November 7, 2012

Comments on Draft Proposal to Improve Drug Distribution Security

Dear Chairman Harkin and Ranking Member Enzi of the HELP Committee, Chairman Upton and Ranking Member Waxman of the Energy and Commerce Committee, Senators Grassley, Feinstein, Alexander, Burr, Whitehouse, and Bennet; and Representatives Dingell, Pallone, Bilbray, and Matheson:

Thank you for the opportunity to provide comments on your Draft Proposal to Improve Drug Distribution Security. We recognize and appreciate the substantial effort made to produce this detailed document.

In my position within Hewlett-Packard Labs, I have been involved in product security, brand protection and anti-counterfeiting, leading the global team in this area since 2005. I am currently on the World Economic Forum's Global Agenda Council for Illicit Trade, and through my role in HP Labs architect and development the mathematical, software, services and hardware technologies to support HP and its partners in the anti-fraud area. We have worked on mass serialization, tracking, authentication and forensic solutions for supply chain and product security, typically with our own company, Hewlett-Packard, as a first customer of our technologies and services.

Hewlett-Packard (HP) is a Fortune 15 company with more than $125 billion in revenue (2012) and manages the world's 9th largest supply chain. HP produces servers, storage, computers, printers and other peripherals, software, services, devices and networking worldwide and is itself a target for counterfeiters and other fraudulent agents. HP is concerned with environmental sustainability, which is impeded by the increased waste associated with counterfeiting and other forms of fraud. In addition, HP is concerned for the safety of its own customers and the customers of companies for which HP provides devices, software and services.

My own experience with the movement of systems and software to a more mobile, distributed and "cloud-based" computing model, has led to the creation of electronic systems for authentication, product validation and logistics. I feel that security of the U.S. pharmaceutical supply chain is best assured by an electronic system that can track and authenticate each package (unit) of drugs as it moves through distribution. HP, as one example, is a technology provider that can simultaneously provide all necessary aspects of such a system, including everything from the mass serialization to the storage of codes and system use logging information.

The draft proposal contains an initial lot-level tracking system that specifies peer-to-peer passage of a drug "pedigree", including by paper. A lot-level system will not adequately protect patients. A drug lot is a nonstandard metric that can contain numerous cases of many thousands of individual bottles or packs of vials. Thus, even unsophisticated counterfeiters may obtain valid lot codes through purchase or clandestine activity during shopping, which they can deploy for illicit trade purposes.

We urge you to ensure swift implementation of a robust, electronic unit-level tracking system. We support giving the FDA authority to create such a system, but the draft includes unnecessary delays. The technology needed to support data storage and exchange for all packages in U.S. drug distribution exists

today. Multiple foreign countries have already established centralized databases to manage and authenticate drug serials. There is no reason patients in the U.S. should have to accept a lower level of protection.

Robust electronic systems to store and exchange data will improve security and support business functions.

Regulators and members of the pharmaceutical supply chain have been working for over a decade to delineate an improved, automated electronic system, i.e. “track and trace”, to take the place of the limited paper pedigree system established under the Prescription Drug Marketing Act of 1987. Such systems permit automated authentication of serialized drug packages to automatically flag drugs that have a fake serial, or that have a serial that has been marked as stolen.

The efficiencies of such a system are remarkable. For example, a very common motif of counterfeiters is to make many copies of the same serialized number, assuming (usually rightly) that such a number will be replicated on many legitimate items. Item-level serialization not only makes such an approach short-lived, but it also allows the legitimate manufacturer to piece together the counterfeit supply chain from the numbers they are using.

It should be kept in mind that preventing fraud depends on the investigation and associated analysis as much as the methods put in place to deter fraud upfront. Electronic systems are more robust to rolling out of new changes as well as analytics.

In addition, electronic systems improve the efficacy of legitimate business, even in the absence of fraud. Inventory, warehouse management, point of sale support and other workflows of high value to the businesses are supported by electronic workflows.

Systems to track and authenticate each package (unit) of drug are achievable today

The technology needed to store and manage data on pharmaceutical serial numbers is available today. HP has rolled out a service, already deployed in-house and for select partners, which provides serialized, non-colliding numbers for multiple product families simultaneously. The service also allows customers, retailers, distributors, warehousers, printers and manufacturers to compare the numbers on labeled items to the numbers created in the global product authentication service. Numbers can be represented alphanumerically under tamper-evident scratch-off code, in 2D barcodes, in RFID, etc. Thus, the technology used to serialize the pharmaceutical labels and packaging are not defined beforehand, making the system flexible and readily deployed taking into account the “asset inertia” of the product and its supply chain.

Electronic systems should support efficient authentication of drug units by all supply chain partners.

All supply chain partners play a role in ensuring the security of the system; therefore, all of them need access to electronic authentication services. Although some smaller companies have expressed cost

concerns, electronic verification services need not be cost prohibitive. One reason is that variable data printing can be used directly for the item level serialization, which means no additional cost over the already incumbent costs of printing the labels and packaging is required. Similar efficiencies can be gained with other variable marking technologies, such as RFID and near-field communications.

Conclusion

I believe that the United States should offer its patients the same level of protection as other countries, and move swiftly to an automated electronic unit-level traceability system. Such a system should include participation from all supply chain members. We support giving FDA the authority to establish such a system, but timelines in the draft are unnecessarily long. The technology needed is available today.

I would be pleased to provide any additional information if helpful.

Sincerely,

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