

FDA reversal OKs morphine painkiller for dying

April 9 2009, By MALCOLM RITTER , AP Science Writer

(AP) -- A liquid morphine painkiller given by family caregivers to dying patients can remain on the market, federal regulators have decided after hearing protests over their decision to remove it. The Food and Drug Administration had announced last week that it was ordering manufacturers to stop making 14 medications including the liquid morphine. All were developed so long ago they had never received FDA approval.

But on Thursday, the FDA's Dr. Douglas Throckmorton told The Associated Press the [morphine](#) liquid will remain on the market until it's replaced by an approved version or some equivalent therapy.

The reversal was welcomed by experts in hospice care and pain relief. One doctors group had told the FDA that last week's order would "cause extreme suffering for many patients who are nearing the end of life."

The order has not changed for the other [painkillers](#), at least for now, said Throckmorton, deputy director of the agency's Center for Drug Evaluation and Research.

The agency said last week that the unapproved drugs might be unsafe, ineffective or poor quality. The order gave manufacturers 60 days to stop making those products.

The liquid morphine is highly concentrated. Other approved forms of liquid morphine are more dilute, and Throckmorton said the FDA had

thought the other forms could take the place of the concentrated form.

But reaction from hospice experts and others "helped us understand" that some patients need the unapproved version, Throckmorton said.

In interviews, experts said they didn't have firm numbers on how many patients use the concentrated liquid. But Dr. Diane Meier, director of the Center to Advance Palliative Care at the Mount Sinai School of Medicine in New York, estimated that it may be at least 2 million Americans a year.

She called Thursday's decision "fabulous.... It's incredibly refreshing and makes me hopeful about our government."

The high morphine concentration is crucial, she and others said. It allows caregivers to rapidly relieve pain by placing just a few drops in the mouth of a person who has trouble swallowing, perhaps because of confusion, lethargy or other conditions.

The more dilute morphine requires much more liquid, which could make an impaired person choke or sputter, or refuse to take the medication, experts say.

Caregivers can administer the concentrated solution at home, where morphine shots often aren't a good option. Without the concentrated liquid, families could end up calling 911 to rush their loved ones to an emergency room for morphine shots, which would be expensive and against patient wishes, said Dr. Porter Storey, executive vice president of the American Academy of Hospice and Palliative Medicine.

Storey called the FDA reversal "a really important step in the right direction," showing "an amazing level of responsiveness we're not used to seeing in our government officials."

But Storey said he was still concerned about the other painkillers ordered off the market, products containing morphine, hydromorphone or oxycodone.

While approved medications with those ingredients remain on the market, Storey noted that opiate painkillers are in short supply. So rather than removing the unapproved versions all at once, exacerbating the problem, he suggested the FDA proceed more slowly.

In a letter to the FDA earlier this week, Storey's organization said the painkillers covered by last week's order "have been used safely and effectively for decades."

Throckmorton said the FDA is open to getting additional information about the other painkillers, and would discuss them with experts in hospice and palliative care.

But Storey said that in a later phone call with physicians and pharmacists, the FDA said that the order against the other painkillers would stand.

Further shortfalls in painkiller supply could spell trouble for chronic pain patients such as 62-year-old Ora Chaikin in New York City, said her physician, Dr. R. Sean Morrison at Mount Sinai.

Chaikin takes an unapproved version of the drug Dilaudid - hydromorphone - when her joint pain flares, which is typically on most days. She said she needs that medication "just to be able to walk, to be able to do daily activities (like) putting a coat on."

Although approved versions of the drug are available, the FDA order makes Morrison worry about their supply.

"It's already hard to get them," he said.

On the Net:

FDA statement on original order:

<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01983.html>

FDA background information:

<http://www.fda.gov/cder/drug/unapproved-drugs/narcoticsQA.htm>

FDA web page on unapproved drugs:

<http://www.fda.gov/cder/drug/unapproved-drugs/default.htm>

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