United States House Energy and Commerce Committee

Subcommittee on Health

Hearing on "Securing Our Nation's Prescription Drug Supply Chain"

Testimony of Walter Berghahn, Executive Director

The Healthcare Compliance Packaging Council

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Chairman Pitts, Ranking Member Pallone and Members of the Committee:

Thank you for providing me the opportunity to share my views and perspective on this matter as someone who has worked in and around the pharmaceutical supply chain for the last 17 years. My name is Walter Berghahn and I am the Executive Director of the Healthcare Compliance Packaging Council, a trade association dedicated to improving medication adherence and patient safety in the US pharmaceutical supply chain through broad adoption of innovative packaging technology.

The HCPC represents packaging material and machinery manufacturers as well as contract packagers who provide materials and packaging services to pharmaceutical manufacturers as well as downstream customers in both institutional and retail pharmacy. This pending legislation and that already established in California SB 1307 directly affects the membership and their customer base. That being said, the membership of HCPC has been supportive of the legislation in California, recognizing that it's goal is consistent with HCPC's, that of furthering pharmaceutical supply chain and patient safety.

For the most part, the US pharmaceutical supply chain is safe. Manufacturers, distributors and pharmacies do their job day in and day out with patient safety in mind. Drugs are produced, packaged and shipped according to FDA guidelines, they make their way through a complex supply chain and arrive in the appropriate pharmacy, hospital or nursing home without incident.

Sounds wonderful but that's not why we're here today. We're here because there are individuals and groups out there intent on selling counterfeit or gray market drugs into the US supply chain. There has been a tremendous amount of effort expended in the last 10 years to tighten up and secure the supply chain. Those efforts certainly have closed many of the cracks and yet counterfeits still

appear and the FDA has opened more investigations in the last few years than ever before, more than 70 incidents in 2010 alone. The companies and organizations testifying before you today are not the

problem. It is the exceptions, the unscrupulous players who knowingly subvert the system to introduce counterfeit, gray market or substandard drugs into the supply chain for economic profit that must be stopped. Some here would suggest that the cost is too high to stop the exceptions and that the supply chain is safe enough.

I'm betting that those people have never had a family member or friend ingest or inject a counterfeit medication and suffer health setbacks or worse as a result. It's easy to say it is too complicated and too expensive when it hasn't hit you personally.

It's been suggested by many that serialization and bar coding technology is not robust, not mature enough for this task and yet bar coding has been in use since the 70's. You cannot go into a store including pharmacies in the US without encountering bar code readers. They are used for inventory management throughout our retail marketplace. 2 dimensional bar coding which will be required for serialization is not as old but is still well established. The Department of Defense issued a paper in 2005 outlining their use and implementation of 2D bar coding for tracking valuable items in both forward and reverse logistics.

Everyday 10's of millions of packages are tracked by Fed Ex and UPS utilizing serialized barcodes to provide item level visibility in transit. Everyday approximately 1.5 million air travelers in the US board planes with 2D bar codes verifying who they are and that they are on the right flight. I'm not suggesting by any means that this process will be easy for pharmaceuticals but the technologies employed are proven and are actively used all around us on a daily basis.

On pharmaceuticals California led the way in the US requiring serialization on pharmaceutical containers taking one step further than Florida's paper pedigree implementation in 2005 that did not track items. California's SB 1307 has been more than generous with time for implementation with initial targets in 2007 and subsequent delays to allow industry time to comply. Currently the pharmaceutical manufacturers would have to serialize 50% of their products by 2015. The rest of the supply chain sees staggered implementation ending with pharmacy and pharmacy warehouses in July of 2017 more than 4 years from today. We would hope that any Federal Legislation would be supportive of California SB 1307 and build on their progress. The industry is actively preparing to meet the deadlines.

The supporting packaging machinery industry is well prepared. Various levels of systems ranging from manual to fully automated exist which can apply, verify, and aggregate 2d bar coded containers in the packaging process. Complete cases exit the packaging process in a pharmaceutical manufacturer or contract packaging plant ready for entry into the supply chain. Companies such as Systech, Optel, Seidenader, Omega, Antares, Laetus, PCE, Visiotec and numerous others are actively engaged in delivering these systems to both branded and generic pharmaceutical manufacturers. Dozens of systems have already been installed in the US in preparation for California and hundreds are in the process of being planned, ordered and constructed. A much larger number have already been deployed globally to meet international requirements for serialization in countries like China, Brazil, Turkey, India and large portions of the EU.

All this work does wonders for securing the supply chain but we would be remiss if we didn't consider that these controls work well within the normal supply chain. Many of the documented problems occur outside normal channels. So how to protect or detect those instances ? In my opinion the best way would be to provide prescriptions the way most of the world does, in the manufacturers original container. This would accomplish two things.

1] it would thwart the introduction of counterfeit products in pharmacy which sadly has been documented, as well it would thwart dispensing of outdated and returned product, also well documented.

2] it would allow the insurance industry to require use of the serial ID for reimbursement, not simply the NDC. This practice would greatly reduce the opportunity for prescription insurance fraud. Since the government via CMS is the largest payer in the US reduction in prescription fraud would seem to be of interest.

Why would this be relevant ? Because even the physicians sited in the recent Avastin counterfeit case in California will submit for reimbursement on these medications. In today's system all they need is a valid NDC number which they can get easily. In the future if they are required to provide a serial number for a dispensed unit then they will not be able to submit illegally purchased items from the internet that did not travel through our secure supply chain. California has noted similar cases where pharmacists have illegally purchased product over the internet and dispensed them in pharmacy but submit for reimbursement with a legitimate NDC number. One has to question whether lot level tracking could stop such activity.

This same type of safety could even be extended to patients. It is not hard to imagine a system to allow patients to scan a 2d barcode using a smartphone to verify that the container they received is valid in fact companies like HP have already launched platforms with this capability for detecting counterfeits in other industries.

In conclusion I would like to address one major difference in the two proposed methodologies being considered. There has been a great deal of discussion about the benefits of item level tracking vs. Lot level tracking. To be sure, lot level tracking is less cumbersome on various industry players but one has to question its effectiveness. Lot level tracking will provide wonderful tools for evaluating what happened, why a counterfeit or diverted drug got into the supply chain. Item level track and trace is aimed at preventing counterfeit packages from entering the supply chain. The difference is staggering. Prevention vs detection after the fact. I would hope that in considering which path to pursue members would look at past instances of counterfeiting and ask the simple question: Would lot level have prevented this product from entering the supply chain.

Thank you for allowing me to provide input to this process.