



Healthcare Distribution
Management Association

Products, Services and Information for Your Health

*John M. Gray, President and CEO
Eric Schuss, Chairman of the Board*

July 9, 2004

The Honorable Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room 159-H (Annex G)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Via electronic submission

Re: RFID Workshop - Comment, P049106

Dear Secretary Clark:

On behalf of the Healthcare Distribution Management Association (HDMA), thank you for the opportunity to comment on the development and implementation of Electronic Product Code (EPC) and Radio Frequency Identification (RFID) within the prescription drug industry. HDMA supports the advancement of EPC/RFID technologies and advocates for full implementation as a key step toward ensuring a safe and secure drug supply chain.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. As government-licensed entities, healthcare distributors managing drug distribution ensure product safety and provide the vital link between manufacturers and healthcare providers by warehousing finished products, processing orders, keeping records, managing inventory, supplying information systems and software, processing recalls and returns, providing accounting services and extending credit.

Introduction

HDMA applauds the Federal Trade Commission's (FTC) efforts to explore current and future applications of RFID in the marketplace, as well as its potential impact on consumers. The FTC's workshop on June 21, 2004 provided an open forum for

Healthcare Distribution Management Association
Formerly National Wholesale Druggists' Association (NWDA)

representatives from federal agencies, consumers, and industry, to present and discuss current applications, test programs, status, and potential uses of EPC and RFID technology.

HDMA is the leading association promoting education, awareness, and eventual adoption of track and trace technology in the healthcare supply chain. We are collaborating with our sister associations and appropriate stakeholders to ensure a timely and realistic approach for industry-wide adoption of EPC/RFID.

HDMA is particularly interested in the use of this technology to help secure the nation's drug supply chain and ensure patient safety. Our organization and its members continue to lead the charge for EPC/RFID and we are certain that it will become the best weapon the pharmaceutical industry has to fight drug counterfeiting. During the past few years, HDMA's member companies have been involved in supporting the development of industry standards, working with various members of the supply chain, and participating in meetings with government, industry, and other associations, in order to ensure that RFID is implemented throughout the pharmaceutical supply chain.

Benefits of RFID

HDMA and its members have been working to develop and implement a feasible track and trace system for prescription drug products. HDMA's primary concern is eliminating the presence of counterfeit drugs in the nation's supply chain. HDMA believes that RFID has the potential to become the best solution to this problem and it is the key component of our anti-counterfeiting strategy. Enabling manufacturers and distributors to track and trace prescription drugs throughout the supply chain will help them to better detect counterfeit drugs and prevent such products from making it through to the consumer. While RFID/EPC is still being studied, it is expected that this technology will improve the efficiency of the supply chain and have the potential to protect patient safety.

The existence of counterfeit, tampered, or adulterated products entering the healthcare supply chain is a great concern to the safety of our nation. With the development of new EPC technology creating the ability to track, trace, and monitor individual product units using RFID, the healthcare distribution industry has the opportunity to transform the evolving pharmaceutical supply chain. HDMA firmly believes that technology will serve as a barrier to entry of unsafe product in the supply chain by establishing a secure electronic means through which every unit of medication can be verified, in terms of its source and path through the supply chain. In addition, RFID has the potential to improve efficiencies in the distribution process, revolutionize inventory management, transform critical processes for handling returns and recalls, and automate inventory rotation, resulting in a more efficient distribution system.

HDMA supports the establishment of a consistent, industry-wide initiative, involving all members of the healthcare distribution supply chain to drive the adoption, implementation, and utilization of EPC tags. In addition, HDMA fully supports the

development of appropriate infrastructures that will uniquely identify and track products and information throughout the healthcare distribution supply chain.

With the use of EPC/RFID, each member of the supply chain will have the ability to locate a specific product and to identify the path the product followed through the supply chain. Each product will be tagged with a unique number that will serve as a link to information about the product's source and distribution history that when accessed, will enable detection of tampering, adulteration, or counterfeiting. The benefits in the area of inventory and logistics management are great, but they are far outweighed by the potential role RFID can play in creating a safe and secure supply chain.

HDMA Efforts to Further the Development and Implementation of RFID

HDMA activities to further the development of RFID have included:

- Promoting EPC/RFID awareness and education throughout the healthcare industry.
- Advocating for industry-wide adoption of an RFID infrastructure/system for track and trace of drug products.
- Educating members of Congress, state legislators, and other government representatives about the benefits of RFID as an anti-counterfeiting measure, as well as the industry's efforts to promote its development.
- Facilitating industry pilot programs and implementation.
- Developing industry standards and best practices.
- Collaborating with industry partners such as the National Association of Chain Drug Stores (NACDS), the Pharmaceutical Research and Manufacturers of America (PhRMA), EPCglobal, Auto-ID Labs, and others.
- Participating in the Accenture/EPC Jumpstart pilot study.

Privacy Concerns

Many consumer protection interest groups have voiced concerns about the abilities of RFID and the impact such a system could have on individual privacy rights. This is of particular concern to the public when one considers the application of new tracking technology in the healthcare arena, in which patient privacy is of utmost concern. However, the potential patient safety benefits available through RFID should be balanced against the privacy concerns raised by consumer advocates.

Currently, all plans for RFID implementation include the development of guidelines for companies that control these new technologies. Patient privacy requirements, such as those addressed by the Health Insurance Portability and Accountability Act (HIPAA), will be adhered to as standards and solutions are developed, to ensure that private medical information is not available to inappropriate parties.

Conclusion

We welcome the opportunity to work with you in the future, should the FTC become more involved or promulgate regulations in this arena. HDMA continues to serve as a leading proponent of EPC/RFID and has invested considerable resources to develop a system to protect the nation's drug supply. We urge you to keep us apprised of any efforts that the Commission plans to pursue related to RFID or its regulation.

HDMA appreciates the opportunity to provide the Commission with these comments. We are available for further discussion should you have questions about any of the points discussed above or need additional information. Please contact me or Anita Ducca at (703) 787-0000, ext. 240 or aducca@hdmanet.org. For more information on HDMA's EPC/RFID activities, please visit our web site at http://www.healthcaredistribution.org/issues_in_dist/electronicP.asp.

Sincerely,

A handwritten signature in black ink that reads "Scott Melville". The signature is written in a cursive, flowing style.

Scott Melville
Senior Vice President, Government Relations