

HDMA Commitment to Patient Safety A Strong Record of Support for Supply Chain Security

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines to patients nationwide. Manufacturers, distributors and pharmacies work daily to help ensure that patients receive the right medicine, at the right place, at the right time. These companies share a primary responsibility to continuously monitor, protect and enhance this secure system against increasingly sophisticated criminals who may try to introduce counterfeit or diverted drugs into the legitimate chain.

For many years, HDMA has been leading supply chain-wide efforts to further enhance patient safety and supply chain security. Efforts have included advocacy for stricter, more uniform licensing and pedigree standards, tougher law enforcement and harsher criminal penalties for the crime of counterfeiting. In the industry, HDMA continues to advocate for best practices and utilization of track-and-trace technologies. Highlights of HDMA activities include:

1. In the late 1980s, HDMA worked closely with the National Association of Boards of Pharmacy (NABP) to develop its Model Rules for Licensure of Wholesale Drug Distributors, which were adopted by the U.S. Food and Drug Administration (FDA) as the state licensing guidelines for all states to use.
2. From the late 1980s through 1992, HDMA was the major force in ensuring that state licensing guidelines were adopted and implemented by the deadline established in the Prescription Drug Marketing Act (PDMA). Support included a campaign among individual state legislative and regulatory bodies to educate them on the rules' structure, intent and benefits, as well as drafting legislative and regulatory proposals.
3. Following the enactment of PDMA, HDMA has, on an ongoing basis, provided continuing education to its members on the requirements of PDMA and the 50 state licensure laws.
4. In early 2001, HDMA joined the EPCglobal Alliance, a group of non-profit institutions and associations that have a common interest in standards-based EPC/RFID technology adoption. HDMA chaired the group in 2005.
5. In September 2002, HDMA established a Counterfeit Task Force to examine a broad range of anti-counterfeit methodologies.
6. Throughout 2002, HDMA worked with Florida's Department of Health and the state legislature to enact legislation that strengthened the state's licensing laws, including active participation on the state's Licensure Subcommittee. As part of this participation, HDMA recommended the state consider certain changes to the law, including:
 - Adding a requirement that licensees post a \$100,000 bond or letter of credit to verify the financial solvency of the applicant
 - Adding a requirement that license renewal be changed to an annual process
 - Adding a requirement that a "designated representative" be appointed in each facility, who would demonstrate a knowledge of the industry and its laws and regulations

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- Adding a requirement for new and detailed information on permit holders to be gathered in the application, including the applicant's ownership, financial viability, experience and education in the industry
 - Supplementing the Florida Department of Health's resources and personnel to better assess and investigate license applicants
 - Adding stronger criminal penalties for those who knowingly break the law
 - Adding requirements that would prohibit cash transactions and designate a standard set of information to be included on Florida's version of a "pedigree."
 - Adding a requirement that distributors perform due diligence to screen potential business partners.
7. In early 2003, HDMA partnered with the Massachusetts Institute of Technology's (MIT) Auto-ID Center to promote education and awareness of Electronic Product Code (EPC) usage in healthcare, particularly as an effective anti-counterfeiting solution.
 8. In July 2003, the HDMA Board of Directors approved a Voluntary Pledge to Report Counterfeit Drugs to the FDA Office of Criminal Investigations, as well as manufacturers, upon the discovery of a suspicious product.
 9. In August 2003, HDMA held the first meeting of the Product Safety Task Force (PSTF). This group was made up of healthcare manufacturing company executives; healthcare distribution company executives; representatives from allied trade associations; representatives from the FDA; representatives from retail outlets such as Wal-Mart and CVS; group purchasing association executives; technology solutions providers; and standards bodies, including the Auto-ID Center and the Uniform Code Council. This task force provided written comments recommending multi-pronged, multi-layered anti-counterfeit solutions to the FDA in response to the agency's Interim Report. The PSTF in particular spoke of track-and-trace technology as a key strategy with the greatest potential to reduce the incidents of counterfeit healthcare products. The PSTF also developed the business requirements needed to implement track-and-trace technologies in the healthcare marketplace, including the following processes: data management issues (ownership, sharing, archiving); data standards for tags; reporting requirements; and tag disablement, tracing and tagging decision criteria. PSTF recommendations may be found on the HDMA Web site, www.healthcaredistribution.org.
 10. In October 2003, HDMA Chairman Jon Borschow, President Borschow Drug, testified before the FDA at an open meeting convened by the agency's Anti-Counterfeit Task Force. In his testimony, Borschow recommended stronger, more uniform state licensure requirements, the adoption of best business practices and use of current and emerging technologies as part of a broad anti-counterfeiting strategy.
 11. In November 2003, HDMA and its members developed *Recommended Guidelines for Pharmaceutical Distribution System Integrity*. These *Guidelines* recommend tough due diligence of potential business partners, including thorough background checks and on-site inspections for compliance with federal and state laws. The *Guidelines* also recommend establishing systems and processes for reporting suspicious products and/or companies. Since their enactment, the HDMA *Guidelines* have been held up as a best business practice model by the FDA.

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12. In November 2003, HDMA provided extensive comments to the FDA Anti-Counterfeiting Task Force, and recommended industry-wide adoption of electronic track-and-trace solutions, stronger licensure laws, increased penalties for counterfeiting and industry-wide adoption of best business practices.
13. HDMA approved in November 2003 a position statement calling for EPC/RFID adoption in the healthcare supply chain, noting that the technology holds the most promise for preventing counterfeit drugs from entering the legitimate medicine supply. HDMA also noted its support for consistent, industry-wide cooperation among all members of the healthcare supply chain to develop appropriate infrastructures and business practices to support the unique identification, tracking and tracing of products from end to end of the supply chain.
14. HDMA enacted in January 2004 a membership bylaws change requiring active members to adopt best practices, such as those embodied in the HDMA *Guidelines*, which include extensive regulatory, financial, security and due diligence processes and procedures. HDMA Bylaws also state that a criminal conviction related to healthcare distribution of a member company or any of its owners or principals may subject that member to expulsion from HDMA.
15. HDMA and EPCglobal in January 2004 signed a Memorandum of Understanding (MOU) calling for both groups explore the potential benefits and applications of EPC technology in the healthcare supply chain, to jointly provide education designed to promote and spread the adoption of EPC technology in the industry and to promote the benefits of EPC technology to HDMA members and the public.
16. HDMA in February 2004 joined Project Jumpstart, the first industry-wide RFID pilot effort aimed at establishing the business case for using RFID/EPC in healthcare. Manufacturers, distributors and retailers were part of this monumental project. HDMA's role in the group was to promote pilot findings and educate members on the benefits of using EPC in healthcare. Pilot findings included 1)RFID/EPC is an essential tool for tagging prescription medicines at the item level, 2) tag read rates need to improve to approach 100% and 3) cooperation among all trading partners is imperative for technology adoption in the industry.
17. In April 2004, HDMA testified before the Nevada State Board of Pharmacy and recommended the Board conduct more pre-licensure screening and inspections and implement stronger penalties for counterfeiting.
18. In June 2004, HDMA introduced its State Model Bill. The Model Bill required licensees to appoint a high-level compliance officer. The bill also required state licensing authorities to have a qualified inspector conduct a physical inspection of the distribution facility **prior** to issuance of license, with regular periodic inspections of all licensees conducted thereafter; conduct criminal and financial background checks on applicants **prior** to issuing a license; publish the dates of the first and most recent inspections; and notify appropriate parties upon license suspension, revocation, expiration or other relevant action.
19. In July 2004, HDMA joined the EPCglobal Healthcare and Life Sciences Business Action Group. In this role, HDMA advises EPCglobal on the business requirements of distributors. This input is then considered by EPCglobal in setting the technology standards for EPC.

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20. In September 2004, HDMA joined the NABP's National Drug Advisory Coalition. The coalition is a cross-industry group, charged with the development of criteria that can be used to determine a national list of products susceptible to counterfeiting.
21. HDMA in November 2004 released a comprehensive research study outlining the features, benefits and business requirements associated with EPC/RFID adoption in the healthcare supply chain. The report, entitled *Adopting EPC in Healthcare: Costs and Benefits*, found that widespread use of EPC/RFID could result in annual benefits of between \$200 million and \$400 million in avoided incidents of counterfeiting.
22. In February 2005, HDMA President and CEO John Gray testified before the Senate HELP Committee on the safety and security of the supply chain, emphasizing the association's commitment to patient health and safety. Gray specifically recommended stronger government regulation, oversight and enforcement of the licensure process; industry-wide adoption new anti-counterfeiting technologies such as EPC/RFID; and the development and implementation of industry best practices across all segments of the supply chain.
23. In March 2005, HDMA recommended the state of Maryland establish a comprehensive licensure program; stronger and more consistent penalties for those who counterfeit prescription drugs; and technological solutions to develop and maintain Maryland's version of "pedigree". HDMA made similar comments in Virginia and in Indiana.
24. In March 2005, HDMA joined the National Health Council, a group committed to the promotion of the health of all people by advancing the voluntary health movement. This movement is driven by volunteers who as individuals, families and communities work together toward the prevention, treatment and cure of disease and disability.
25. HDMA has continued to work with 36 states in late 2005 and early 2006 to promote stronger licensure standards and enhanced pedigree requirements.
26. HDMA in August 2005 convened a group of distributors, manufactures, pharmacies, national and state regulators, standards setting groups and supply chain associations, with the goal of establishing consistent data requirements for electronic pedigrees. These standards are intended to be applicable across all 50 states.
27. HDMA in 2005 joined the FDA Counterfeit Alert Network (CAN), a group established by the FDA to rapidly inform the healthcare industry and the public in the event of a counterfeiting emergency.
28. On November 1, 2005, HDMA submitted written testimony to the House Subcommittee on Criminal Justice, Drug Policy & Human Resources, emphasizing the association's commitment to patient health and safety and supply chain security. HDMA specifically recommended tough, uniform licensing and pedigree requirements, industry-wide adoption of new anti-counterfeiting technologies and the development and implementation of best practices across the supply chain.

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29. In November, 2005 HDMA co-sponsored the first annual RFID in Healthcare Summit with the National Association of Chain Drug Stores (NACDS). The summit focused on providing education on RFID/EPC pilot progress in the industry and the need to address challenges such as data management/sharing, read rates, standards development and more.
30. In early 2006, HDMA strengthened its membership requirements to include only primary, full-service distributors that predominantly buy directly from manufacturers and predominantly sell directly to healthcare providers.
31. HDMA President & CEO, John Gray and senior HDMA staff testified before the FDA Counterfeit Drug Task Force Public Workshop on February 8-9, 2006. Testimony highlighted HDMA's core beliefs for stricter, stronger enforcement and harsher criminal penalties for counterfeiting; support for current and emerging technology solutions such as EPC/RFID; best business practices and more uniform licensing and pedigree requirements. HDMA also advocated for implementation of the PDMA rule.
32. In an effort to combat the theft and illegal trafficking of prescription medications HDMA in June 2006 joined a partnership of law enforcement and professional pharmacy organizations using RxPATROL[®], an information clearinghouse designed to collect, analyze and share information on pharmacy robberies, burglaries and theft of controlled substances. RxPATROL (Pattern Analysis Tracking Robberies and Other Losses) is designed to help pharmacists guard against potential robberies and burglaries, and to assist law enforcement efforts to apprehend and prosecute pharmacy theft suspects.
33. HDMA in June 2006 hosted a 90-minute live Webinar on Florida pedigree requirements, attended by 70 HDMA member companies. The Webinar reviewed the Florida law and regulations, focusing on pedigree requirements and criminal penalty provisions for counterfeiting.
34. In late 2006, HDMA formed a broad supply chain coalition to develop the milestones, business cases and processes needed for track-and-trace technology implementation. Called Rx SafeTrack, the group includes representatives from leading healthcare companies and allied associations, including PhRMA, NACDS, NCPA and GPhA.
35. In October 2006 HDMA hosted a full, one-day Seminar entitled, "Federal and State Pedigree Initiatives: Preparing for Implementation." The program, attended by 130 manufacturers and distributors, outlined the statutory and regulatory requirements of the PDMA and the unique pedigree requirements at the state level.
36. In February 2007, HDMA announced support for the Counterfeit Drug Prevention Act of 2007 (HR 780), which significantly increases criminal penalties for counterfeiting patient medications from one to three years imprisonment, to 20 years or more.
37. HDMA in May 2007 released the *HDMA Product Recall and Withdrawal Guidelines*. These voluntary guidelines provide insights into current industry recall and withdrawal practices, as well as strategies for manufacturers and distributors of healthcare products to effectively communicate product recall or withdrawal information to trading partners, in order to further enhance patient safety.

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38. In August 2007, HDMA partnered with the American Hospital Association, the American Red Cross, BIO, NACDS, National Community Pharmacists Association (NCPA) and PhRMA to launch Rx Response, a program designed to help support the continued delivery of medicines during a severe public health emergency. Rx Response will help support information sharing among partners, community volunteer relief organizations and local, state and federal agencies responding to major disasters by helping to coordinate communications, support the continued delivery of critical medicines and, where possible, addressing challenges.
39. HDMA in September 2007 announced public support for the Food and Drug Administration Amendments Act (H.R. 3580), which gives the FDA new authority to establish standards for numerical identifiers that will facilitate the tracking and tracing of prescription medicines from end to end of the supply chain.
40. HDMA in September 2007 hosted a two-day Seminar, entitled *California Track and Trace: Preparing for Implementation*. This Seminar provided an in-depth look at the California pedigree law from the perspective of the state Board of Pharmacy, as well as practical strategies already being used by manufacturers, distributors and pharmacies to comply with the law.
41. HDMA in early 2008 issued a letter of support for the Online Pharmacy Consumer Protection Act (S. 980), introduced by Senators Diane Feinstein (D-CA) and Jeff Sessions (R-AL). S. 980 would help address the growing problem of illegal Internet pharmacies.
42. HDMA in March 2008 issued a press release in support of the President's call for Congress and the Administration to work together to combat illegal online sales of prescription medicines.
43. In March 2008 HDMA's knowledge partner, the Center for Healthcare Supply Chain Research, released the *Rules of Engagement • Phase II: The Blueprint for Data Management & Data Sharing*. This ground-breaking research presents a future vision for tracking and tracing prescription medicines from the beginning to the end of the healthcare supply chain, and outlines the technologies and steps that can enable companies to share and manage item-level product data.
44. HDMA in March 2008 joined the Pain Care Forum. The Pain Care Forum and its member organizations advocate for public policies that support the safe and effective treatment of pain.
45. In April 2008, HDMA publicly supported the introduction of the Safeguarding America's Pharmaceuticals Act of 2008 (HR 5839), introduced by U.S. Representatives Steve Buyer (R-IN) and Rep. Jim Matheson (D-UT). This comprehensive bipartisan legislation would establish uniform, federal requirements for the tracking and tracing of prescription medicines from the manufacturer, to the distributor, to the pharmacy. Part of an overall strategy to help combat criminal counterfeiting, the legislation would strengthen current federal laws and regulations and further secure the nation's prescription medicine supply.
46. In May 2008, HDMA submitted public comments to the Food and Drug Administration, as part of the Agency's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA). In comments, HDMA stressed primary healthcare distributors' long-standing efforts to enhance the safety and security of the supply chain through the industry-wide use of track-and-trace technologies.

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HDMA also encouraged FDA to base unique identifier requirements on specific and existing standards created by GS1 and EPCglobal. Lastly, HDMA recommended that FDA consider the industry-wide use of a single, interoperable, non-line-of-sight technology, such as RFID.

Note: Activities will be added periodically to reflect new processes, policies and positions.

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About HDMA

The Healthcare Distribution Management Association (HDMA) is the national association representing primary, full-service healthcare distributors, including national and regional companies. Each day, the member companies of HDMA are responsible for ensuring that more than 13 million prescription medicines and healthcare products are safely delivered to 144,000 pharmacies, hospitals, nursing homes, physician offices, clinics, government and other providers in all 50 states. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system nearly \$34 billion each year. HDMA and its members are the vital link in the healthcare system, working daily to provide value, remove costs and develop innovative solutions to deliver care safely and effectively.