry information available only in the *Directory* includes:

- Contact information for thousands of leaders in the healthcare distribution industry;
- Complete HDMA member corporate information, including details on corporate headquarters and individual contacts;
- Top pharmaceutical manufacturers' contact information; and
- Information on influential suppliers and service providers to the healthcare industry — in the U.S. and abroad — identified by type of organization and product or service provided.

The *HDMA Directory* is an important, user-friendly resource for your company. Network with your peers, improve productivity and enhance your knowledge — [click here](#) to access the *Directory* today! (HDMA login and password are required to view the *Directory*.)

For more information or for questions about accessing the *HDMA Directory*, contact [Lisa Gallagher](#).

[top of page ^](#)

Regulatory Update: FDA Reopens PDUFA Comment Period, Releases Draft Guidance on “Dear Health Care Provider” Letters; OSHA to Hold Public Hearing on Fall Protection Systems Proposed Rule

FDA Reopens PDUFA Comment Period

FDA announced on November 10 that the comment period to solicit input on the reauthorization of the *Prescription Drug User Fee Act* (PDUFA) program will reopen. The *Federal Food, Drug, and Cosmetic Act* requires public review of the recommendations for the human drug review program after negotiations with the regulated industry conclude. FDA is reopening the comment period for the expected duration of the public part of the reauthorization process to ensure that all interested stakeholders have the opportunity to share their views on the matter. Comments are due to FDA by October 31, 2011.

For more information, see the [Federal Register notice](#) or contact [Anita Ducca](#).

FDA Releases Draft Guidance on “Dear Health Care Provider” Letters

FDA recently released draft guidance for industry and FDA staff entitled “Dear Health Care Provider Letters: Improving Communication of Important Safety Information.” Dear Health Care Provider (DHCP) Letters are correspondence — usually in the form of a mass mailing from a manufacturer or distributor of a human drug or biologic or from the FDA — intended to alert physicians and other healthcare providers to important new information about a marketed drug or biological product. This draft guidance provides recommendations on when to use a DHCP letter, the types of information to include in a DHCP letter, how to organize that information and formatting techniques to make the information more accessible. Public comments may be filed until January 11, 2011.

For more information, see the [Federal Register notice](#) or contact [Anita Ducca](#).

OSHA to Hold Public Hearing on Fall Protection Systems Proposed Rule

The Occupational Safety and Health Administration (OSHA) is convening an informal public hearing on January 18, 2011 regarding the Walking-Working Surfaces and Personal Protective Equipment (Fall Protection Systems) proposed rule, published on May 24, 2010 (73 FR 28862). (The hearing will continue on subsequent days if necessary.) Parties intending to present testimony or question witnesses must notify OSHA in writing by November 30, 2010. Parties requesting more than 10 minutes or planning to submit documentary evidence must provide the full text of their testimony and documentary evidence by December 21, 2010.

For more information, see the [Federal Register notice](#) or contact [Anita Ducca](#).

[top of page ^](#)

From the States: New Mexico Proposes Adding Tramadol as a Schedule IV Controlled Substance

The New Mexico Board of Pharmacy recently proposed adding Tramadol as a Schedule IV Controlled Substance. The Board will hold a hearing on the proposed rule at the next Board of Pharmacy meeting, to be held January 12, 2011 in Albuquerque. Comments are due December 29, 2010. The meeting agenda and proposed rule can be found [here](#).

For more information, contact [Elizabeth Lankford](#).

[top of page ^](#)

NAMD Becomes Independent Affiliate of NGA

The National Governors Association (NGA) [announced](#) that the National Association of Medicaid Directors (NAMD), an executive branch organization, has taken steps to become an independent affiliate of NGA. NAMD President Carol H. Steckel is the former Medicaid director for Alabama. NAMD’s mission is to serve as a point of communication between states and the federal government and provide an information network among the states on issues pertinent to the

Medicaid program.

For more information, contact [Thomas Phan](#).

[top of page ^](#)

CMS Issues Final Rule to Withdraw Rx Reimbursement Provisions Under the *Deficit Reduction Act*

CMS published a [final rule](#) that withdraws earlier Medicaid drug reimbursement provisions challenged in litigation and revised by the federal health reform law. In addition to finalizing the withdrawal of these provisions, CMS instructs manufacturers to ignore the definition of *bona fide* service fee at §447.502 in the calculation of AMP, indicating the agency will provide further guidance on the treatment of bona fide service fees “in future rulemaking.”

For more information, contact [Thomas Phan](#).

[top of page ^](#)

CMS Releases Proposed Rule Implementing Healthcare Reform Changes to Medicare Advantage and Part D

CMS issued a proposed rule on November 10 that would implement changes established under the new healthcare law on Medicare Advantage (MA) and prescription drug benefit (Part D) programs. The proposed changes range from requiring MA entities to disclose certain data for utilization analysis to calling for agents and brokers to receive CMS-endorsed training.

For more information, contact [Thomas Phan](#).

**HDMA 2011
BUSINESS &
LEADERSHIP
CONFERENCE**

*Sunday, June 5–Wednesday, June 8, 2011
JW Marriott Desert Ridge, Phoenix, Ariz.*

Distributed by the Healthcare Distribution Management Association (HDMA)
901 N. Glebe Road, Suite 1000, Arlington VA 22203 | Phone: (703) 787-0000 | Fax: (703) 812-5282
<http://www.healthcaredistribution.org>

[Click here to unsubscribe.](#)