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Whiting: FDA finally starts to tackle opioid epidemic



ORANGE COUNTY REGISTER

With the prescription drug epidemic killing, on average, someone every other day in Orange County, the Food and Drug Administration this week finally took its first significant step to slow the death rate.

It may not seem like much, but the FDA's move to clamp down on relatively easy access to hydrocodone indicates a long-awaited paradigm shift.



James and Teri Kennedy visit a roadside memorial where their still alive son was dumped off the I-5 Freeway near J Serra High School. Joey Kennedy died after several years of opiate addiction.

CHRISTINE COTTER, FOR THE REGISTER

Still, for 44 people in Orange County – according to my review of coroner records – the FDA's move is too little too late. Each one accidently overdosed last year of hydrocodone-related causes.

Consider that the Drug Enforcement Administration itself recommended such a move by the FDA *four years ago*. Since the DEA asked to make it more difficult to get hydrocodone, also known as Vicodin, more than 100,000 people have died from prescription opioids.

James Kennedy is the father of a young man named Joey whose life and death I profiled last year. After learning of the FDA's move, Kennedy told me: Joey's "introduction to prescription pain

medication started with Vicodin and that quickly led him to stronger and more lethal pharmaceutical opioids.

"I am happy to see the FDA is finally doing something about the overprescribing of Vicodin and its generic counterparts, but that is not enough."

Kennedy, of San Clemente, pointed to the staggering amounts of opioids manufactured legally in the U.S. He said flooding the market with such drugs "has created a significant increase in addiction to pain medication, which will unfortunately continue forward until all opioids are very tightly controlled."

Still, the FDA's move to curtail an epidemic that kills more people than car crashes is a start.

Consider that last month the agency was all proud that it required changing labels on opioids.

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Earlier this week, Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, noted the move to reclassify hydrocodone as a Schedule II drug came after considerable work. She wasn't kidding.

Woodcock said the FDA's decision followed "extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which we received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities."

Sure, we want the FDA to carefully evaluate drugs. But given the delay, the number of deaths and the clout of what critics call Big Pharma, the question rises who the FDA really works for.

I started writing about the opioid epidemic three years ago when it was mostly affecting teens and young adults along our golden coast and in South County. At that time, so-called "pharm parties" with young people snorting crushed pills stolen from parents' medicine cabinets were all the rage.

They still are.

Like the DEA, I called for tighter drug controls. It doesn't take a medical degree to figure out the way to slow drug flow is to tighten the faucet.

Yet, as the epidemic spread, the FDA had meetings. Earlier this year, I examined 2012 county coroner reports and found a 25 percent spike from the year before in women dying.

What was equally disturbing was that the epidemic also was spreading to other age groups. Of women ages 40 and over, the number of opioid deaths jumped from 35 to 49, a 40 percent increase.

I call that an outrage.

The FDA uses different words. In announcing the reclassification of hydrocodone, the agency said it has "become increasingly concerned about the abuse and misuse of opioid products."

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Reviewing coroner records, I also found that, on average, a young person in Orange County dies every other week.

Additionally, the Orange County Coroner office announced several months ago that from 1999 to 2012, local residents dying solely from prescription drugs increased 114 percent.

But if you're a parent, the biggest number is one.

Elaine Werner-Hudson lives in South County and lost her son, Josh, to prescription opioids. After the FDA's announcement, I contacted Werner-Hudson and learned something I didn't know.

Josh's addiction started at the age of 24 with, yes, hydrocodone. Three years later, Josh was dead.

In his journal, Josh shared his first hydrocodone experience. Explaining the initial high, in context, is revealing.

"It was a wonderful warm night," Josh wrote. "It just had rained earlier and it smelled wonderful. I took two of these pills before I left, and I am filled with positive emotion. I feel better than I ever have."

Looking back, Josh continues, "Nothing could have harmed me that night. I was in love." Then things get dark. "I found that nothing in life is as good when I didn't have my pills.

"So even though I had everything, I started the long painful process of letting it all go without the knowledge I was doing so."

Josh lost everything.

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Werner-Hudson, founder of an addiction and survivor's addiction help group called Solace, echoes dozens of Orange County parents I've talked to about the epidemic.

"Drug companies have downplayed and profited from the addiction potential of these drugs," Werner-Hudson said. "For years their studies reported minimal risk of addiction and dependence. With all of the opioid related deaths in past years in Orange County and around the U.S. I find this incomprehensible.

"The FDA is responsible for regulating and overseeing these profit-making companies, but didn't intervene until now."

Still, Werner-Hudson finds hope with the FDA's most recent move. "The significance of making the drug harder to obtain will save many lives."

Some pain medication experts, however, are less sure.

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Dr. Robert Kutzner is a pain specialist with offices in Costa Mesa and Fountain Valley and can be found at http://www.MDHealthClinics.com. Instead of pointing fingers at the FDA, Kutzner is frustrated with the state of California for failing to enforce regulations already in place.

Kutzner offers that state-mandated guidelines for prescribing pain medication in workers' compensation cases would go a long way in resolving the epidemic – if the guidelines weren't ignored and virtually unknown.

The doctor's right. In a column a month ago, I reported that even the physician in charge of the program, worker's comp Executive Medical Director Dr. Rupali Das, admitted doctor education was needed.

Called the "Medical Treatment Utilization Schedule," the book-length document includes dozens of pages outlining detailed procedures for opioid treatment. Significantly, it also includes a host of non-opioid procedures such as therapy.

"We don't need more government," Kutzner maintains. "We need more compliance with the guidelines that already exist.

"Remember that the drugs that are on the (FDA) schedule list are there because they are addictive, abused."

Dave Macleod of Huntington Beach understands Kutzner's point too well. He lost his 18-year-old son, Tyler, last year.

Of the FDA, Macleod says, "It's about time they started making it tougher for these kids to easily get these so-called pain killers. They are sold on the streets to our kids and are more readily available than any other drug."

Until the FDA, pharmaceutical companies and doctors get serious about change, there only will be more Joeys, Joshes, Tylers.