On October 24, 2013, The Food and Drug Administration (FDA) released a statement concerning Hydrocodone containing opioid medications, which many chronic pain patients take daily to lessen their pain so they can function. FDA intends to recommend that they be changed from a Schedule III drug classification to a Schedule II drug classification which would be more restrictive. If you missed the FDA statement, it is located below:

Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research  
[10-24-2013] Over the past several years, the U.S. Food and Drug Administration (FDA) has been carefully evaluating and weighing the appropriate use of opioid analgesic drug products. For the millions of American patients experiencing an acute medical need or living with chronic pain, opioids, when prescribed appropriately, can allow patients to manage their pain as well as significantly improve their quality of life.

However, in recent years, the FDA has become increasingly concerned about the abuse and misuse of opioid products, which have sadly reached epidemic proportions in certain parts of the United States. While the value of and access to these drugs has been a consistent source of public debate, the FDA has been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse.

In 2009, the U.S. Drug Enforcement Administration (DEA) asked the U.S. Department of Health and Human Services (HHS) for a recommendation regarding whether to change the schedule for hydrocodone combination products, such as Vicodin. The proposed change was from Schedule III to Schedule II, which would increase the controls on these products. Due to the unique history of this issue and the tremendous amount of public interest, we are announcing the agency’s intent to recommend to HHS that hydrocodone combination products should be reclassified to a different and more restrictive schedule. This determination comes after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which we received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.
By early December, FDA plans to submit our formal recommendation package to HHS to reclassify hydrocodone combination products into Schedule II. We anticipate that the National Institute on Drug Abuse (NIDA) will concur with our recommendation. This will begin a process that will lead to a final decision by the DEA on the appropriate scheduling of these products.

Going forward, the agency will continue working with professional organizations, consumer and patient groups, and industry to ensure that prescriber and patient education tools are readily available so that these products are properly prescribed and appropriately used by the patients who need them most.

For those of you unfamiliar with the technicalities of the “scheduling” or classification system for drugs and how or if this will affect your ability to get your medications, here is a clarification. Right now, hydrocodone is available on the market in combination with over the counter medicines like Tylenol (acetaminophen) or Advil (ibuprofen). These combination hydrocodone-containing medicines which include Vicodin, Lortab and others are now able to be refilled for up to 6 months on a single prescription. When there are no refills left or whenever prescribing these medicines your doctor can call, fax or electronically submit the prescription to your pharmacy.

This tightening by the FDA would now mean that these medications could no longer be refilled. Since most practitioners only write for a month’s supply on a single prescription, you will only be able to get a month’s supply. When you run out you will have to go back to your practitioner for another appointment for a script. Also, prescriptions for these medications can no longer be called in, faxed or electronically submitted to your pharmacy. You must get a physical script and bring it to the pharmacy.

U.S. Pain Foundation immediately issued a press release and sent a statement to all our Pain Warriors expressing our concerns on the issue, both as chronic pain patients and as a foundation for chronic pain advocacy. **U.S. Pain Statement on the FDA Announcement:**

The U.S. Pain Foundation today announced disappointment in the FDA’s decision to restrict access to pain medications that are critical to the daily lives of the estimated 100 million Americans who are living with chronic pain.
While US Pain understands and supports the need of the government and law enforcement agencies to reduce prescription drug abuse, doing so on the backs of those who responsibly use these medications is unfair.

The FDA recommendation of rescheduling of hydrocodone combination products to Schedule II will place a huge burden on those who struggle to live with pain everyday.

Patients who rely on these medications will now be forced to see their doctors at minimum every 90 days and in many cases every 30 days even if they have been on a stable, effective dose of their medication for years. They will now need to obtain a physical, written prescription, as refills, faxes, electronic submissions and calling in these medicines to pharmacies will no longer be allowed. This will be extremely burdensome for patients who are disabled by their pain and may lack the money, energy, and means to travel, even locally, to their doctors and pharmacies. The added costs for additional office visits may mean that patients could no longer afford these necessary medicines. The shame and stigma so common among people with pain who have lost their ability to work in exchange for a torturous yet invisible disability would only be made worse by having to repeatedly return to the doctor's office just to get a script.

This decision is certain to clog an already overburdened healthcare system because of the increased visits it will require to primary care providers as well as pain specialists who are already limiting access to new patients due to workload.

People with moderate to moderately-severe pain would simply be left to suffer with debilitating pain without their medication until they could get an appointment. Research has now shown that untreated or undertreated pain can become chronic and cause changes in the central nervous system, spinal cord and brain that amplify nerve signals which self-stimulate and worsen over time. We know that pain of this intensity has a deleterious effect on patients' ability to work, sleep, socialize and engage in normal activities of daily living.

Hydrocodone combination products are the most commonly
prescribed medications in the country and for good reasons --they are effective for both acute and chronic pain and are useful and appropriate for a wide range of painful conditions and diseases. The number of Americans now living with pain is staggering. Pain is the number one reason why Americans visit their doctors. The Institute of Medicine has documented that there are more than 100 million Americans living with chronic pain in this country. Approximately 47 million Americans used hydrocodone-containing analgesics in 2011 for pain relief. The costs to individuals, insurers, Medicare and Medicaid for all the additional unnecessary doctors' appointments rescheduling will require is astronomical at a time when our nation is grappling with unsustainable increases in healthcare costs and mounting government deficits.

Attempting to curb prescription drug abuse by restricting access to the most commonly used and highly effective pain medication will unjustly punish millions of law-abiding citizens with pain. Data has shown that 70% of medications that are abused were not prescribed to the individuals abusing them.

Rather than a simplistic, misguided solution to a complex problem, we need equitable solutions to medication abuse that do not harm people forced to live their lives with debilitating pain.

U.S. Pain is not the only one expressing concern about the new FDA regulations. Chronic pain patients have expressed their concern about these new regulations and how they are going to affect the millions of patients who use these medications as part of their daily regimen to manage their pain. U.S. Pain asked chronic pain patients to share their anonymous thoughts about the changes they will be facing. Here were just a few of the reactions:

**From Georgia:** “The new regulations would mean that I have to figure a way to get to a doctor more often (no public transport), then figure out a way to find the money to pay for the doctor when he knows me and my illnesses well ... The saddest part is that I don't WANT to take the pain meds, but it is a choice between debilitating pain or the meds.”
**From South Carolina:** “It doesn’t matter how it’s controlled. The ones that don’t need it for pain are going get it; and those that do need it, will pay the price because of it.”

**From California:** “I understand the need for regulations, but there is a difference between being medically dependent on a medication and abusing that drug. We take these drugs because we need them to get through the day, not because we want to; this is our painful reality. I suffer from chronic, incurable pain. This is not the life I chose, but this is the life I have. I am not abusing my medications; I am taking them as prescribed by my doctor in an attempt to limit my debilitating pain. Maybe we should be looking at the doctors who prescribe these medications to unworthy patients, not making things more difficult for the patients who obviously need these medications.”

U.S. Pain wants you all to know that we will continue to advocate for pain care and patient rights, including both medications and complimentary therapies. While U.S. Pain understands and supports the need of the government and law enforcement agencies to reduce prescription drug abuse, doing so on the backs of those who responsibly use these medications is concerning and unfair.

We encourage you – patients with pain – to comment on the effects the FDA regulations will have on you by viewing the links below.

**Cindy Steinberg, Director of National Policy and Advocacy for U.S. Pain Foundation, was interviewed on NPR’s show, *Marketplace*. Please listen by clicking the below link.**

**NPR link:** [http://www.marketplace.org/topics/health-care/whats-schedule-ii-narcotic](http://www.marketplace.org/topics/health-care/whats-schedule-ii-narcotic)

Cindy was also interviewed, and quoted, in an article by syndicated health writer, Judy Foreman:

**Common Health Blog:** [http://commonhealth.wbur.org/2013/10/fda-opioid-control-tightens](http://commonhealth.wbur.org/2013/10/fda-opioid-control-tightens)