

COVECTRA

Multi-Layered Brand Protection

Combating Diversion: Serialization as an Immediately Do-able Solution

More than *23,000 people are dying each year* from prescription drug abuse alone in the US, which is more than those who perish in traffic accidents. This is a statistic important enough to beg the questions: what programs are currently being undertaken by the pharma industry and our government to reduce the growing incidence of prescription drug diversion and abuse, and what technology exists today that can be implemented to provide a more powerful tool? Serialization can be effective in tracking and tracing the distribution pathway of opioids to ensure they are getting into the hands of those who legitimately need them, and are used in the manner prescribed by physicians.

Here are just some of the most heart-wrenching facts related to prescription drug abuse:

- The group of *7 million* illicit pain medicine users is growing by 15% per year.
- *6 out of 10 high school seniors* have misused prescription drugs.
- In 2011, over *1.2 million people* were treated in hospital emergency rooms for prescription drug overdose.
- *20% of the 48 million people over the age of 12* have used prescription drugs for *non-medical* purposes.
- Legitimate pain patients are often *denied access* to pain medications because of strict DEA sanctions and physicians' reluctance to dispense.
- Physicians who have gone through special education programs on the problem report that certain opioids are so strong that patients become addicted after taking only four unit doses.

The White House Office of National Drug Control Policy (ONDCP) states that prescription drug abuse is the fastest-growing drug problem in the US. The CDC (Centers for Disease Control and Prevention) classifies this trend as a public health epidemic.

Not only is the prescription drug abuse epidemic causing intense suffering to individuals and families, but it is also costing the healthcare system and taxpayers dearly – reportedly up to \$72.5 billion annually in direct costs. The average cost to treat a prescription drug abuser, with numerous bouts in rehab, emergency care, and other treatments, amounts to *8.7 times more* than for a non-abuser. Those disabled by addiction are unable to work effectively, costing employers time and money. The hidden cost to families that must care for family members severely disabled by pain medication addiction has not been properly calculated, but one can be sure the numbers are staggering.

Efforts to stop the flood of diverted prescription medications have been piecemeal, and have barely put a dent in this increasing problem. Education of physicians, patients and the nation's youth in the dangers of abusing medications; penalties to doctors who dispense irresponsibly; and battling criminals who all too easily tap into the lucrative business of diverting drugs illegally—all are measures that have done little to stem the tide. The scale of the problem has federal and state law enforcement agencies overwhelmed. Because drug monitoring and enforcement programs that are part of state Prescription Drug Monitoring Programs (PDMP) stop at state borders, valuable data input by physicians who carefully track their patients' use of their medications goes unheeded when patients cross state lines. Some states have little physician oversight even within their own boundaries.

Programs such as National Take-Back Day, with a recent haul of over 120 tons of unused prescription drugs, have helped collect some drugs that could otherwise have been sold, abused, stolen, or flushed into the water supply. School and community centers have developed special programs to educate students and the public.

With such a complex distribution system of health provider payers, pharmacies, distributors, wholesalers, pharma manufacturers, hospitals, government agencies, and law enforcement, all these measures have barely scratched the surface, since it is impossible to fix the problem without a partnership between the numerous parties in this distribution chain.

ePedigree, the standardized track and trace protocol being debated between government agencies and the healthcare industry, is realistically still years away. However, the core technology of ePedigree, serialization, is available *today*. Serialization is the assignment of a unique serial number in the form of a GS1 approved 2D barcode and human readable numeric code on all levels of packaging – similar to the placement of a license plate on every pharmaceutical package, as well as its shipping case and pallet. This serialized 2D barcode and human readable number can be used to easily link medications dispensed at the pharmacy to the patient receiving the drug. The scanned barcode with its embedded serial number can be sent to a database, maintained indefinitely, and referenced later if the medication is diverted to an illegal user. The serial number on the diverted medication can be input by law enforcement or other authorized personnel through using a scanner or entering a human readable number into a website. The assigned patient name can be compared to the name of the person in possession of the medication, and discrepancies can be identified on the spot. It is important to note that patient identity can be protected in accordance with HIPAA and 42 CFR Part 2 regulations.

A Specialty Pharmacy Provider (SPP) can provide shipment directly to a clinic, physician's office, or even directly to a patient. Although processing and shipping through an SPP is slightly more costly, the control and transparency obtained by reliably scanning barcodes and electronic signatures at the outgoing and incoming points through the shipping process by an SPP more than offsets the total expenses incurred by a broken distribution system for powerful drugs, which when abused, can cause severe addiction, illness, and even death. This results in a transparent supply chain from point of packaging through distribution, into the pharmacy, and into the hands of the patient. For controlled substances and other high-value medications, this track-and-trace capability can greatly differentiate a product over its competition.

Physicians, payers, pharmacists, and patients—the “four P’s”—all benefit:

- **P**hysicians have peace of mind knowing they are prescribing controlled medications that can be traced to their patients of record. They know each dose is monitored by a serial number, and therefore their liability is mitigated.
- **P**ayers, such as Insurance companies, HMO's, etc., benefit from the decrease in emergency hospitalizations and other related health risks.
- **P**harmacies can much more easily check if purchasers are legitimate, and alert physicians or law enforcement if they suspect diversion or abuse.
- **P**atients will be less tempted to misuse or divert medications knowing they are being monitored properly. They know, too, that they will be held accountable for verifying their medication use.

In addition, law enforcement will finally have an easy way to check if drugs are legitimate or not, and the exact point in the distribution chain where illegal activity is occurring can be more specifically identified.

Finally, pharmaceutical manufacturers stand to significantly benefit as well. Medication blister pack pill packaging that is printed with a unique serial number on each unit dose—making each powerful, abuse-able prescription drug track-able and trace-able—will gain the loyalty of physicians, payers, pharmacies, and ultimately the patients, who will all know that they are in good hands.

The best news is, serialization as a solution to the sobering problem of drug diversion and abuse is a technology that already exists, and it can be implemented today. All stakeholders in the supply chain—physicians, payers and patients—can use serialization to collaborate in solving this growing problem facing our society.

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