"*Securing our Nation's Prescription Drug Supply Chain*"

**Statement for the Record**
House Subcommittee on Health

Neil S. Alpert
President, LaserLock Technologies

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LASERLOCK
TECHNOLOGIES

Chairman Pitts, Ranking Member Pallone, Jr. and members of the House of Representatives Committee on Energy and Commerce, Health Subcommittee, thank you for the opportunity to submit testimony to you for the record regarding the April 25, 2013 hearing entitled, "Securing Our Nation's Prescription Drug Supply Chain."

Like so many of history's great companies, LaserLock has evolved over time. Founded in 1999, we have been leading the development of cutting-edge authentication and anti-counterfeiting technologies. And, as this hearing indicates, the timing for such technologies couldn't be any more important.

In an age of global chaos, a major source of funding for terrorist groups and organized crime is counterfeiting. Every day, consumers unknowingly purchase counterfeit products from legitimate vendors, and perpetuate a global system of thievery and deception. And when these groups turn to the counterfeiting of pharmaceuticals and the American drug supply, they are not just eating away at someone's bottom line. More so, they are holding hostage the national security and public health of people in the United States and around the world.

Our shared mission is simple – to protect patients, health care providers and the companies that support them from the dangers of the global counterfeiting trade. By offering cost-effective solutions that authenticate products, pharmaceuticals, documents, and the supply chain more effectively than ever before, LaserLock continues to be a global thought leader in the fight to protect America against the proliferation of counterfeit goods, including pharmaceuticals.

LaserLock strives to create an environment where everyone has the ability to both verify the authenticity and provenance of any material. We believe that, counterfeiting and identity theft have become global problems affecting everyone. We don't want people to die from counterfeit medicines, foods or beverages. We don't want governments and or citizens held hostage by terrorists and organized crime. We don't want the woman who saved for five years to buy her first designer handbag to discover she has spent her savings

on a worthless counterfeit.

LaserLock is considered to be a leader in the anti-counterfeiting and authentication of products and packaging and has been for over a decade. We imagine a world where there are authentication solutions available to every American. We want everyone to be able to trust in the integrity and reliability of the products they purchase and use. We believe this will be a better world for all of us, and we commit ourselves to realizing this vision. We believe the best way to predict the future … is to invent it.

## Problems in the Pharmaceutical Supply Chain

The World Health Organization estimates that 1% of all drugs in the United States are counterfeit. With the Kaiser Family Foundation estimating the number of prescriptions filled each year in the United States at around 3.7 billion, this translates to roughly 37.6 million prescriptions filled annually with counterfeit pharmaceuticals. This places nearly every American consumer of prescription drugs risk of consuming either an ineffective or harmful medication. This needs to be stopped and can be done so with three easy steps utilizing existing solutions: authentication technology, mobile devices and authentication databases. Consumers should be confident that when they purchase pharmaceuticals that their medication works as advertised.

Counterfeit drugs are dangerous by their very nature: they are not produced under safe manufacturing conditions and they are not subject the same regulatory scrutiny as legitimate medications. Fake pills can look identical to their genuine counterparts but may contain an incorrect amount of the active ingredients or no active ingredient whatsoever. Additionally, noxious ingredients have also been found in counterfeit drugs with fatal consequences. For example, in October 2012 counterfeit ingredients found in steroids from a compounding pharmacy near Boston killed 11 people with fungal meningitis and sickened more than 100. While the U.S. pharmaceutical distribution system is among the safest in the world, the incidents of counterfeiting continue to increase annually. One of the reasons is that as technology

improves, counterfeiting becomes easier. Unfortunately, counterfeiters only have to reproduce an authentic looking package; what's inside doesn't matter to them.

Counterfeit pharmaceuticals not only affect the consumer, but have also produced a wide range of negative effects on the pharmaceutical industry itself. These typically manifest as lost revenue, decline in brand value, lower incentives to invest in research and development, and higher protection and auditing costs. The lack of data available to researchers of this problem prevents any strong quantifiable insights at the industry or company level. Nonetheless, what data is available does suggest that the problem threatens the financial health and competitiveness of the U.S. pharmaceutical industry.

The U.S. Customs and Border Protection Agency (CBP) has reported that between fiscal years 2004 and 2009, the domestic value and seizures of pharmaceuticals increased overall. According to Pfizer, the factors that contribute to the rise of pharmaceutical counterfeiting are unregulated wholesales and re-packagers in the supply chain, the growth of Internet pharmacies, advances in technology that make counterfeiting easier and the increased importation of prescription drugs from abroad.

In the past, counterfeits were confined to illegal or unauthorized channels of distribution. More recently, legitimate channels of distribution in the U.S. and other countries with advanced economies have been increasingly infiltrated by counterfeits.

As has been exhaustively covered in this hearing, the pharmaceutical supply chain lacks a reporting structure capable of comprehensively documenting the movement of a product from the producer to the end consumer. This lack of documentation along the supply chain creates a blind spot each time the product changes hands. These blind spots are precisely what counterfeiters look to exploit. Introducing an industry-wide system that holds all participants accountable within the distribution network is needed to deter and end unnecessary public health problems and economic losses.

Counterfeiting is widely acknowledged as an attractive funding ploy for sophisticated criminal organizations and global terrorism. Pharmaceuticals are easy to transport and carry much lighter criminal penalties in the event they are detected.

At a time when counterfeit pharmaceuticals are flooding the global market, the pharmaceutical industry, public health advocates, and security professionals are trying to educate the public about the need for caution when purchasing their medicines and the importance of closing our borders to these potentially dangerous products. We agree with the subcommittee that a uniform code of standards needs to be applied and industry alone cannot dictate how to deliver it, yet serialization, or the concept of uniquely identifying medicines at the unit level (vs. batch or lot), while required for resilient track and trace capabilities, is not sufficient to significantly reduce counterfeiting. When serialization is implemented through the use of overt markings, such as visible barcodes, Datamatrix or QR codes, we are simply providing the counterfeiter with precisely the information they need to perpetrate their deception.

We are convinced that by combining covert and overt anti-counterfeiting techniques it is possible to implement a comprehensive system that:

- Is dynamic, flexible and adaptable – new anti-counterfeiting characteristics can continuously be added and updated
- Incorporates overt characteristics that provide the 'visible' information required by broad numbers of stakeholders, patients, etc.
- Incorporates covert characteristics that allow 'restricted knowledge' to be compartmentalized and made available exclusively on a "need to know" basis
- Incorporates covert characteristics which can be linked to the overt characteristics, but would rely on 'restricted knowledge' for authentication, thereby creating significant barriers to compromise by attackers.

We believe the only way to implement a comprehensive solution for securing our nation's prescription drug supply chain is through the innovative use of both overt and covert anti-counterfeiting techniques.

## Designing a More Secure Supply Chain

It is our conviction that securing the supply chain requires several key technological elements and multiple layers of authentication. As the United States moves toward a uniform national policy of tracing pharmaceuticals through the distribution system, such a system should incorporate the most recent developments in authentication technology and advances in cloud computing.

As a system, a secure, modern, prescription drug supply chain should utilize available technologies to solve the entire problem of counterfeit pharmaceuticals, of which we assert that serialization is just one piece. In order to be effective it must protect both the health and safety of the American people while at the same time not place any unnecessary financial or logistical burden on manufacturers, wholesale distributors, pharmacies and re-packagers. Counterfeiting is easy to do; the solution to prevent it should be just as easy.

The prescription supply chain must contain elements that protect the serialization markings themselves from being counterfeited. If something can be seen, it can be copied. It is also critical that the system allows consumers to walk into any of the 60,000 pharmacies in the United States and verify that the drugs they are buying are authentic. This is fully achievable with existing technology designed specifically to secure supply chains.

### Integrating Technologies

We believe there are three technological components to designing the ideal tracing system:

- Authentication Technology
- Mobile Devices
- Authentication Databases

In combination, these technologies will work with each other to create a simple, cost-effective and easy to integrate solution to securing the prescription drug supply chain.

**Authentication Technology**

Innovative anti-counterfeiting and authentication technologies will be critical to designing a secure system. Packages must be marked with both overt and covert solutions to create multiple layers of security. We believe utilizing both solutions provides the best way to mitigate the risks of counterfeiting. Security inks that can be seamlessly integrated into the printing process are the best approach to doing this. A single ink that contains multiple security characteristics would be the best way to thwart and confuse counterfeiters.

As this legislation proposes, the key to tracking pharmaceuticals across the entire supply chain is to serialize each lot with a standard numerical identifier, which can be represented in a variety of markings including barcodes and QR codes. It is critical that these serialization markings are protected against counterfeiting, since they become the front line of defense in identifying real or counterfeit prescription drugs. Ideally, these markings must be printed covertly on the package, invisible to the human eye but able to be read by the proper optical equipment.

To serialize each package as a solution is insufficient. If a counterfeiter were able to infiltrate the serialization data, it would in theory be able to pass off counterfeit drugs as authentic as long as they were entered into the supply chain first. However, if the serialization markings are printed with a secure covert ink that could be read only by high-tech optics built into everyday smartphones, then it would be impossible for an organization without access to such technology to counterfeit the serialization, even if they were to come

into possession of the necessary data. By utilizing invisible technology, you take that ability away from the counterfeiter, creating a barrier to the data.

**Mobile Devices**

While it is generally recognized that the hologram has lost its status as the premier anti-counterfeiting technology, its value as a technology was that it required no external device to activate it. It is difficult to use security inks described above without external devices to activate or read them in the same way. Thus, a device would be needed. Such a device should be handheld, possess image gathering capabilities, communication and data transmission capabilities. While there are a number of devices that fit this category, smartphones have penetrated the U.S and global markets to the point of ubiquity and utilizing them would eliminate the need to buy and bring costly equipment into the supply chain. The optics capability to read the covert markings described above would be integrated with permission levels on any smartphone and the simplicity of such a system would be astounding.

**Authentication Database**

To create a resilient solution that delivers complete and accurate authentication information requires communication. There are 2 primary drivers behind this conclusion:

1. Restricted Knowledge – the specific information about what covert characteristics are being used, how they are being used and what information they contain – can be securely stored in the cloud and released on a strictly "need to know basis" and only to other authenticated systems (for instance systems printing the marks and system inspecting the marks.
2. During authentication of the pharmaceutical, the information that is returned to the user can be determined based on who the user is. A patient, for instance might be told the name of the medicine, the manufacturer and the expiration date. A distributor, could additionally be provided batch #, lot #, data of manufacture, etc.

Another key to improving the resiliency of the system and specifically for guarding against replay attacks, where a criminal makes a exact copy of the product packaging, including serialization information is to maintain

information about the state of a product (manufacture, distribution, dispensing, consumption). A centralized secure cloud can insure real-time access to information that can be correlated with other data, such as date/time, location and individuals performing authentication. Analytics can be easily applied to detect anomalies or discrepancies associated with individual items.

The cloud service can also facilitate compartmentalization of information. Product information can remain with the manufacturer, distribution information with the distributor, etc. The cloud service focuses on the authentication and management of the unique identifiers themselves, not the underlying product specific information.

**Minimizing Disruption**

The key to designing a secure, modern, prescription supply chain system that can be implemented in the real world is minimizing the disruption it would cause to the existing pharmaceutical supply chain. An ideal system should be able to be seamlessly integrated into the current pharmaceutical packaging and manufacturing process. This would leverage existing production equipment and processes and minimize implementation costs.

Both security inks and mobile devices play a crucial role in minimizing such disruption. Inks can be integrated directly into the printing process and would require no additional steps, minimizing costs other than the cost of the ink and the services of a third party logistics provider to provide the form of the markings. Nothing would need to be attached separately to the packaging and so there would be virtually no disruption in the current packaging production process.

Similarly, if the system were to run on a smartphone, a secure application could be developed with differing levels of access across the supply chain that would prevent the need for manufacturers, wholesale distributors, pharmacies and re-packagers from having to make massive purchases of equipment.

**Universal Availability**

The final key component of an ideal track and trace system is its accessibility to both the supply chain and the consumer. We believe it is paramount that consumers have the ability to authenticate their prescription. Again, the ubiquity of smartphones plays a crucial role in allowing the same technology used to track and trace a pharmaceutical product through the supply chain to also be used by the consumer to verify that their prescription is authentic. By utilizing smartphones, you provide every consumer with the ability to easily authenticate their medicine at the point of purchase, increasing their own degree of confidence in the drugs that they buy. By utilizing smartphones in the battle against counterfeiters, for the first time this gives the consumer the advantage.

A mobile application would be downloaded to any given smartphone. One version of the application would be for those in the supply chain, allowing them to read covert markings and transmit the tracking information to the secure cloud at each step along the chain. The second version would be widely available to the public, and would read the same marking, but would simply alert the consumer of the product's authenticity. We see this as a fundamental right of all consumers to be able to verify the authenticity of their pharmaceuticals.