Augmenting RFID Track and Trace Technology: Addressing Full Dimensions of Prescription Drug Crime

Modern medications rank among the greatest achievements of science and technology. They are finely honed instruments painstakingly developed to combat illness, alleviate pain and postpone human mortality. Given to the intended patient at the correct dose and time, they are indeed the "magic bullets" conceptualized by the father of pharmacology, Paul Ehrlich. However, this very power to influence the human body makes them increasingly sought after instruments for experimentation and abuse. This is especially the case for a large and increasingly powerful group of drugs that affect the human nervous system: pain relievers, psychostimulants, and anxiolytics. For the wrong person, at inappropriate doses, and at the wrong time, they can be toxic, addictive, and deadly. This constitutes the growing problem of prescription drug abuse, designated a priority of the National Institute of Drug Abuse

Modern prescription medications, because they are valued for both legitimate and illegitimate purposes, are expensive and subject to barter. Individual pills, capsules or dermal patches with wholesale costs above $25 are common. Medications represent the largest expenditure for most managed health care systems, private or public, soon to include the Medicare Program for which drug benefits are estimated to cost $110 billion annually. Health care is now the largest sector of the US economy. Drugs diverted from the supply chain between manufacturer, shipper, distributor, pharmacy, or from the intended patient by illicit resale or fraudulent claim of loss, represent significant costs to the maximally stressed health care budget. Furthermore, diverted drugs open the doors to both abuse and multiple forms of counterfeiting.

Because pills possess high value, it is not surprising that criminal elements unlawfully import medications, transport them without maintaining mandated sanitary or temperature controls for added profit, mislabel them as higher potency, or directly substitute counterfeited duplicates. It is now clear that at least one rogue state, North Korea, relies on these methods to finance military programs. The possibility that such a dedicated enemy would join forces with terrorists to substitute toxic or infectious agents in the form of high quality counterfeits of a well known medication cannot be dismissed.

In our view, a successful approach to "the" prescription drug problem must address all three of the interlocking crimes: (1) Abuse- by patients, adolescents and young adults,or profit driven prescribers; (2) Diversion-from the supply chain, pharmacy, prescribed patient or clinic; and (3) Counterfeited drugs-whether mishandled and unsafe products, diluted or adulterated variants, or bogus chemicals made to exquisitely resemble the original tablet. A partial approach to one of these problems in isolation will not succeed and could even worsen the situation: for example, meticulous electronic authentication of a supply bottle will not exclude theft and unsafe transport of this container to a dispensing pharmacy or insertion of inauthentic pills by the elaborate resealing/relabeling methods known to well organized counterfeiters.

Our analysis began with the observation that, unlike currency, credit cards, stock or bond certificates, valuable pills do not contain markers connoting the need for care in possession and handling: securely designed coding of sufficient depth to validate and potentially track the barter instrument.

Much of our research and development has, therefore, focused on novel methods to place a durable serial code on or within hard or powdery pills, capsules, and dermal patches. Technologies we have explored include advanced optical encoding strategies employing ink jet or laser with protection against effacement; implementable applications of a nanocode utilizing biologically inert, readily available oligonucleotides carried by patient- safe ferrite beads, and tamper resistant RFID tags of distinctive design, sequestered from digestion by established cellulose based inclusion materials, within individual pills. These capabilities lead to the most advanced and complete tracking systems for following medications from production through the distribution chain. RFID at the package level and Epedigree track and trace are perfect complements to our systems because, when a pedigree breach is detected, the serial code numbers of diverted pills are instantly available to law enforcement officials. As readily identified stolen property, the diverted medication is not easily resold and therefore loses much of its value.

To specifically address the neglected problem of post-prescription abuse, we have elaborated a sequence of Secure Coding-Registration-Monitoring (SCRM). This computerized portal system is based on registering medication serial numbers to prescription numbers at the time of dispensing in a format designed for consistency with federal privacy standards incorporated in the Health Information Portability and Accountability Act. As a powerful anti-diversion plan, it brings the capability to associate the prescribed patient, his physician, dosing, and dispensing pharmacy with each medication unit (pill, capsule, or dermal patch). In particular implementations of these methods, identifying information maybe obtained from elements recovered from a comatose or deceased patient.
Based on the SCRM data system, we have developed inexpensive methods for facilitated monitoring of the use of medications by patients for their physicians. Combined with encoding of pills to associate them with a specific prescription, monitoring provides a powerful additional check limiting diversion, detecting patterns of early addiction or covert experimentation with the patient's medicines by others, such as children.

The SCRM system addresses the following problems:

1. Product authentication-Secure Coding and a novel Pill Print capture process at the point of manufacture achieve the most rapid and powerful counterfeit detection system for the bartered unit, the individual pill. This capability is synergistic to RFID authentication of a container or package. Note that authentication of the container alone may create a false sense of security regarding the integrity of pills within.The SCRM systems are well designed to frustrate even sophisticated counterfeiters who wish to erase, paint over, duplicate or clone a chemical additive, or inactivate a traditional RFID device

2. Country of origin determination-Through relational data basing, the securely encoded serial number identifies production site
3. Batch tracking to patient, MD-Because our systems include post-prescription traceability, listing of every patient and his physician who received a particular batch of medication or received medication produced on specified days is instantly available
4. Deterrence of illicit resale-Patients are told that their medicines contain markers which implicate them if found on the street or within an overdosed patient; loss of further medication or criminal prosecution are powerful deterrents to diversion
5. MD prescription abuse-MDs know that the tracking serial number through registration to a prescription number at the pharmacy identifies them (and the size of their prescriptions, other patients they have prescribed to)
6. Fraud and theft of pills – When pills are reported stolen, registration data lead to the exact serial number on pills; these pills are not lost in the universe of medication but become forensic evidence of a fraudulent claim. Recognizable as stolen property, the diverted pills lose value
7. Abuse of medication-Facilitated monitoring detects early overuse of pills or removal of pills from a compliant patient's container (e.g., by a child); poison pill strategy in our biometric dispensers destroys pills after inappropriate attempts to open; two of our patent pending formulations of opioids inactivate the agonist if the pill matrix is breached
8. Non-adherence to MD prescription-The failure to take prescribed medications (the converse of abuse) leads to worsening illness, hospitalization, morbidity and greatly increased health costs; monitoring and controlled dispensing immediately identify omitted doses
9. Wasteful prescribing, inefficient use of medications-Through coding, registration and monitoring, every pill enters an inventory of medications dispensed until consumed by the patient- prescribing of excessive medication, costly to the health care system and a path to experimentation and abuse, is easily detected
10. Liability reduction for manufacturer, distributor, prescriber. Powerful, cost effective systems curtail diversion and theft while providing an appropriate, flexible dose for the intended patient
11. Cost effectiveness: SCRM implementation utilizing optical inscription adds less than 2 cents to the cost of a $3-4 specialized opioid tablet

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