



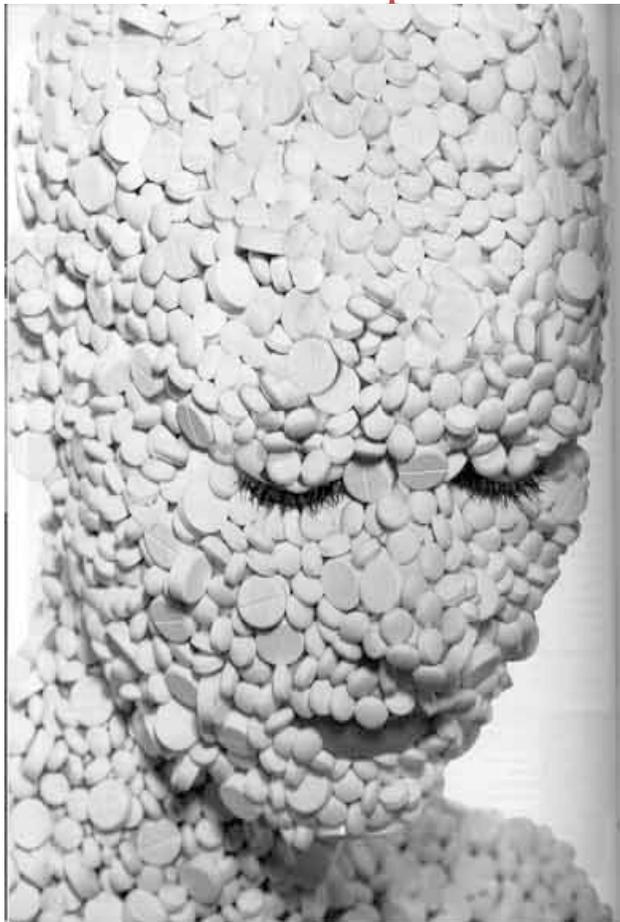
<http://www.TheRehabCenter.com>

Focus on long-term opioids in the treatment of chronic non-cancer pain

In this edition, we highlight recent developments that crystallize the controversy regarding the use of long-term opioid medications for chronic, non-cancer pain.

We summarize a series of recent documents advocating for and against changes in the FDA's regulatory stance regarding the prescription of these.

At present, the FDA indicates opioid analgesics for "moderate to severe pain." The Physicians for Responsible Opioid Prescribing (PROP) recently submitted a petition to the FDA asking for changes to opioid analgesic labels. The petition states that the present FDA guidelines suggest that opioids are safe and effective for long-term use, whereas this is not substantiated by current research. It cites



From Newsweek, 6/22/1997

numerous findings of widespread harm and danger associated with the prescription of opioids and makes appropriate recommendations.

The Congressional Caucus on Prescription Drug Abuse followed up with a letter to the FDA Commissioner requesting expedited review of this petition

In response, the APS issued a letter asking the FDA not to change its labeling of opioid products at this time. We review these important documents below.

The original documents can be read by going to our website, www.TheRehabCenter.com, and clicking on the links on the home page, under "News and Articles."

Scientific Bases for
the PROP Petition

Page 2

Specific Actions Requested
by the PROP for Changes to
Opioid Analgesic Labels

Page 2

The APS Responds

Page 3



The PROP petition

The Physicians for Responsible Opioid Prescribing (PROP) comprises clinicians, researchers, and health officials from fields that include Pain, Addiction, Primary Care, Internal Medicine, Anesthesiology, Neurology, Emergency Medicine, Toxicology, Rheumatology, and Public Health.

The PROP submitted a Citizen Petition to the Dockets Management Branch of the FDA on July 25, 2012, which was followed by a request for expedited review of said petition by the Congressional Caucus on Prescription Drug Abuse, dated July 26, 2012. The PROP petition listed the following data, along with references for these, as bases for their petition that the FDA alter its regulatory stance regarding chronic opioid therapy (COT) for chronic non-cancer pain (CNCP).

Statements of Scientific Basis for Petition:

1. Over the past decade, a four-fold increase in prescribing of opioid analgesics has been associated with a four-fold increase in opioid related overdose deaths and a six-fold increase in individuals seeking treatment for addiction to opioid analgesics.
2. Prescribing of opioids increased over the past 15 years in response to a campaign that minimized risks of long-term use for CNCP and exaggerated benefits.
3. Long-term safety and effectiveness of managing CNCP with opioids has not been established.
4. Recent surveys of CNCP patients receiving COT have shown that many continue to experience significant chronic pain and dysfunction.
5. Recent surveys using DSM criteria found high rates of addiction in CNCP patients receiving COT.
6. A large sample of medical and pharmacy claims records found that two thirds of patients who took opioids on a daily basis for 90 days were still taking opioids five years later.
7. Patients with mental health and substance abuse comorbidities are more likely to receive COT than patients who lack these risk factors, a phenomenon referred to as *adverse selection*.
8. Three large observational studies published in 2010 and 2011 found dose-related overdose risk in CNCP patients on COT.
9. COT at high doses is associated with increased risk of overdose death, emergency room visits and fractures in the elderly.

Specific Actions Requested

The PROP Citizen Petition listed the following requested changes:

Specific Actions Requested For Changes To Opioid Analgesic Labels:

1. Strike the term “moderate” from the indication for non-cancer pain.
2. Add a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain.
3. Add a maximum duration of 90-days for continuous (daily) use for non-cancer pain.

The American Pain Society takes issue and requests that the FDA not change labeling

In a letter to the FDA Commissioner dated August 8, 2012, the APS registered their objection to the PROP Petition, stating that it is their belief that there is *“an insufficient scientific evidence base to support these recommendations,”* despite the multiple studies and published accounts referenced in the PROP Petition (see the online report for the full list of references). It is noteworthy that the APS did not report any scientific evidence to support their objection to the PROP recommendations. Nor does the APS offer any evidence that might contradict the PROP’s contentions; namely, that COT has **not** been proven either safe or effective for CNCP, and that the increase in opioid prescriptions has been associated with considerable harm and damage to society overall.

Although no reference is made to any substantiating studies, the APS makes the following claim: *“It is clear that there are sub-populations of patients with chronic pain for whom the risk-benefit balance is better for opioids (sometimes beyond the limits proposed by the PROP physicians) than for alternative treatments; for some patients, opioids are clinically appropriate for treatment of moderate pain, or at doses higher than 100mg morphine equivalents per day, or for longer than 90 days or a combination of these.”*

The letter then goes on to call for further research, recognizing that, *“At present, we lack adequate evidence to predict which patients are which.”*

The risks of addiction, accidental falls, and death are not specifically addressed in this letter.

Multidisciplinary Care Identified as Means to Improve Pain Outcomes and Reduce Reliance on Opioids as Cornerstone of Treatment

Despite the admitted lack of research support for the contention that COT is in fact appropriate for some patients with CNCP, the APS letter does put forth some salutary recommendations worthy of note.

It states that there is *“a clear need for developing new pain treatments and more widely disseminating current available therapies that achieve desired levels of pain relief and increased quality of life while producing less harm to patients and society.”*

The letter also states that, *“Efforts are needed to increase the availability of multidisciplinary care in order to provide patients with comprehensive evaluation and treatment of their*

pain. This will both improve pain outcomes and reduce reliance on opioids as the cornerstone of treatment for chronic pain.”

We applaud this recommendation, as it is in fact been long borne out by research and clinical experience. For over 25 years, The Rehab Center has been the premier provider of comprehensive treatment aimed at restoration of function and quality of life for patients with chronic pain throughout North and South Carolina.

We remain committed to offering the best possible treatment to help patients reduce their pain and suffering while minimizing the risks of addiction, accidents, and death.