Uploaded to the VFC Website

July 2014

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Fighting Abuse But Hurting Pain Patients: FDA Seeks New Opioid Limits

FILED UNDER: **Medicine/Science**, **pain**

Longtime nationally syndicated health columnist Judy Foreman is the author of the forthcoming book, "A Nation in Pain — Healing Our Biggest Health Problem" coming out in February, 2014 from Oxford University Press. She looks here at the FDA's latest move to tighten control of painkillers.

By Judy Foreman

In a move designed to combat drug abuse but likely to put further burdens on pain patients, the US Food and Drug Administration **has just announced** that it is recommending tighter controls over opioid pain relievers such as Vicodin and Lortab that contain hydrocodone.
The shift in policy –- the subject of a controversial hearing in January –- will limit the number of refills a patient can get before going back to the doctor for a new prescription. It will also mean that a patient must physically take each prescription to a pharmacy, instead of allowing doctors to call the prescription in. For patients in severe, chronic pain and those with physical limitations, these requirements are likely to pose significant difficulties.

In the statement on its Website, the FDA said that opioids (narcotics) do allow people living with chronic pain to "manage their pain as well as significantly improve their quality of life." But the FDA also said it had become "increasingly concerned" in recent years about the "abuse and misuse of opioid products."

The FDA said that by early December, it would formally submit its recommended changes to the Health and Human Services Department. It added that the National Institute on Drug Abuse is expected to concur with the new recommendations and that a final decision on the new policy will be made by the Drug Enforcement Administration, which, in 2009, asked for the change. In bureaucratic language, the change involves moving products that contain hydrocodone in combination with another drug such as acetaminophen from classification as a Schedule III drug to classification as a more restricted Schedule II drug.

In practice, said Cindy Steinberg, a chronic pain patient and National Director for Policy and Advocacy at the US Pain Foundation, a nonprofit advocacy group, the change will impose serious hardships on the 47 million Americans who currently take hydrocodone-containing products.
With hydrodocone-containing products in their current, Schedule III classification, a pain patient can see a doctor once a year, get a prescription with five refills — meaning a supply of the drug for six months — and then call the doctor for another prescription good for another six months, which the doctor can call in to the pharmacy.

Once hydrocodone-containing products are placed in Schedule II, a pain patient would be able to get a supply of the drug for up to three, not six, months at a time. A patient will then have to have another visit with the doctor and physically take each new prescription to the pharmacy. Instead of seeing a doctor just once a year, a patient would have to go to the doctor every three months.

The change is “extremely detrimental” for pain patients, said Steinberg in a telephone interview, not just in terms of pain control but in terms of the costs of added visits to the doctor and even the ability to get those extra visits in an already-overburdened health care system.

Steinberg testified at the FDA’s hearing on the proposed change last January that “rescheduling hydrocodone combination medications is a drastic measure that will have far-reaching negative consequences; chief among them will be loss of pain control for millions of Americans.”

In **a telephone interview with The New York Times**, Dr. Janet Woodcock, director of the FDA’s center for drug evaluation and research, said the FDA was aware that changing the prescribing rules would affect patients but that the impact on public health caused by abuse of the drugs had reached a tipping point.