

COVECTRA

Multi-Layered Brand Protection

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COVECTRA OFFERS TECHNOLOGY SOLUTIONS IN RESPONSE TO FDA REMS STRATEGY TO REDUCE OPIOID DRUG ABUSE

REMS (Risk Evaluation Management Strategy) Initiative Enacted Following Release of White House Action Plan To Address National Prescription Drug Abuse “Epidemic”

WESTBOROUGH, MA – May 23, 2011 – COVECTRA, a multi-layered brand protection solutions provider offering [serialization, authentication, and track and trace technology services](#), today announced its commitment to provide pharmaceutical companies with effective tools for combating abuse and diversion of opioid prescription drugs. The company’s solutions assist manufacturers in complying with new FDA guidelines, which require them to develop and implement a [risk management strategy \(REMS\)](#) to ensure the benefits of a drug or biological product outweigh its risks.

The REMS program is intended to work with the new [White House action plan](#) which includes: expansion of state-based prescription drug monitoring programs; recommending convenient and environmentally responsible ways to remove unused medications from homes; supporting education for patients and health care providers; and reducing the number of “pill mills” and doctor-shopping through law enforcement.

With reports that unintentional drug overdosing is a growing epidemic in the US, and is now the leading cause of injury death in 17 states, the FDA is requiring that manufacturers of certain opioid products implement a REMS. The program will require manufacturers of long-acting and extended-release opioids (including OxyContin, Avinza, Dolophine, Duragesic, and eight other brand names) to provide educational programs to prescribers of these medications. In addition, the program will provide materials prescribers can use when counseling patients about the risks and benefits of opioid use.

“The FDA estimates that more than 33 million Americans age 12 and older misused opioids during 2007 – up from 29 million just five years earlier—and it’s clear that abuse and diversion are issues which the industry needs to address,” stated COVECTRA president and CEO, Steve Wood. “Additionally, an unintended consequence of this prescription drug problem in the US is the impact on healthcare costs, as well as physicians increasing reluctance to prescribe prescription painkillers due to fact that they are subject to controls that limit the number of patients they prescribe to,” he added.

COVECTRA offers products and services designed to help pharmaceutical manufacturers meet their REMS requirements while gaining valuable insight into their product's supply chain movement and patient use. Through the company’s unit dose serialization and trace and trace platform, pharmaceutical manufacturers improve patient safety without creating barriers to medication access by the patient.

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The company's flagship product **AuthentiTrack™** provides unprecedented capabilities enabling unique identification down to the unit dose that can be leveraged for complete supply chain visibility, product integrity and track and trace applications. Building on experience in printing and packaging line integration, high volume transaction processing and product security techniques, **AuthentiTrack™** creates a platform by which applications targeting specific business problems can be rapidly deployed. The Patient Tracking, Abuse and Diversion Monitoring module is an **AuthentiTrack™** native application designed to provide insight and control to pharmaceutical brand owners of abused and misused products. Through this offering, brand owners gain visibility into patient treatment and the overall effectiveness of pharmaceutical manufacturer sponsored patient services programs.

The new REMS plan proposed by the FDA focuses primarily on educating doctors about proper pain management, patient selection, improving patient awareness about how to use these drugs safely, and other requirements. REMS components include medication guides, patient package inserts, and a communication plan for healthcare providers. Elements to assure safe use such as requirements for those who prescribe, dispense, or use a drug will also be included in the program. The FDA wants drug makers to work together to develop a single system for implementing the REMS strategies.

“Serialization technology offered by companies like COVECTRA will speed up the securing of the opioid supply chain for a very low cost investment to brand owners,” said Steve Wood. “Not only does serialization easily provide a way to track and trace the authenticity, safety, and verification of the drug user, but it also provides brand owners and patients a way to stay connected to make sure prescription drugs are used safely during the treatment program. In addition to helping drug manufacturers meet their REMS requirements, there are multiple benefits to serialization for pharma companies that will quickly provide return on their investment. It's a win-win for both the pharmaceutical companies and the consumers,” he explained.

A timetable for REMS submission will be specified in the FDA plan. The FDA is now notifying opioid makers that they must propose a REMS strategy within 120 days of this April announcement. Doctor training, patient counseling, and other risk reduction measures developed by opioid makers as part of the REMS are expected to become effective by early 2012.

Doctor training is not yet mandatory under the REMS plan; however, federal agencies are working to get Congress to link mandatory physician training to the already required Drug Enforcement Administration registration number that doctors must have to prescribe controlled substances.

About COVECTRA

Uniquely, COVECTRA provides solutions from unit package authentication and verification to serialization of all levels of packaging. COVECTRA's products include security labels with overt and covert security feature serialization, authentication and track-and-trace software applications. COVECTRA also provides professional services to assist clients with brand protection strategies, security label designs, and printing and packaging material and equipment specification.