



March 2, 2006

Randall W. Lutter, Ph.D.
Associate Commissioner for Policy and Planning
United States Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Lutter:

On behalf of the Healthcare Distribution Management Association (HDMA), the National Association of Chain Drug Stores (NACDS) and the Pharmaceutical Research and Manufacturers of America (PhRMA), we would like to thank you for the opportunity to present our respective anti-counterfeiting strategies at the FDA Anti-Counterfeiting Initiative Workshop on February 8th and 9th. We would like to emphasize our commitment to join together on behalf of industry-wide solutions to further advance patient safety, supply chain security and business efficiencies.

We believe that each sector of the healthcare supply chain — manufacturers, distributors and pharmacies — must work together to ensure a safe and reliable supply of medicines for patients nationwide. Our respective associations and members have and will continue to work on pharmaceutical supply chain issues ranging from public policy initiatives to technology solutions to battle criminals who engage in counterfeiting.

Our associations have initially identified three key areas upon which we will focus our time and resources together to ensure a successful roadmap to adoption of electronic authentication technologies throughout the healthcare supply chain. The areas on which we must gain consensus include: 1) data management and data sharing; 2) inclusion of the National Drug Code (NDC) in the EPC numbering scheme; and 3) use of two-dimensional barcodes and/or RFID.

A current research project, being conducted by the HDMA Foundation and Rutgers University, is designed to address the business case for data sharing/management and to recommend a protocol for data access. The research project is also designed to help establish the rules of engagement to support a more streamlined, transparent supply chain. We will continue to facilitate positive public policy, health and safety outcomes, as individual association CEOs, with a primary responsibility to maintain one of the safest and most secure supply chains in the world.

In the meantime, please do not hesitate to call upon each of us. Thank you for your leadership on anti-counterfeiting solutions and your commitment to protecting citizens across our nation.

Sincerely,

John M. Gray
HDMA President & CEO

Craig Fuller
NACDS President & CEO

Billy Tauzin
PhRMA President & CEO