Johnson & Johnson
HEALTH CARE SYSTEMS INC.

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Thank you for your introduction, Mr. Chairman. I work for, and am representing, Johnson & Johnson Health Care Systems Inc. Johnson & Johnson Health Care Systems Inc. is the principal supply chain commercial entity within the Johnson & Johnson Family of Companies in the U.S. Thank you for the opportunity to speak here today. Securing Our Nation Supply Chain is an important concern for our company.

We believe it is vital that the patients who use our products receive our genuine products. We have already taken steps to secure our supply chain and protect our products. As a member of PhRMA (Pharmaceutical Research and Manufacturers of America) and BIO (Biotechnology Industry Organization), and a participant in PDSA - the Pharmaceutical Distribution Security Alliance, I will share with you our perspectives on serialization and track & trace, our serialization experience, and views on the proposed legislation.

Serialization regulations have become increasingly common across many countries, including the European Union, Turkey, Argentina, China, India, and Brazil.

In the U.S., the California law requires manufacturers to serialize and pedigree all pharmaceutical products sold in the State of California – 50 percent of our products by January 1, 2015 and the remaining 50 percent by January 1, 2016. Additionally, more than 50 percent of the states have pedigree laws with varying approaches – that is, some require electronic pedigrees, others use paper, some start the pedigree with the primary distributor, others start it with the secondary wholesaler, etc.

This patchwork quilt of regulations leaves us with a complicated, inefficient regulatory landscape, creating unforeseen gaps where bad actors can introduce illicit drugs into the legitimate supply chain, thereby, placing our citizens at risk of counterfeit medicines. While the risk of encountering counterfeit medicines may be small within the legitimate domestic supply chain, when a patient receives a counterfeit medicine, the effects can be extremely dangerous, have long lasting impact, and can be even life threatening.

Our company believes that Federal serialization and track & trace legislation is necessary to properly secure our pharmaceutical supply chain by eliminating varying and conflicting state

regulations. Federal legislation should help close the gaps where illicit drugs enter the U.S. supply chain, as well as provide additional mechanisms to help authenticate the legitimacy of medicines distributed and dispensed within the US to help protect the patients who use our medicines.

Next, I'd like to share our company's domestic serialization experience.

We are preparing our packaging sites, distribution centers, business and information technology systems to serialize and track & trace our products so that we can comply with the California e-Pedigree law. Here is an example of the first product that we have serialized for the U.S. market. This product is PREZISTA ® (darunavir) 600mg tablets.

For your reference, I have attached a label of serialized PREZISTA® 600mg to my testimony.

Let me draw your attention to the product license plate on the side of the label. This space is similar to the Prescription Drug Product Identifier prescribed in the House bill. We provide both machine and human readable forms for easy, accurate identification. Similarly, we apply a standard, serialized bar code to every homogeneous case to facilitate handling during distribution. This identification space complies with both the FDA's Serial Number Identifier guidance, and the widely adopted international standards developed by GS1.

Additionally, we are establishing processes to exchange serialized data with the distributors who distribute our products, and with the pharmacies that dispense our medicines to patients who need them. We are required to provide this information to the distributors and pharmacies so that they can use it to help verify both the authenticity of the package as well as the transactions related to the product.

Bottom line, while it is complicated work and a lot still remains, we are doing our part to comply with the California law. However, if any other states were to adopt slightly different regulations, the inconsistencies could compromise the integrity of the supply chain, hence, supporting the need for Federal action now to secure our national supply chain.

Lastly, I would like to comment on the proposed legislation.

In 2011, our company, along with several other PhRMA and BIO members, and other supply chain participants helped form PDSA. PDSA's mission is to help enact a federal policy proposal for one unified national system enhancing the security of the domestic pharmaceutical distribution system for patients, and to define a migratory implementation pathway.

Johnson & Johnson Health Care Systems supports Representatives Latta and Matheson for tackling this important issue and making progress on a legislative solution. This legislation incorporates many of PDSA's proposed provisions including a uniform national standard with a phased implementation.

It is vitally important that both government and the private sector work together to protect our nation's drug supply in a manner that makes sense. We believe this legislation will help us secure the domestic pharmaceutical supply chain by providing additional protection to our citizens, patients who depend on the integrity of our medicines to treat their diseases and life-threatening conditions, from counterfeit medicines.

Johnson & Johnson Health Care Systems commitment to patient safety is unwavering. We look forward to Congress' enactment of this legislation, and we are committed to working with Congress, the FDA and our supply chain stakeholders to implement it successfully.

Again, thank you for the opportunity to provide this testimony to the Committee.

Before concluding my remarks, I'd like to recognize Steve Drucker, an industry colleague from Merck, who passed away last week. We will miss Steve's immense contributions; unwavering commitment to patient safety; and especially his humorous insights. Our thoughts and prayers go out to Steve's family, especially his wife, Anne; and to the entire Merck team.

Exhibit 1 - Serialized Label for PREZISTA® 600mg

PREZISTA ® (darunavir) 600mg tablets