

Safer painkillers sought

By [Chris Tisch](#), Times Staff Writer

Published Sunday, May 18, 2008 8:22 PM

In the face of increasing deaths from overdoses of prescription painkillers, several pharmaceutical companies are trying to bring to market drugs they say are abuse resistant.

Last year, about 2,000 Floridians — 500 in the Tampa Bay area — fatally overdosed on prescription drugs. The vast majority of the lethal drugs were opioid painkillers like oxycodone, hydrocodone and morphine.

Pharmaceutical companies say many of the people dying are abusing the drugs by crushing, biting, snorting or injecting time-released pills. This provides a powerful, heroinlike high.

The Food and Drug Administration has encouraged manufacturers to study ways to make their drugs less susceptible to abuse.

Several companies are seeking approval of new formulas this year. Some of the drugs are rubbery or gel-like and can't be crushed. Others have substances embedded in the pills that offset the euphoric affects of the drug if it is crushed or manipulated.

"Our goal is to address a public health concern," said Dr. Joseph W. Stauffer, chief medical officer at Alpharma Pharmaceuticals, which hopes to have an abuse-resistant morphine pill on the market by next year.

But this month, a panel of FDA advisers expressed skepticism about an abuse-resistant form of OxyContin. Panelists said OxyContin maker Purdue Pharma hadn't provided enough evidence that its new product would deter abuse.

"I'm fascinated with the poor scientific rigor" of the data presented by Purdue, FDA panel member Jeffrey R. Kirsch said. "It's almost insulting."

Purdue said in a statement it would continue working with the FDA on the product.

Larry Golbom of Pinellas County spoke against FDA approval of the new drug during the panel meeting in Maryland. Golbom is a pharmacist with a family member who become addicted to prescription drugs. He hosts a radio show about prescription drug addiction on Sunday nights on WGUL-AM 860.

"There is no logical sense to making more of this product available on our streets," Golbom said. "To present the concept that this is a safer drug would be a tremendous disservice to the medical profession and the American public."

Golbom believes most of the people who die of painkiller overdoses don't snort or inject the drug, but swallow the pills whole.

The *St. Petersburg Times* analyzed the autopsy reports of nearly 800 prescription drug deaths over a two-year period for a series published in February. The analysis found there is no way to be certain if the fatal drugs were swallowed or taken another way.

Golbom worries that FDA approval of additional drug types would give doctors a false sense of security.

"The fact is that oxycodone is a highly addictive drug in the same category as heroin," Golbom said. "The reality is that pain relief is a side effect of this drug."

Last year, Purdue agreed to pay \$634-million to settle criminal charges that it misled doctors about the risks of OxyContin, which had more than \$1-billion in sales last year.

Golbom said the drugs proposed by other companies also should be scrutinized. He said the FDA needs to better define when opioid painkillers should be prescribed.

But Stauffer said the indications are clear. He said the new drugs will help ensure that drug abuse is deterred, while those who need painkillers can continue to receive them. "There are dual public health issues at stake here," he said.

Stauffer said only a small percentage of people prescribed painkillers become addicted. He said the drugs help far more people than they hurt.

Alpharma's abuse-resistant drug has gone through trials that have found it to be safe and effective, Stauffer said. The pills are embedded with a substance that blunts the euphoric high users would receive if the pills were crushed.

King Pharmaceuticals also hopes to submit by June an application for its abuse-resistant oxycodone drug, Remoxy.

The gel-like Remoxy, which has successfully completed trials, does not lose its time-release mechanism if crushed, said James E. Green, King's executive vice president of corporate affairs.

Green acknowledged there is no way to ensure drug abusers won't find some way to defeat the abuse-resistant features of the new drugs.

"I don't know that you'll ever have anything that is tamper-proof," Green said. "You just don't want it to be easy for people to tamper with."

The drugs could mean billions of dollars for the companies.

Last year, sales of opioid painkillers totaled \$6.37-billion in the United States, a 52 percent increase over 2002.

Dr. Lynne Columbus, a Palm Harbor pain physician, said the abuse-resistant pills are a good idea.

"I think they will help a lot," she said. "It will give us a medication we can prescribe and sit back and relax and know people can't bite it and overdose."

Information from Bloomberg News, Dow Jones Newswires and the Associated Press was used in this report. Chris Tisch can be reached at 727-892-2359 or tisch@sptimes.com.