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Fuisz Comments On Opioid Abuse Detection Systems, Tamper Resistance And The Proposed STOPP Act (HR 6160)



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MIAMI, Dec. 20, 2012 /PRNewswire/ -- Fuisz Pharma LLC today addressed tamper resistance in the context of the Stop Tampering of Prescription Pills Act (STOPP) (H. R. 6160). This law would require the makers of generic opioids to demonstrate comparable tamper-resistance features to the reference, branded opioid tamper-resistant formulations.

Richard C. Fuisz, M.D., founding member of Fuisz Pharma (http://en.wikipedia.org/wiki/Richard_Fuisz) commented: "I have been a physician licensed in 5 states for 45 years. I have seen the development of a Mobius strip attitude toward addictive pain drugs and opioids in particular. These drugs are simultaneously underprescribed to those who need them and yet are heavily abused. In the discussion of how to curb abuse, the real issue is in the closet, namely, how do I identify the patient who is abusing opioid medications.

"REMS systems can 'educate' and superficially 'monitor' but heretofore they have not provided any objective criteria for physicians and other caregivers to readily identify the snorting abuse of opioid medications – a primary mode of abuse. When a dye is admixed in such a manner that it cannot be separated from the opioid, the abuser is going to leave a temporary stain in his nose if he is a snorter. The non-snorter will be clean. This same tool can be used by law enforcement, family members and others to identify abuse before the situation escalates. It is simple and effective.

"Opioid abuse resulted in 425,000 emergency department visits in 2009 involving non-medical use of opioid analgesics. Wouldn't it be helpful if ER personnel and law enforcement could readily identify the snorting of opioid formulations?"

Dr. Fuisz continued: "The crush-resistant and gel style formulations are only part of tamper resistance. They offer no discernment of abuse. The other component of tamper resistance is discernment and discovery of abuse – like a trooper posted on the interstate. We want to identify and deal with abuse before the accident occurs."

Joseph M. Fuisz, managing member of Fuisz Pharma LLC, commented: "The STOPP Act is a needed step to further encourage tamper resistance features in the opioid space.

"To date, most efforts have been directed at formulations like crush resistance that can make it difficult to extract the active opioid. If the drug is too locked up, it will not be readily bioavailable. The result is that with the passage of time it is logical to expect that a portion of the abusing population will develop work-arounds to defeat the crush resistance or similar methods.

"Fuisz has developed an abuse detection method, based on the issued Gruber patent (US 7,214,385), which enables physicians and other caregivers to readily detect abuse such as nasal snorting and illicit use. This feature can be deployed as a stand alone, or in conjunction with other abuse resistant formulation features."

Fuisz Pharma is a private pharmaceutical technology company originated by the Fuiszes. The Fuiszes have made substantial contributions in drug delivery including orally dissolving tablets and novel particle coating systems at Fuisz Technologies; inventing and developing thin film drug delivery technologies at Kosmos Pharma and MonoSol Rx, as well as independently developing extruded sheet technology, and have extensive experience working with big and specialty pharma. Fuisz Pharma is also active in diagnostic systems. Fuisz Pharma has its headquarters in Miami and is not affiliated with MonoSol Rx. www.fuisz.com.

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