JULY 1, 2009, 8:30 AM ET

FDA Panel: Down With Percocet & Vicodin. Long Live NyQuil!

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By Jacob Goldstein

NyQuil got a pass from that FDA advisory committee that met this week to discuss acetaminophen, the generic painkiller in all kinds of over-the-counter medicines. But the panel recommended a ban on prescription drugs that combine acetaminophen with a narcotic — drugs such as Percocet and Vicodin. The panel also suggested requiring a prescription for extra-strength Tylenol.

The committee's task was to advise the FDA on ways to reduce the risk of liver injury associated with acetaminophen, which can occur at doses not much higher than those considered safe. Patients taking narcotics often need higher and higher doses to achieve the same effect; so patients taking combination pills could unwittingly be getting too much acetaminophen if they raise their dose.

It's important to point out that the panel was not advising a ban on any of the ingredients in those combination drugs, only on combining them in a single pill. So if the FDA follows the panel's advice and bans Vicodin, a doctor could still prescribe a patient acetaminophen and hydrocodone, the two ingredients that are combined in Vicodin.

The advisers also recommended making extra-strength doses of acetaminophen (such as the dose in Extra Strength Tylenol) available only by prescription, and lowering the maximum daily dose for over-the-counter acetaminophen to 2,600 milligrams from its current level of 4,000 milligrams.

The panel voted to keep over-the-counter cold medicines that contain acetaminophen, a category that includes NyQuil and lots of other cold combos. Most acetaminophen overdoses occur from prescription drugs, the WSJ notes.

For more, read coverage from the New York Times and Bloomberg News, and check out the meeting documents on the FDA's Web site. A few corporate notes: Tylenol is a J&J drug; Abbott sells Vicodin; Procter & Gamble sells NyQuil; and Endo sells Percocet.

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5:24 pm August 5, 2011

Pharme922 wrote:

Hello! dekefkd interesting dekefkd site! I'm really like it! Very, very dekefkd good!

6:33 pm October 2, 2010

Van der vart wrote:

Vicodin is a drug widely used in hospitals and that this proved that it is good to control chronic pain, but as stated in findrxonline, has side effects that can be dangerous if not taken in an appropriate manner.

3:27 pm September 9, 2009

Terry wrote:

The ONLY reason for a ban is that they are EFFECTIVE and INEXPENSIVE…bet the alternative will be 500.00 per DAY !! just wait and see…big Pharma kills america once again !!

About Health Blog

Health Blog offers news and analysis on health and the business of health. The blog is written by Katherine Hobson and includes contributions from staffers at The Wall Street Journal, WSJ.com and Dow Jones Newswires. Write to us at healthblog@wsj.com.

Katherine Hobson has been writing about health and business for more than 15 years, including stints covering cancer, nutrition, exercise science, the U.S. economy and the U.K. beer industry.

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6:12 pm July 26, 2009

jpgakis wrote:

Abbott doesn't sell very much Vicodin. 99.0+% Rxs are generic. Watson makes most of the doses.

12:42 am July 15, 2009

Pithius wrote:

The FDA Meeting Issue Background Document is at:
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM164897.pdf

Options 1(a) and 1(b) propose limitation of acetaminophen to 325mg per dose for OTC sales (and possible inclusion of all prescription formulations).

Option 5(b) proposes eliminating all prescription medications complexed with acetaminophen.

What is not (directly) stated by the FDA is the single most significant factor at play. Hydrocodone (Vicodin, Lortab) complexed with acetaminophen is a Schedule III medication. Hydrocodone (alone) is under Schedule II. And there currently is NO SUCH PRODUCT manufactured!

Thus, the FDA [if they choose to vote for Option 5(b)] will (effectively) "re-schedule" hydrocodone from Schedule III to the *much* more restrictive Schedule II (written prescriptions only, maximum 30-day supply, etc.).

Addressing the current non-existence of any hydrocodone (only) product, the FDA Background Document (lazily) states: "For development of hydrocodone single-agent formulations, implementation would include:" … "Submission of NDAs and ANDAs for single-ingredient hydrocodone products, which may also require clinical studies for demonstration of efficacy."

A reported 460,000 prescriptions for hydrocodone with acetaminophen are written and filled every business day in the United States. (Despite) the fact that the public comment window has passed, all affected patients, physicians, and institutions would be wise to protest – loudly.

http://t.co/zHsyBWAF
23 hrs ago

ShirleySWangWSJ: Thanks @ scotthensley @ doctorwes @ MDMonseau for RT/MT
1 day ago

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