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An Urgent Call for Congress to Deploy a Full Armament of Available Technologies and Resources To Combat Drug Counterfeiting in the U.S.

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Prescription drug counterfeiting is a threat to the health and safety of U.S. citizens. The size of the problem cannot be accurately measured but one source estimates drug counterfeiting has the potential to become a \$75 billion industry by 2010.¹ Costs in human life and increases in health care expenses due to the ingestion of counterfeit drugs cannot be predicted.

Medical professionals, caregivers and consumers are exposed to counterfeit drugs through a range of sources, from legitimate distribution channels to fraudulent Internet sites. Counterfeit drugs can infiltrate legitimate supply chains in a variety of ways, including “salting” and repackaging. Salting happens when counterfeit drugs are added to legitimate drug supplies during legal packaging or repackaging operations. The result is a supply that has both legitimate and counterfeit drugs in legitimate packaging. Repackaging occurs legitimately for a variety of reasons, including changing package labeling or package insert labeling to meet local language requirements or to break down bulk shipments into individual doses. The original packaging and the new packaging are then at risk of being illegally reused/used to ship counterfeit drugs. Anytime a drug is packaged or repackaged, there is the potential for “salting” or for the packaging to be used or reused by counterfeiters.

Counterfeit drugs place patients at risk when their active ingredient levels aren't accurate and when their secondary ingredients include harmful chemical additives. The physical risk to consumers from taking counterfeit medications is then compounded if consumers choose NOT to take needed medications for fear they might be counterfeit.

The problem is complex and extensive enough that heads of global security at Pfizer, John Theriault, and Novartis, James Christian have testified before the Health Subcommittee of the House Committee on Energy and Commerce on the critical need to broaden security measures to mitigate the severe and growing threat of drug counterfeiting to patients and our nation's drug supply. Mr. Theriault warned that the importation of counterfeit, unapproved pharmaceuticals into the U.S. is increasing exponentially, and that regulatory and law enforcement agencies need additional resources to stem this growing crisis. Mr. Christian stated that new technologies “enable companies to track cardboard, not product,” emphasizing the importance of a broad concerted effort including both advanced technologies and increased regulation and law enforcement to make progress against the plague of counterfeit medicines.

The Food and Drug Administration's Revitalization Act (formerly PDUFA) (approved by the U.S. Senate as bill S.1082 and the U. S. House of Representatives as bill H.R. 2900), takes a significant step in requiring some of the key elements to combat counterfeiting, but does not go far enough. The two bills are summarized below.

Section 514 of the Senate bill, S.1082, requires that the packaging of all prescription drugs include the following within a specific period of time:

- ◆ A standardized numerical identifier unique to each package applied at the point of manufacturing and repackaging.
- ◆ Technologies visible to the naked eye that identify product authenticity without the need for a reader, microscope, lighting device or scanner.
- ◆ Overt, optically variable counterfeit-resistant technologies similar to those used by the Bureau of Engraving and Printing to secure U.S. currency.
- ◆ A highly secure manufacturing and distribution environment.
- ◆ Additional non-visible security features.

Section 910 of the House bill, H.R. 2900, expands the application of promising technologies including:

- RFID (Radio Frequency Identification)
- Nanotechnology
- Encryption Technology
- Track and Trace Technologies

The Senate bill, S. 1082 stops short of including two significant components in the battle to protect the lives of patients – applying counterfeit-resistant technologies on the dosage form itself (not just on the packaging) and extending the funding, authority and reach of the U.S. government to pursue and prosecute drug counterfeiting at all points in the supply chain to the same degree U.S. currency counterfeiting is pursued. House bill, H.R. 2900, provides opportunity for necessary increases in security measures but only by not limiting technology applications to the package. Each bill should have, and it is hoped that the final version will incorporate the need for increases in legislation and law enforcement and the need for application of all available technologies to help thwart drug counterfeiting.

Innovative on-dosage technologies now exist to complement the technologies required on drug packaging in S.1082, and H.R. 2900 and must be a key element in the solution to combat counterfeit drugs.

David Schoneker, Director of Global Regulatory Affairs for Colorcon, an expert in the field of solid dose design points out that, “Protecting the dosage itself, which is ingested by the patient, should be a critical concern in the hierarchy of counterfeit-resistant technologies. Protection must start with the dosage because the distribution process for drugs involves repackaging, which is a vulnerable point for counterfeit product introduction, where the dosage becomes separated from the “protected” package. Counterfeit-resistant measures, such as protecting the package and supply chain, and increasing legal and law enforcement measures, will be far more effective when the dosage itself is also protected.”

On-dosage identification technologies can help mitigate the security concern of repackaging by helping ensure that the dosage itself is identifiable, protected and authenticated.

Further, solid dosage forms can be designed with unique features that are more difficult for counterfeiters to duplicate, encouraging them to turn their sights elsewhere. There are many proven, economical on-dosage technologies available today that can make drugs extremely difficult to fake but easy to identify. These technologies or markings can link the dosage to the package counterfeit-resistant technologies or markings, which is particularly important during repackaging. For example, salting authentic products with counterfeit ones in authentic packaging could more easily be identified because each dosage would need to link to the packaging technology used.

Ironically, point #2 of the Senate bill emphasizes utilizing some of the measures the federal government uses to secure U.S. currency but does not address the need to exercise all of them. With U.S. currency, security identification is applied to each piece of currency, not the wrapper around each stack, and federal government agencies have broad authority and resources to pursue counterfeiters around the globe. Protecting U.S. consumers will require all possible means to be exercised aggressively if drug counterfeiting is to be curbed.

Listed below are examples of available on-dosage anti-counterfeiting technologies, including human sensory, overt and covert electronic scan-able and chemical taggant identification. Several of these technologies are similar to those used for U.S. currency.

- ◆ Dosage serialization and standardized numerical identifiers can be placed on each tablet. Serialization numbers are recorded in a database to identify the tablet pedigree, and can be linked to serial numbers on the package.
- ◆ Overt optically variable technologies:
 - Pearlescent color-shifting dosages. By tilting the tablet, the color shifts as specified on the package insert and/or on the package, making it very hard to duplicate. Numerous manufacturing and material parameters must be known and applied to properly simulate the color shift.
 - Watermark technology. By tilting the tablet, a watermark appears or disappears on the surface. The watermark could be described on the package insert or package, or exemplified on the package. It would be identifiable by patients, pharmacists and health care providers, while making it difficult for a counterfeiter to replicate.
- ◆ High-definition and laser-imprinted bar codes and images on the dosage form, which provide identification control from the manufacturing plant to the patient, and restrict the potential for error in repackaging and dispensing. Identified by a scanner, bar codes can also provide information that would link to the package. Other high-definition images, similar to images available on U.S. currency, can be applied to a dosage that would be difficult for a counterfeiter to replicate; the images could be described on the package insert, label or package.
- ◆ Non-visible covert and encrypted security features, including chemical markers (taggants), can be added to the dosage form itself which can provide rapid

authentication of a drug in the field within a few minutes. These features cannot be reverse-engineered by a counterfeiter.

- ◆ Sensory identification. Adding a flavor or aroma identifier can help patients identify the authenticity of a drug. Lipitor[®] counterfeits were detected by patients when they noticed a difference in the taste of the counterfeit drug.
- ◆ Laser imprinting of proprietary patented film coatings (similar to first point above).

On-dosage identification technologies can also provide benefits beyond anti-counterfeiting, such as: a reduction of medication error at the dispensing and patient levels, prevention of look-alike dosages, improved patient compliance, and track-and-trace bar code technologies harmonized with Europe.

On-dosage security technologies as an addition or option to the referenced packaging security need to be included in the final combination of Senate bill S.1082 and House bill H.R. 2900 because they identify and authenticate the actual drug dosage, and are economically advantageous. These technologies enable patients, pharmacists and health care providers to better identify counterfeit drugs before administration. Additionally, some of these technologies can help patients themselves identify counterfeits before ingestion, without the need for sophisticated equipment. Sensory perception is typically the only tool that patients have to help them identify potential counterfeits that may get into the supply chain, especially when the drugs are sourced on the internet. The inclusion will significantly boost the bill's effectiveness in deterring drug counterfeiting, protecting intellectual property, and improving the health and safety of the American people.

Finally, to more effectively fight drug counterfeiting, we need a comprehensive process that includes on-dose and on-package identification technologies, tighter distribution controls, greater governmental oversight and, more aggressive law enforcement. The inclusion and coordination of all of these efforts is critical if we are going to be successful in reinforcing our commitment to keeping U.S. medicines the best and safest in the world.

1. Lewcock, Anna. New law to crack down on drug fakers. In-Pharma Technologist.com, 5/16/07. www.in-pharmatechnologist.com/news/ng.asp?n=76586-congress-counterfeit-draft-b, accessed 6/13/07.

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