

ATTACHMENT A

www.recalloxycontinnow.org

RECALL OXYCONTIN NOW

The Lee Coalition for Health in Lee County, Virginia has initiated the **National Petition** to recall OxyContin. While this is a complicated issue with many factors to consider, we feel that the pain and suffering brought to countless families and communities by the abuse of the drug far surpasses the benefits. It is clear by now that the best interests of the public health are served by the recall of OxyContin.

Why Recall OxyContin?

1. Fifteen months ago, we knew that some counties in Maine and our region in southwest Virginia were areas of heavy OxyContin abuse, dependence, and addiction. It's apparent over the last year that there has been extensive and rapid spread of this problem. There are major problems in Maine, Pennsylvania, New Jersey, Ohio, West Virginia, Maryland, Kentucky, Virginia, North Carolina, South Carolina, Florida, Louisiana, Mississippi, Wisconsin, Alaska, and Washington. It is being seen in a number of other areas. It is a national problem.
2. There are a number of important measures to take in trying to cope with this problem. Public education, prevention initiatives, more prudent physician prescribing, better tracking and detection systems for prescription fraud or diversion, more comprehensive law enforcement efforts, and greatly expanded treatment capacities -- are all critically important measures. However, all of these will move too slowly and will fall short in halting the rapid and devastating spread of the OxyContin abuse epidemic in the United States.
3. The pain and suffering brought to countless families and communities by the abuse of the drug greatly surpasses the benefits of the drug.
4. It is important to understand that there are very good alternatives to OxyContin for patients with severe pain. A recall of OxyContin would not mean that the medical community would be abandoning the treatment of severe pain. As physicians, this is one of our largest responsibilities -- the thoughtful and compassionate treatment of pain. There are several other good pain medications on the market that are as effective and as strong as OxyContin. These include transdermal fentanyl patches, sustained release morphine pills and methadone tablets. Patients with severe pain can be reassured that we do have equally effective medications and at least some of these have less abuse potential than OxyContin.
5. OxyContin can, should, and will be re-formulated to a preparation of much less abuse potential. It needs to be off the market until that is done.

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Prior to going online July 20, 2001 - Over 6.950 signatures received

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To: international

National Petition to Recall OxyContin

Whereas, OxyContin abuse has reached epidemic proportions in many regions of the United States and has been destructive of countless futures, families, and communities; Whereas, public education; prevention initiatives; more prudent physician prescribing; improved treatment services; and more comprehensive law enforcement efforts---are all critically important, but much more is needed to halt the increasingly widespread abuse of Oxycontin; We, the undersigned, call upon the FDA and Purdue Pharma to recall OxyContin until it can be reformulated to a medication of minimal abuse potential.

Sincerely,

The Undersigned

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The National Petition to Recall OxyContin Petition to international was created by and written by Art Van Zee, MD. This petition is hosted here at www.PetitionOnline.com as a public service. There is no express or implied endorsement of this petition by Artifice, Inc. or our sponsors. The petition scripts are created by Mike Wheeler at Artifice, Inc. For Technical Support please use

www.recalloxycontinnow.org

700 online Signatures

1-16-05

6950 signatures prior to going online

450 additional (pen and paper)

**signatures since petition introduced
in California October 2004**

1-16-05

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300 250 200 150 100 50

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our simple Petition Help form.

Epidemic of OxyContin Abuse

Dr. Art Van Zee

July 20, 2001

In my experience in primary care general internal medicine for the last 25 years in Lee County, there has always been a certain level of drug abuse -- both of illegal drugs and prescription drugs. However, there has never been anything like what we have witnessed in the last two years. There has been a virtual epidemic of Oxycontin abuse and subsequent opioid (narcotic) addiction. Oxycontin has been snorted or injected IV, males and females, from mid-teens to early forties. There have been numerous over-doses (some fatal), infections, increasing Hepatitis C, and occasional case of endocarditis related to this. Numerous young people have been losing their jobs, vehicles, houses, and children to this addiction. Many of these young people are very good kids, coming from good solid families, and who have had bright, promising futures until they did make the mistake of recreationally using and abusing prescription drugs. Oxycontin became rapidly addicting for them, and they have suffered severe consequences of their opioid addiction, devastating not only their own lives but the lives of their families and loved ones. There are very few families in our region who have not been directly or indirectly affected by this problem. The medical, personal, social, and societal toll has been, and continues to be, huge. The medical community has not had the capacity or resources to deal with the large scale opioid dependence that we have had. In-patient and out-patient facilities are limited. At our closest in-patient drug detoxification facility -- "The Laurels" in Lebanon, Virginia, the percent of patients using opioids has increased from 18% to 44% in the last 4 years. Our closest methadone maintenance clinic in Knoxville is a two and a half hour drive, and many parents leave at 4A.M. to drive their children down to the clinic. The DRD Knoxville Medical Clinic can document what a tremendous increase in opioid addiction there has been in the region in the last few years. The Life Center of Galax opened an out-patient methadone maintenance clinic in March, 2000 -- anticipating about 15 patients at the end of the first year, based on the known prevalence of heroin in the region. They had 30 admissions within the first two weeks of opening, and within 6 months had 254 patients, 95% of them entering the program with Oxycontin addiction. Law enforcement has been over-whelmed by the associated problems, as drug related crime has sky-rocketed. The county sheriffs in the region document that 70 - 80% of the major crime over the last two years has been drug related, and most of that Oxycontin.

The county Social Services Departments have likewise been over-whelmed. The number of children needing to be placed in foster care has tripled over the last 4 years in Lee County, primarily related to Oxycontin abuse.

In the spring of 2000, the Oxycontin abuse epidemic appeared from the media to be primarily located in southwest Virginia and Maine. Numerous other states now have major problems with this including Pennsylvania, Ohio, West Virginia, Kentucky, Maryland, North Carolina, South Carolina, Florida, Alabama, Mississippi, Louisiana, and Alaska. Other states including New Jersey, Arizona, Wisconsin, Michigan, and Kansas are beginning to record significant problems. Clearly, this is a growing national problem.

Alternatives to OxyContin

There are several strong pain medications (opioids) which are just as effective as treating severe pain as in Oxycontin. There are no studies in the medical literature which demonstrate Oxycontin has clear cut superiority over immediate release oxycodone, controlled release morphine, transdermal fentanyl patches, or methadone when used in the treatment of severe pain. Some of these have less abuse potential, and some of these offer significant cost savings over Oxycontin. In reviewing oxycodone and Oxycontin in the September 17, 2001 issue, The Medical letter concluded:

"Oxycontin is a q12hour controlled-release formulation of oxycodone that can be used effectively in the treatment of pain due to cancer and, occasionally, other types of chronic pain. There is no evidence that oxycodone offers any advantage over appropriate doses of other opioids, and it appears to have the same potential for addiction as morphine."

Some of the studies are summarized briefly below--

Comparison: Immediate release oxycodone versus Oxycontin

Hale ME, et al Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back pain Clin J Pain 1999 Sep;15(3): 179-83 ** Conclusions: 47 Patients randomized "controlled-release oxycodone given every 12 hours was comparable with immediate-release oxycodone given four times daily in efficacy and safety...."

Kaplan R, et al Comparison of Controlled-Release and Immediate-Release Oxycodone Tablets in Cancer Pain J Clin Oncol 1998 Oct;16(10):320-7 ** Conclusions: 160 patients, double blind study "CR and IR oxycodone were equally effective in the management of cancer-related pain" - - ".the adverse event profiles of CR and IR oxycodone were similar. Overall, however, significantly fewer adverse events were reported for CR oxycodone compared with IR oxycodone..." (somewhat less nausea and vomiting with CR oxycodone)

Stambaugh JE, et al Double-Blind, Randomized Comparison of the Analgesic and Pharmacokinetic Profiles of Controlled and Immediate-Release Oral Oxycodone in Cancer Pain Patients J Clin Pharmacol 2001 May;41(5):500-6 ** Conclusions: 32 Patients "CR provides equivalent analgesia as IR oxycodone with the same patient acceptance profile" "..similar incidences and numbers of reports of individual adverse events considered related to the IR and CR drug"

Comparison: Controlled-release morphine versus controlled-release oxycodone (Oxycontin)

Heiskanen T and Kalso E. Controlled-release oxycodone and morphine in cancer related pain. Pain 1997 Oct;73(1):37-45 ** Conclusions: 45 Patients in a double-blind, randomized, cross-over "the two opioids provided comparable analgesia" "the total incidence of adverse experiences reported by the patients was similar, but significantly more vomiting occurred with

morphine, whereas constipation was more common with oxycodone."

Mucci-LoRusso P, et al Controlled-release oxycodone compared with controlled-release morphine in the treatment of cancer pain: a randomized, double-blind, parallel-group study. *European Journal of Pain* (1998) 2:239-249 ** Conclusions: 100 patients-- "controlled-release oxycodone was effective as controlled-release morphine in relieving chronic cancer-related pain.." "the side-effect profiles of CR oxycodone and CR morphine were similar overall in this trial."

Bruera E, et al Randomized, Double-blind, cross-over trial comparing safety and efficacy of oral controlled-release oxycodone with controlled-release morphine in patients with cancer pain. *J. Clin Oncol* 1998 Oct;16(10):3222-9 ** Conclusions: 23 patients "There were no significant differences detected between the two treatments in ...adverse events, or clinical effectiveness..."

There are no studies that we are aware of comparing controlled-release oxycodone (Oxycontin) with transdermal fentanyl or oral methadone for treatment of severe chronic pain.

There are a few studies comparing transdermal fentanyl with oral morphine.

Transdermal fentanyl versus oral morphine

Payne RJ Quality of life and cancer pain: satisfaction and side effects with transdermal fentanyl versus oral morphine. *Clin Oncol* 1998 April 16(4):1588-93 Conclusions: 504 patients "these data suggest that patients are more satisfied with transdermal fentanyl compared with sustained-release morphine"

Ahmedzai S.J. Transdermal fentanyl versus sustained-release oral morphine in cancer pain: preference, efficacy, and quality of life. *J. Pain Symptom Management* 1997 May; 13(5):254-61 Conclusions: both were equally effective in terms of pain control: there was less constipation and sedation with fentanyl.

Art Van Zee, MD
Lee Coalition for Health
10/1/2001

What is the Lee Coalition for Health?

Lee Coalition is a non profit- coalition of professionals and other concerned citizens founded 10 years ago to promote health and wellness issues in Lee County, Virginia. Some of the Coalition projects have included:

- An annual free cancer screening for Lee County residents for the last 10 years.
- Tobacco education in the middle schools.
- Smoking cessation classes.
- Fire prevention activities.
- Healthy heart cook- books.
- A community smoking cessation contest.
- After prom party.
- Asthma camp.
- Drug, alcohol, and tobacco prevention and treatment initiatives