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Protect The Patient By Detecting Counterfeit Pharmaceuticals

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Counterfeiting of pharmaceuticals has dramatically increased over the past 30 years. Deaths and injury to patients has likewise increased. This article will explain how you can take 100% control of every tablet, capsule, pharmaceutical, and device from manufacturing to the patient.

HISTORICAL PERSPECTIVE

The Pure Food and Drug Act of 1906 banned adulterated or mislabeled drug products. In reality, the act banned counterfeit drugs since they are both adulterated and misbranded. The Durham-Humphrey Amendment of 1951 established the separation of Prescription Drugs and OTC Drugs. The purpose of the act was to again improve the safety of America's drug supply requiring a prescription for the more dangerous drugs.

As a lucrative drug trade developed, so did its industrialization and automation. Along with the legal drug trade, the counterfeit and fraudulent supplies of legitimate drugs flourished as well. In the 1980's, counterfeit Oral Contraceptives appeared in the U.S. market. The number of counterfeit products increased over the next 20 years leading to recognition of the problem by the World Health Organization with its passage of the Declaration of Rome in 2006. Globally there are thousands of deaths annually due to counterfeit drugs. Noteworthy is the fact that last year in the United States it was estimated that about 1% of our drug supplies are counterfeits.

EXTENT OF PROBLEM

While it is believed that the drug supplies in the United States, Canada, European Union, Australia, New Zealand and Japan have a very low rate of counterfeit drugs, many other countries are not that secure. It has been noted that elsewhere around the globe, drug supplies are estimated to be 30% counterfeit. Despite third world nations exhibiting high rates of counterfeit drugs, the highest estimates are drugs from the Internet Pharmacies where estimates of counterfeits reach 50%. When one considers the annual sales of counterfeit drugs to be valued in billions of dollars US, it is readily understood why that drug trade flourishes.

PREVIOUS ANTI-COUNTERFEITING SOLUTIONS OFFERED

For decades now we have been talking about Chain of Custody Documents, Pedigree Certificates, Track and Trace RFID, e-Pedigree, Taggants, Holograms, 2-D Barcodes, Task Forces, Declarations, VIPPS, MHRA Counterfeit Reporting, UDI, IMPACT, Summits and other solutions. Each of these initiatives has its own merit and its own place in the drug supply system. The problem with many solutions is that many times they involve a human element and the human element can be corrupted, compromised and essentially counterfeited.

ANTI-COUNTERFEITING SOLUTION FOR THE FUTURE WHICH IS NOW

As previously mentioned, the problems with many of the solutions heretofore presented are simple. Each part of the manufacturing, packaging, labeling, distribution and dispensing

sequences can be compromised, duplicated, copied, made fraudulent, counterfeited, etc. The most basic fraudulent or counterfeiting activity that one has to overcome is that which is closest to the patient. For example, if an unscrupulous doctor or pharmacist knowingly purchases counterfeit drugs, outdated drugs, recalled drugs, etc. and fills prescriptions with them or dispenses them, the only parties that know are the source and the physician or pharmacist. The only one affected is the patient. All of the e-pedigrees, RFID, IMPACTS, VIPPS, etc. don't do a thing to help that patient. The solution that we are proposing is very simple: **CONNECT THE PATIENT WITH THE DETECTION OF THE COUNTERFEIT**. Eliminate all possibilities of compromise in the supply chain.

CONNECTING THE PATIENT WITH THE DETECTION OF A COUNTERFEIT

Right to the point, the system is as follows:

The tablet, capsule, soft gel or other pharmaceutical product (including device) is cold laser marked with a Tri-Star Technology cold laser marking system. The mark is indelible and does not adversely affect the product. EACH INDIVIDUAL tablet, capsule or pharmaceutical product receives its own unique serialized "Identifier" mark. The mark has in it an identifier alpha/numeric, lot number, exp. date, and any other relevant information. The data is recorded in a data base. The marked tablet gets inserted into a marked bottle in such a way that the data base knows the "identifier" of each tablet therein. The labeled bottle is also marked, the package marked, the case marked, the skid marked and the shipment marked. Traceability from skid, case, package, bottle all the way down to each tablet is stored in a secured data system. If at any time during transit, storage, warehousing, or distribution, a skid, carton or bottle of product is compromised, that part of the chain can link with the secured data system and enter the mark for the compromised material. The last stage of the product distribution occurs through the pharmacy or dispensing physician to the patient. The patient receiving let's say 30 tablets of Drug X at his local pharmacy can elect to see the status of every tablet in the Rx vial he just received. He simply opens his cell phone, accesses an APP like the one produced by CertiRx Corporation, opens the APP, takes a picture with a cell phone, cell phone APP performs a check with the secured data system. The cell phone then indicates the appropriate response: Drug is DRUG X; or Drug is Counterfeit or Drug is Expired or Drug is Recalled or Drug is Contaminated and should not be used, contact FDA . Think about it, instantly the PATIENT knows the status of the drug he is about to take. Each tablet has its own mark. If tested again, the APP will state that the tablet is DRUG X and was tested previously, possibly counterfeit.

To bring this technology into your company and for a demonstration please contact:

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ABOUT THE AUTHOR

Dr. Urban has practiced Pharmacy for over 40 years in many different settings. He is a Research Pharmacist, a Manufacturing Pharmacist, a Consultant Pharmacist, a Clinical Pharmacist and a Retail Pharmacist. Joe received his B.Sc. Pharmacy from Philadelphia College of Pharmacy and Science, his MBA in Pharmaceutical Business from St. Joseph's University, and his Doctor of Pharmacy Degree from Shenandoah University. Dr. Urban is also registered as an Expert Witness for Pharmacy Matters and has served as an Expert Witness giving testimony in a Drug Counterfeit Case.