

STOPP Act Specifics

According to recent data from the Centers for Disease Control and Prevention, deaths related to drug abuse exceeded those related to motor vehicle accidents for the second year in a row. That data further suggests the number of deaths from drug abuse is on the rise. Prescription drugs are the country's fastest growing area of drug abuse, second only to marijuana but ahead of cocaine, heroin, methamphetamine and other drugs.

There are three categories of prescription drugs that are most abused: stimulants, depressants and pain medication. Of the three, abuse of opiate-based pain drugs – comprising some of the most powerful medications available – has increased dramatically. While the benefits of these products in treating and managing pain are widely recognized, the growing misuse and abuse of these products has resulted in a sharp increase in fatal overdoses and heroin addiction. In fact, more people die of prescription opioids than cocaine and heroin combined[i].

The time-released characteristics of powerful opioids are compromised when crushed or dissolved resulting in the full potency of the drug being released all at once, and studies have shown that drug abusers tend to crush or otherwise break down time-released products into a form that can be snorted or injected for a more intense high.

In 2010, the manufacturer of time-released OxyContin introduced abuse-deterrent features that make it more difficult for the drug to be misused. Yet, FDA recently approved the generic of an opoid-based drug that employs abuse deterrent technologies despite the fact that the generic failed to include similar preventative technology. And there are more of these drugs currently waiting for approval. The availability of these new generics that are not abuse deterrent will compromise the benefits of the preventative technologies currently being employed.

The STOPP Act is the first federal legislation that directs pharmaceutical manufacturers to invest in research and production to formulate tamper resistant drugs in order to compete with drugs of a similar nature that already employ tamper resistant technologies.

The STOPP Act will have no impact on patients that rely on the pain management features of these drugs when dealing with chronic pain and end-of-life pain issues. The practical effect of legislation will be to make the abuse of opioids and other controlled substances more difficult, while at the same time insuring that those who need pain relief receive it.

The bill also grants the FDA waiver authority for drugs that are absolutely critical and experiencing drug shortages for the period in which those drugs are in high demand and there is no tamper resistant alternative.

[i] Dr. Len Paulozzi, The Prescription Drug Overdose Epidemic and the Role of the PDMPs in Stopping It, Brandeis University