

HDMA Commitment to Patient Safety Through Supply Chain Integrity A Strong Record of Support & Efforts for Healthcare System Security

HDMA and its members are committed to continuously improving supply chain practices and business processes to aggressively combat counterfeit drugs on behalf of patient safety. In the government arena, HDMA has actively called for stricter, more uniform licensing, tougher enforcement and harsher criminal penalties. In the industry, HDMA continues to advocate for best practices and to actively work on electronic track and trace solutions.

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 according to federal law by the deadline established in the 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 requirements of PDMA and 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
 - 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; process and computer validation; reporting requirements; stakeholder issues such as the existence of multiple reader types; 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 of healthcare distributors, the adoption of best business practices on the part of distributors and stated that emerging technologies EPC/RFID should be used 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* raise the standard of practice throughout the entire distribution system by recommending drug purchasers conduct tough due diligence, 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 product and/or entities suspected of unlawful activity. Since their enactment, the HDMA *Guidelines* have been held up as a best business practice model by the FDA.
 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 distributor 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 pharmaceutical supply chain, noting that the technology holds the most promise for preventing counterfeit drugs from entering the marketplace. 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 that support the unique identification, tracking and tracing of product information throughout 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 pharmaceutical supply chain, to jointly provide education designed to promote and spread the adoption of EPC technology in the pharmaceutical 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 pharmaceutical products at the item level, 2) tag read rates improve to approach 100% and 3) cooperation among all industry 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, provide an appropriate standard of liability regarding the purchase of a contraband and counterfeit drug and implement stronger penalties for counterfeiting activities.
18. In June 2004, HDMA introduced its State Model Bill. The Model Bill requires licensees to appoint a high-level compliance officer. The bill also requires 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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21. 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.
22. 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 distributor 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; technological solutions to develop and maintain Maryland's version of "pedigree;" and uniformity among the states that adopt laws and regulations that address the inspections, investigations and enforcement in distribution facilities across the country. HDMA has 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 more effective transaction history 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 began working with the FDA to join the 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. In an effort to further secure patient safety and to ensure tight regulation of the distribution industry, HDMA in October 2005 called for tough, uniform federal licensing standards for prescription drug distributors.
29. On November 1, 2005, HDMA President and CEO John M. Gray testified before the House Subcommittee on Criminal Justice, Drug Policy & Human Resources, emphasizing the association's commitment to patient health and safety. Gray specifically recommended uniform, tough, federal standards, and to maintain an optional role for states to inspect facilities. Gray also recommended industry-wide adoption new anti-counterfeiting technologies such as EPC/RFID and the development and implementation of best practices across all segments of the supply chain

30. In November, 2005 HDMA co-sponsored the first annual RFID in Healthcare Summit with the National Association of Chain Drug Stores (NACDS). The summit was focused on providing the industry with 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.

About HDMA

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

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