

Senator warns FDA on danger of newest painkillers

January 8 2012, By MICHAEL GORMLEY, Associated Press

Following fatal shootings in two New York pharmacy robberies, a U.S. senator is warning that a new batch of "super painkillers" now under review could force repeats of recent violent robberies that left six people dead.

"It's tremendously concerning that at the same time policymakers and law enforcement professionals are waging a war on the growing prescription drug crisis, new super-drugs could well be on their way, flooding the market," said Sen. Charles Schumer, D-N.Y. "The FDA needs to grab the reins and slow down the stampede to introduce these powerful narcotics."

A message seeking comment from the <u>Food and Drug Administration</u> was not immediately returned Friday.

The Associated Press reported last month about addiction experts' fears over four drugs being tested that contain a more powerful version of one of the nation's most abused painkillers - hydrocodone.

Schumer is particularly concerned about legalizing the drugs for prescriptions because they would be prized commodities in the black market.

Experts say painkiller addiction has been driven partly by a loophole in the 1970 Controlled Substances Act that classified pure hydrocodone - a super painkiller - as a strictly controlled Schedule II drug. But the law



put combination products, such as pills containing hydrocodone and acetaminophen, into the less strict Schedule III.

Because of the loophole, patients can refill a prescription for a hydrocodone-acetaminophen drug like Vicodin up to five times. A prescription for a similar oxycodone product, such as Percocet, can be filled only once. Critics say the loophole has flooded American medicine cabinets with hydrocodone.

In 1999, the <u>Drug Enforcement Administration</u> and FDA began reviewing whether they should reschedule hydrocodone combination products. But an AP review of regulatory documents and court filings shows the agencies have repeatedly passed the rescheduling study back and forth, with no final decision made.

A New Year's Eve robbery at a Long Island pharmacy netted prescription <u>painkillers</u> and cash and left the robber and a federal agent dead. In June, four died in another Long Island pharmacy robbery in which 11,000 hydrocodone pills were stolen.

If the pure hydrocodone drugs are approved, Schumer wants a "robust post-market surveillance" of the drugs as they are marketed, advertised and sold.

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