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**FDA Advisory Panel takes aim at drugs containing acetaminophen**

Provided as a Client Service by Cypress Care Pharmacy Services
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**Background**

The Food and Drug Administration (FDA) convened a public advisory committee meeting June 29 and June 30, 2009 to review acetaminophen use in both over-the-counter (OTC) and prescription products. This Advisory Panel reviewed the potential for liver injury, and potential interventions by the FDA to reduce the incidence of liver injury.

Currently, the FDA has not acted on the recommendations of their advisory panel. Cypress Care Pharmacy Services offers this update to increase awareness of possible implications stemming from this panel's recommendations. The FDA is not required to follow the advisory panel's recommendations. However, it typically does.

Acetaminophen is an active, non-narcotic ingredient found in many prescription-only medications. The acetaminophen is typically included in prescription drug products along with a narcotic pain reliever. In these cases, acetaminophen acts as an extra pain reliever and also helps reduce fever or inflammation. Examples of prescription-only pain relievers that contain acetaminophen and a narcotic pain reliever include:

- Percocet ™ (oxycodone and acetaminophen)
- Vicodin™ (hydrocodone and acetaminophen)
- Lortab™ (hydrocodone and acetaminophen)
- Ultracet ™ (tramadol and acetaminophen)
- Darvocet™ (propoxyphene and acetaminophen)

Acetaminophen is also the active ingredient in Tylenol and many combination OTC products. Examples include:

- Excedrin™
- Nyquil™
- Theraflu ™

Acetaminophen is a safe drug when used according to FDA-approved labeling. However it can be dangerous when taken too often or in larger quantities than approved. The current maximum dose of acetaminophen is 1,000 milligrams (1 gram) at one time, or a maximum daily dose of 4,000 milligrams (4 grams).

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**How are your claimants protected?**
Currently Cypress Care utilizes a state of the art Drug Utilization Review (DUR) program that monitors acetaminophen use. The current DUR identifies daily doses above the 4000mg/day max threshold if contained in a single prescription.

The current DUR program will also identify and alert pharmacists when patients receive multiple acetaminophen containing products. In this case, the Cypress Care DUR system prepares a duplicate ingredient alert.

**How big is the acetaminophen improper use issue ?**
Data presented to the FDA noted that 28 billion doses of medications containing acetaminophen were distributed in the United States in 2005. This data also indicated that among 22 medical centers throughout the United States, acetaminophen was the leading cause of acute liver failure from 1998-2003. A high number of these liver injuries occurred due to accidental acetaminophen overdoses. To put this into perspective, overall incidence of acetaminophen-induced liver failure is relatively low. Some experts suggest an incidence rate as low as 0.14%.

**What are the alternatives ?**
NSAIDs (Non-Steroidal Anti-Inflammatory Drugs), a class of drugs known to cause GI discomfort and bleeding, would likely fill part of the void. Single-ingredient opiates like OxyContin would likely also be used to fill the void. Currently, the only immediate-release opiates that would have similar analgesic effects are tramadol and oxycodone, both of which have a recognized abuse potential.

The most-prescribed combination acetaminophen product is Vicodin (hydrocodone/acetaminophen). If banned, there is not a single ingredient hydrocodone product approved yet by the FDA. A single-ingredient hydrocodone product would likely be a considerably more expensive branded product. This was the case when OxyContin was introduced as an oxycodone-only product to serve as an alternative to Percocet (oxycodone/acetaminophen).

**In Summary:**
Cypress Care Pharmacy Services continues to support prudent use of acetaminophen-containing products. An FDA ban on combination products would not likely have any positive effect, financially or therapeutically, on patient care, healthcare costs, or our clients.

**References:**
Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee. June 29-30, 2009 meeting. Food and Drug Administration, Center for Drug Evaluation and Research. http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/drugssafety-riskmanagementadvisorycommittee/ucm170188.pdf <Accessed July 16, 2009>

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