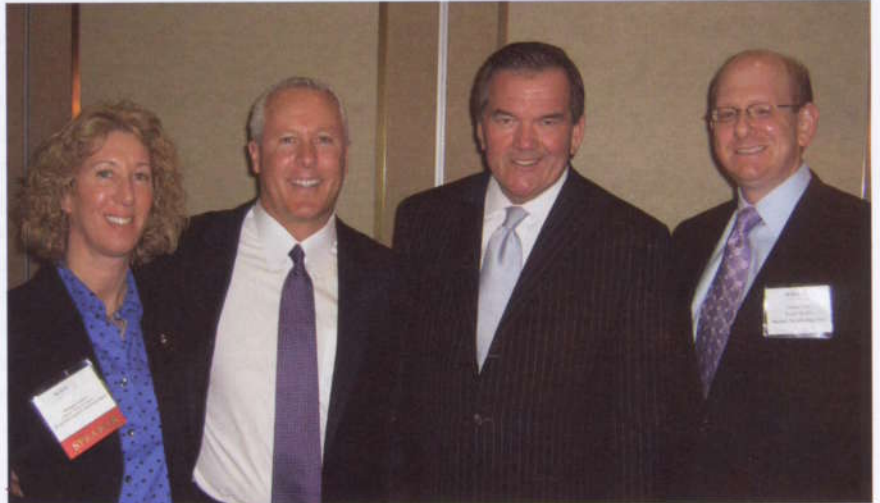


The Future and Safety of the Supply Chain Among Discussions at Secure Pharma 2008

By Bruce Kneeland



From left, Philippa LeVine, DEA; J. Aaron Graham, Purdue Pharma; Tom Ridge, former Pennsylvania Governor and director of Homeland Security; and Adam Fein, Pembroke Consulting.

It seems that despite the best efforts of industry associations, company executives and government regulators, no industry wide consensus has been reached on the most practical ways to protect the integrity of the pharma-

ceutical supply chain. Two years ago, most published reports postulated that Radio Frequency Identification (RFID) would be the “magic bullet” the industry required. Now, based on comments made by many of those that presented

at Secure Pharma 2008, it does not appear that RFID will be able to overcome some of its technical and economic hurdles and be able to meet the regulatory deadlines scheduled to take effect in the near future.

Secure Pharma 2008, held at the Philadelphia Hilton, Feb. 26-27, attracted more than 300 people. Most of the attendees were from pharmaceutical manufacturing and distributor companies that came because they were eager to find ways to solve the problems of counterfeiting and drug diversion that beset the industry. Donna Wall, a clinical pharmacist with Indiana University Hospital and a member of the Indiana State Pharmacy Board, told the participants that counterfeit pharmaceuticals are estimated to be one percent of all the products dispensed in the United States. She further told of a recent raid that resulted in the capture of 11 million doses of counterfeit steroids.

Paul Maloney, of Carr Maloney PLC, a law firm with expertise in helping companies deal with law suits stemming from



John Lundquist, left, and Alan Clock, both of XStream Systems.



Paul J. Maloney, Carr Maloney P.C., one of the program presenters.



Brian Sharpiro, left, of Aceto, with Andrew Van Ostrand of HIDA.

counterfeit and/or adulterated product claims, said the supply chain suffers from a lack of quality control. For example, he indicated that sub-potent or adulterated product coming from China's growing Active Pharmaceutical Ingredient (API) industry has been reported to be as high as 14 percent of the product it produces. He further added that in the recent past a company could claim that it was unaware of problems of this type and use that as a legal defense. But, now that the problems are well know, the time has come for



Terry Murphy, left, Wyeth Pharmaceuticals, and Andrew Harrison, Baxter Healthcare.

them to implement procedures that will safe guard the products they produce.

One highlight of the conference was the presence of former Pennsylvania Governor and the First Secretary of Homeland Security, Tom Ridge. The former secretary is a member of the board of directors for Secure Symbology, one of the event's exhibitors and sponsors. In the company's booth, he made mention of the threat to national security from the revenue generated by unscrupulous manufacturers of counterfeit product known to finance terrorist activity.

The event did attract a number of suppliers of technology designed to be employed by manufacturers and distributors. It was also pointed out during the session that pharmacies are going to need to become involved in helping to solve the problem and, according to some, they need to start paying attention to the regulations and exploring ways to insure the products they dispense to consumers are legitimate.

One new piece of technology that was discussed during the event appears to be approaching the problem from a completely unique direction. Up until this time, most of the efforts in ensuring the supply chain have involved tagging, tracing or otherwise making it difficult to insert product into the supply chain through more regulation and procedures. But, a new product from XStream Systems is reported to be able to use a modified type of x-ray analysis that can actually determine if the chemical structure of the product contains all the necessary ingredients in the proper order.

According to Alan Clock, vice president of Sales and Marketing for XStream Systems, this new technology can be used to "scan" the product, without the need to open the package and determine if the product


is counterfeit, or even if the cold chain has been broken in shipment resulting in molecular degradation. Clock believes the benefits of this technology will make it possible for any member of the supply



One of the program's five round table discussion groups.

chain to be absolutely certain the products they handle are legitimate and can be sold and dispensed with confidence.

Secure Pharma 2009 is slated for next February in Philadelphia, Penn., where topics of discussion are expected to address life-threatening vulnerabilities in the supply chain to ensure patient health and brand integrity.

For more information, contact www.securepharma2009.com. 



About the Author

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