Written by **Daniel Sayani** on January 18, 2011

FDA to Limit Acetaminophen in Pain-Killers

The U.S. Food and Drug Administration announced yesterday that it will limit the active pain-reducing ingredient in the pain medications Percocet and Vicodin.

FDA officials indicated that they would order drug manufacturers to reduce the amount of acetaminophen to 325 milligrams per tablet or dosage unit in pain medications such as Percocet or Tylox, which are a combination of acetaminophen and the opiate-derived oxycodone, and Vicodin or Lortab, a combination of acetaminophen and hydrocodone.

The announcement comes as the latest attack waged on chronic pain sufferers by the FDA, Drug Enforcement Agency (DEA), and other regulatory agencies which are attempting to take an even greater role in controlling which medications, procedures, and medical services are available to patients.

Within a three-year period, the FDA plans to completely phase out what it deems "high-dose" prescription medications containing acetaminophen. Sandra Kweder, M.D., deputy director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research (CDER), asserted:

> FDA is taking this action to make prescription combination pain medications containing acetaminophen safer for patients to use.
>
> Overdose[s] from prescription combination products containing acetaminophen account for nearly half of all cases of acetaminophen-related liver failure in the United States; many of which result in liver transplant or death.

The FDA claims that these latest efforts are necessary in order to "protect" the public against the possible side effects of these medications, such as liver damage. However, a side effect as dramatic as liver damage typically occurs only after prolonged use of acetaminophen-containing products (including over-the-counter Tylenol), especially when combined with alcohol, or when multiple acetaminophen-containing products are taken at the same time.

Research also suggests that many reported cases of acetaminophen overdose-related liver damage may not be the result of accidental overdoses, but instead, suicide attempts. In a study that included all patients admitted to an inner city hospital over a 39-month period for acetaminophen overdoses, the number of suicide attempts exceeded the accidental cases by nearly three-fold.

The research (Acetaminophen Toxicity in an Urban County Hospital), published in the *New England Journal of Medicine* (Volume 337: 1112-1118), by Dr. Frank V. Schiedt, also found that the suicidal patients ingested almost twice as much acetaminophen as those in the accidental-overdose group, and that those who accidentally overdosed on acetaminophen showed greater levels of liver necrosis (i.e., sustained liver failure), possibly due to concomitant alcohol abuse.

Research (and common sense) also indicates that severe liver injury generally results only when individuals misuse acetaminophen-containing prescriptions or over-the-counter drugs. Such misuse often entails either their taking more than the prescribed dose of an acetaminophen-containing product in a 24-hour period, taking more than one acetaminophen-containing product at the same time, or drinking alcohol while taking the drug.

The FDA requirements, which seek to include mandatory labeling on prescriptions alerting patients to the possible risk of liver damage, do not consider these broader circumstances.

The federal government is once again unnecessarily intruding upon the sanctity of the patient-doctor relationship — contrary to the fundamental Lockean notion that the individual is the effective owner of his body, and has the right to determine what he will do with it (while acknowledging that God, as Creator, is ultimately in control of the body — and prohibits individuals from doing anything contrary to self-preservation, according to John Locke's *Second Treatise on Government*).

Even more ominous was the FDA's recommendation in July of 2009 that these prescription medications be phased out completely. An FDA panel voted 20-17 last summer to eliminate Percocet, Vicodin, and Lortab, claiming that "their role in deadly overdoses" was sufficient grounds for declaring a ban on them.

In response to the earlier proposed ban, the *New York Times* reported that Johnson & Johnson released a statement saying it "strongly disagrees" with the proposed restrictions on acetaminophen, adding that such limits would be likely to "lead to more serious adverse events as consumers shift to other over-the-counter products" such as Advil and aspirin.

Linda A. Suydam, president of the Consumer Healthcare Products Association, said the committee had ignored studies showing that doses sold by her members — two pills of 500 milligrams, up to four times a day — were safe. "I think this is a very effective dose and one needed for individuals who experience chronic pain," she added.

Many doctors also believe that efforts at limiting acetaminophen dosages or banning medications such as Vicodin and Percocet are irresponsible and ill-informed. According to Dr. Sean Mackey, Chief of Pain Management at Stanford University Medical Center, these FDA restrictions will only place more burdens on health care providers and patients. He notes, "More people will be suffering from pain" … and "more people will be seeing their doctors more frequently and running up health care costs."

Dr. Gil Fanciullo, a pain management specialist at Dartmouth-Hitchcock Medical Center in Lebanon, N.H., and member of the American Pain Society, notes, "If these drugs were not available to our patients, there would be a stampede toward the doctor to try to figure out an alternative treatment for them because they're such widely used drugs." The results would be either under-treatment of pain, or putting patients on even stronger narcotics. Better labeling of medicines that have acetaminophen is the answer, rather than making them less available, he affirms.

While medicine is waging the war against pain, the FDA is waging war against pain sufferers.

The FDA's latest effort to limit the legally-permissible amount of acetaminophen in pain medications, like its earlier effort to ban these truly life-preserving medications for pain sufferers, represents a years-long assault on chronic pain sufferers, carried out in the interests of "fighting the drug war" and "protecting the public."

According to Dr. Ronald T. Libby, Professor of Political Science at the University of North Florida, in his

book, *The Criminalization of Medicine: America's War on Doctors*, the federal government, through its excessive regulations and restrictions, has made the work of physicians in the field of pain management incredibly difficult.

Libby says that the DEA, emboldened by the FDA's punitive policies, has been instrumental in making many physicians shy away from prescribing opioids such as Vicodin and Percocet, "causing millions of Americans to suffer from chronic pain even as therapies were available to treat it." Indeed, many health care professionals and epidemiologists believe that chronic pain is the number one public health crisis faced by the United States, exacerbated by the fact that chronic pain often goes untreated because of government regulations. Libby explains,

> The DEA's painkiller campaign has cast a chill over the doctor-patient candor necessary for successful treatment. It has resulted in the pursuit and prosecution of well-meaning doctors. It has also scared many doctors out of pain management altogether, and likely persuaded others not to enter it, thus worsening the already widespread problem of underrated untreated chronic pain.

Such regulations serve to curtail efforts toward raising consciousness on chronic pain as an epidemiological concern which demands a concerted, sympathetic response on behalf of health care providers. According to Dr. Peter Croft's book *Chronic Pain Epidemiology: From Aetiology to Public Health*, "little attention has been paid to chronic pain as a public health problem or to the potential for its prevention, even though it can be studied and assessed using concepts and ideas from classical epidemiology," although chronic pain poses a long-term demographic, economic, and occupational strain on society as a whole.

The FDA's proposals to limit accessibility to pain medication are fundamentally flawed, according to Karen Lee Richards, co-founder of the National Fibromyalgia Association, an organization devoted to representing the interests of the more than estimated five million Americans who suffer with the disease (according to 2005 Centers for Disease Control and Prevention statistics). Richards says that FDA regulations on pain medication aimed at reducing the number of acetaminophen overdoes are ineffective:

> Personally, I'm not convinced banning these drugs will make a significant difference in the number of acetaminophen overdoses. On the other hand, as long as both components of the medications are still available and the only difference is taking two tablets instead of one, it might help make patients more aware of what they're actually taking so they don't unintentionally get an overdose of acetaminophen.

Bureaucracy is no substitute for personal responsibility. According to FDA Acetaminophen Policy Panel member Dr. Jan Engle, head of the Department of Pharmacy Practice at the University of Illinois-Chicago, "If you keep track of what you're taking, none of this is an issue for you." Consumer education, rather than nanny-like scolding, is the proper approach to mitigating acetaminophen-related complications.

While the new FDA restrictions fall short of the earlier recommended ban on medications such as Percocet and Vicodin, as of January 14, 2014, prescription pills may contain no more than 325 milligrams of acetaminophen. However, over-the-counter acetaminophen is not facing the same restrictions currently, as the FDA has stated that it has no intention of imposing such restrictions on over-the-counter drugs because of the more lengthy and complicated requirements for doing so.

So in three years, over-the-counter acetaminophen will actually be stronger than the acetaminophen

prescribed by doctors — which is illogical, considering the FDA's long-term goals of reducing the medicine's toxicity.

According to Sidney Wolfe, director of health research at the Washington-based consumer group Public Interest, "It is inexcusably poor judgment on the part of the FDA to have failed to take action concerning this major source of acetaminophen consumption and, consequently, acetaminophen toxicity."

By imposing such restrictions on prescriptions, doctors and pharmacists will likely face reduced reimbursements and will see lower overall revenues, while patients may actually be at greater risk, as they will be taking higher dosages of acetaminophen without medical supervision.

The FDA has merely fired the next shot in a government-initiated battle that seems interminable for those who live with the horror of chronic, debilitating pain.

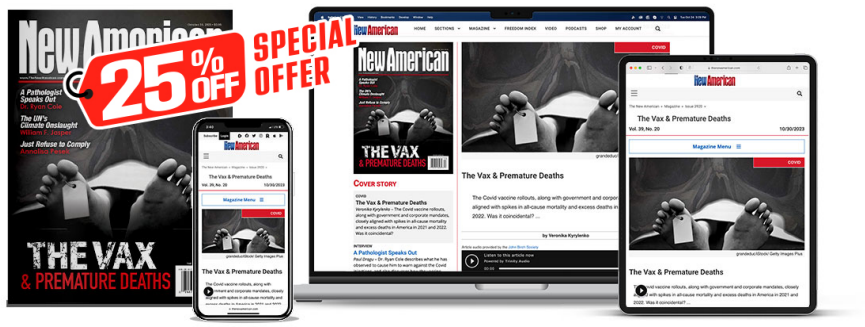
Photo: Tylenol 3, a compound of Tylenol (300 mg) and Codeine (30 mg)

Subscribe to the New American

Get exclusive digital access to the most informative,
non-partisan truthful news source for patriotic Americans!

Discover a refreshing blend of time-honored values, principles and insightful perspectives within the pages of "The New American" magazine. Delve into a world where tradition is the foundation, and exploration knows no bounds.

From politics and finance to foreign affairs, environment, culture,
and technology, we bring you an unparalleled array of topics that matter most.



What's Included?

24 Issues Per Year
Optional Print Edition
Digital Edition Access
Exclusive Subscriber Content
Audio provided for all articles
Unlimited access to past issues
Coming Soon! Ad FREE
60-Day money back guarantee!
Cancel anytime.

Subscribe