

Attachment C

OXYCONTIN RISKS AND THE FDA

Drug safety is rapidly becoming a major public health issue as fueled by current events which reveal that the FDA has often failed to properly monitor the long-term risks of many pharmaceuticals that were often rapidly approved. The arthritis "painkillers" are now "under the gun", especially after the recent withdrawal of Vioxx by Merck & Co. because of an increased risk of cardiovascular events, even though the FDA had known about problems with this drug for years. Likewise, attention has now turned to Pfizer's blockbuster arthritis drug, Celebrex, because of a similar finding in just one study released by the drug company yesterday. Amazingly, the FDA has also been well aware of adverse events caused by the powerful time-released opioid, OxyContin during the last five years, especially after the indications for use were expanded from severe to MODERATE chronic pain. Yet they continue to exhibit inertia under the influence of the manufacturer, Purdue Pharma and other pain-related interests who have trivialized the potential adverse effects of this drug, while ignoring the continual pleas to remove moderate pain from indicated uses, despite mounting evidence of addiction, crime, overdose, and death. In addition to money and politics which have been well-documented, what are the actual medical reasons why the use of this very effective but potentially deadly pain reliever should be LIMITED only to patients with chronic pain caused by cancer, or other types of intractable tissue lesions which cause severe pain?

The important message of the pain movement, that pain is often under-treated, MUST also include the understanding that good medical management may require a whole range of options including pharmacological agents other than opioids as well as valuable non-drug therapies, the selection of which is based upon correctly diagnosing both the cause and type of chronic pain. There is no question that the case for opioids has been overstated, while at the same time other types of pain therapies have been understated, markedly increasing the volume of prescriptions for OxyContin sustained-release capsules which have then spilled into our streets and schools. In many instances, chronic pain and opioid therapy have become synonymous, as pain is superficially viewed as a "disease unto itself". In other words, symptoms have often been treated with opioids irrespective of cause. This is contrary to the principles of good medicine which teaches medical students to always search for the cause of symptoms, such as fever, cough, and pain. What if cough were treated in isolation without a complete evaluation for its potential underlying causes? Opioid drugs, which are also effective cough suppressants, would then be the main avenues of treatment, while the underlying causes of cough such as allergies, bronchitis, pneumonia, tuberculosis, or cancer may go undetected. Thus, unless pain is related to its cause, many untoward outcomes may ensue, particularly from the excessive, non-selective use of potent chemical compounds like OxyContin.

The brain plays a major role in the generation of the sensation and feeling of pain and in many instances may be the only source of pain [central pain], especially when pain does not originate from tissue destruction like cancer, but from a wide range of psychosocial stress [e.g. states of anxiety and/or depression which may be associated with muscle and joint pain as in fibromyalgia].

Broadening the indication for OxyContin to moderate pain opened up the use of this drug to a large population of patients with this type of central pain originating from biological brain mechanisms, but requiring therapies other than opioids which may have profound adverse effects on the brain. In this group of patients, opioids may not only be harmful but occasionally lethal. In addition, the broadened indications for OxyContin have increased prescriptions to addicts and drug dealers which has fueled the explosion of addictive behavior, crime, and recreational drug use. The many tragic consequences from the wide availability of this powerful drug are vividly and well-documented on this excellent web site.

How can the FDA be holding an expert review in two months to re-evaluate all of the remaining Cox-2 inhibitor painkillers, while at the same time refuse to re-consider meeting to limit the indications for one of the most potent of all painkillers, OxyContin, especially in view of the numerous tragedies which have already occurred? Since higher doses over a prolonged time are major factors in the increased cardiovascular risks of the Cox-2 drugs, why are these issues not being addressed with OxyContin as well? Does anyone actually believe that chronic pain patients, with stress-related pain of central origin who are taking inappropriately high doses of OxyContin over time, have adequate mental and physical function, and are not at major risk for addiction, overdose, death, intentional suicide, and theft by others of their high-priced, time-released capsules so popular on the street? Unlike the situation with the Cox-2 agents, the dangers with OxyContin extend well beyond individual victims to widespread psychosocial effects upon families, friends, and society at large.

OxyContin is a valuable drug for severe chronic pain produced by documented tissue damage, but not for most of the large population of patients with non-tissue, central pain falling under the current troublesome "moderate" pain indication, which can usually be adequately treated with non-opioid interventions, as related to the correct diagnosis and derived from competent medical and psychosocial evaluations. The proper management of chronic non-malignant pain must be individualized and not oversimplified with a "trigger-happy" swift approach which promotes the economic interests of the drug companies at the expense of human lives. Is another disaster looming on the horizon with the approval of similar broad indications for the use of the new sustained-released opioid, Palladone? When will the FDA finally rise to the occasion and seriously monitor long-term drug safety issues while actively taking steps to limit the dangers of OxyContin and all other worrisome prescription drugs? Passive "intervention" influenced by the pharmaceutical industry will no longer suffice.

Perhaps the lessons of these recent events will engender more caution on the part of providers, drug companies, and healthcare regulatory agencies, and SOME DAY lead to a safer, less drug-oriented, more comprehensive approach to patient care.

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