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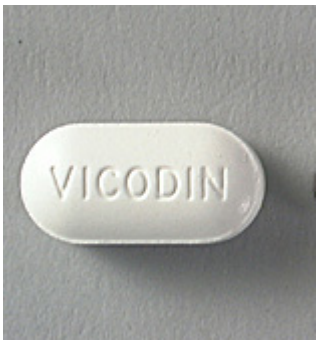
Is the FDA going schizo on us?

By ACSH Staff — December 5, 2013



What on earth is going on over at the FDA?

Recently, they have been facing some very difficult issues regarding narcotic pain medications. In particular, as pointed out by ACSH s Dr. Josh Bloom in his December 2nd op-ed [1] in The New York Post, they just enacted a rule change that, ostensibly in the interest of combating drug abuse, will make it much more difficult for patients with legitimate need for drugs to control moderate-to-severe pain to get the medicines they need a seriously flawed idea.

Yet, they now found themselves in the middle of another narcotics controversy, and it involves some rather odd circumstances to say the least.

Last month, the FDA granted approval to a pill, which is pure hydrocodone (the narcotic found in Vicodin). The drug is called Zohydro, and it is the hydrocodone equivalent of OxyContin, the only difference being that OxyContin contains oxycodone, which is about twice as potent as hydrocodone.

Both pills have three things in common: 1)They are pure narcotics without the acetaminophen (Tylenol) that is contained in Vicodin or Percocet; 2) The dose of narcotic is much higher than that found in Vicodin or Percocet; 3) They both are time-release medications, formulated such that the patients need to take them much less frequently and also get a constant dose of the drug over a long period of time. This can be a big advantage to people who suffer from severe chronic pain.

Paradoxically, despite the higher amount of narcotic in OxyContin and Zohydro, they are actually safer than Percocet and Vicodin. This is because when people overdose on either of these drugs, it is the liver toxicity of acetaminophen that is often the real killer.

According to an October, 2013 article in The Wall Street Journal [2], Acetaminophen overdose is a leading cause of acute liver failure in the United States, with 63 percent of unintentional acetaminophen overdoses attributed to the use of hydrocodone-acetaminophen combination products.

Stranger still is that the FDA overruled the advice of their expert panel, which voted 11-2 against approving Zohydro. It is unusual for the guidance of FDA expert panels to be rejected by the FDA

as a whole.

All of this makes Dr. Bloom wonder what is going on over there. He says, This appears to not be a case of a rudderless ship. It s more like a ship with two rudders steering the ship in different directions. It would be comforting to understand their rationale here. That is, assuming that they actually have one.
