

The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing

There appear to be at least three major factors which have played a major role in the epidemic of OxyContin abuse which has affected so many regions of the country. First, there has been an obvious problem with physician mis-prescribing and over-prescribing of this drug. Secondly, this epidemic has been a vicious indicator of the alarming degree of prescription drug abuse in this society. Thirdly, the promotion and marketing of OxyContin by Purdue Pharma has played a major role in this problem. Below is a more detailed look at some of these promotion and marketing practices.

1. Beach Hats and CDs

Long past the time last year when Purdue Pharma was aware of rapidly increasing abuse, addiction, over-doses, and accelerating drug related crime in certain regions of the country--the company was giving out to physicians beach hats sporting the "OXYCONTIN" logo in bold letters, CDs of swing music ("Swing in the Right Direction") and pedometers--OxyContin--"A step in the right direction". While Purdue has since stopped this kind of promotion amidst a barage of criticism, it is reflective of their attitude, marketing, and promotion.

2. Pain Management Talks and Seminars

In recent years, Purdue brought in 2,000 to 3,000 doctors to three day retreats in Arizona, California, and Florida for company sponsored work-shops on pain management. Some of these physicians were then recruited by Purdue to serve as paid speakers at Purdue sponsored medical meetings.¹ It is well documented that this type of pharmaceutical company sponsored symposia very significantly influence physician prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.²

¹New York Times, March 5, 2001 "Use of Painkiller Grows Quickly, Along with Widespread Abuse"

²Orlowski JP The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns. Chest 1992; 102(1):270-3

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Additionally, Purdue sponsored an estimated 7,000 "pain management" seminars around the country--stressing the importance of aggressive treatment of pain with an enthusiastic emphasis on opioids for chronic non-malignant pain.

3. Other targeted marketing and promotion to physicians

It is well documented that drug companies compile "prescriber profiles" on individual physicians--detailing the prescribing patterns of physicians nation-wide--in an effort to influence or sway doctors' prescribing habits. Through the profiles, a particular drug company can identify the highest and lowest prescribers of a particular medicine in a single zip code, county, state or the entire country.³ Purdue acquired from I.M.S. Health, a leading pharmaceutical market research company, the information of which physicians prescribed the largest numbers of opioids.⁴ This information would apparently prove quite useful in the company's attempt to influence physicians' prescribing habits nation-wide.

4. Purdue and the Marketplace--Creating the Demand

Over the last 15 years, there has been a substantial change in the medical community in regards to many issues concerning pain and pain management. There was increasing attention paid to improving the treatment of pain not only with acute pain and cancer related pain, but with chronic non-malignant pain. There was increased attention by pain management specialists on the role of opioids in all three of these clinical situations. There were small and limited studies that suggested that there might be a role for opioids in chronic non-malignant pain in selective patients. Purdue Pharma not only recognized the changing clinical land-scape, but saw this as a business opportunity. Purdue, which had introduced a sustained-release morphine--MS Contin--in 1985 for the treatment of cancer pain, began to promote MS Contin for noncancer pain as well.

³ New York Times Nov 16, 2000 "High-Tech Stealth Being Used to Sway Doctor Prescriptions"

⁴ Personal meeting--Lee Coalition for Health with Purdue Pharma, March 26, 2001 information by Michael Friedman, Exec VP, Purdue

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Purdue's promotion and marketing of MS Contin did result in a strong "Warning Letter" from the FDA in 1996--"...we have concluded that Purdue is disseminating promotional materials for MS Contin that contain statements, suggestions, or implications that are false or misleading in violation of the Federal Food, Drug, and Cosmetic Act.... This violation is occurring despite repeated notification to Purdue by DDMAC that claims of product superiority were unsupported and were false and/or misleading and in violation of the Act."⁵

Purdue actively promoted to patients and doctors that unmet pain needs were of epidemic proportion; that it was much more treatable than had been previously thought; and that in many cases, it could, and should, be treated with opioids. Purdue contributed generously to patient-advocacy organizations, including the American Pain Foundation, the National Foundation for the Treatment of Pain and the American Chronic Pain Association.⁶ In Canada, Purdue has co-sponsored the "Patient Pain Manifesto" --recently announced by the Canadian Pain Society--which calls for a "Bill of Rights" for patients and their families regarding pain treatment.⁷ Through its web-site "Partners Against Pain" Purdue consistently over-stated the benefits of opioids in chronic non-malignant pain while trivializing the risks, particularly the risks of addiction. (see attached documentation--"Partners Against Pain" by this author)---All of the above mentioned direct and indirect marketing and promotion for the liberalization of the use of opioids in chronic non-malignant pain raises a multitude of serious questions for the medical community in general, the pain management community in particular, for the FDA which is charged in part with regulation of the pharmaceutical industry for the protection of the public health, and for the DEA which is left with having to deal with so much of the difficulties of a catastrophe like this--whether it is the amphetamine disaster of a few decades ago, or the tragic

⁵ FDA letter to Dr. Richard Sackler, President, Purdue--available for review on the FDA web site

⁶ New York Times Magazine July 29, 2001 "The Alchemy of OxyContin: From Pain Relief to Drug Addiction"

⁷ Greg Woods reports, Wednesday, June 6, 2001

OxyContin disaster now.

While no experienced practitioner of medicine or any student of the issues involved would suggest that there is never a place for opioids in chronic non-malignant pain, the issues in contention revolve around how selective one needs to be in initiating treatment with opioids for chronic non-malignant pain, and what the risks are of addiction. Dr. Russell Portenoy, an expert of international eminence in these issues and an advocate for opioid therapy in very selected patients with chronic non-malignant pain, wrote in his review of the subject in 1996--"The limited number of controlled trials, combined with disparities and inherent biases of the survey literature, preclude definitive conclusions about the risks and benefits of long-term opioid therapy. Nonetheless, it is reasonable to infer from these conflicting results that there is a spectrum of patient responses. On one end of this spectrum is a "successful" subpopulation that achieves sustained partial analgesia, without the development of treatment-limiting toxicity, functional deterioration, or aberrant drug-related behaviors. Some of these patients achieve functional gains as pain declines. On the other end is a subpopulation that deteriorates during opioid therapy. This deterioration can be characterized by worsening pain and disability, the development of aberrant drug-related behaviors, or both."

"Most pain specialists endorse this view of opioid therapy and, consequently, no longer debate the role of opioid therapy in absolute terms. For pain specialists, the issue is not whether opioid drugs should ever be used in the treatment of chronic pain, but when and how. Although this shift in consensus may not be shared by all specialists, and has certainly not disseminated widely to other professional disciplines, it is noteworthy, and suggests that the use of opioid therapy for chronic non-malignant pain must now be evaluated as a potentially salutary therapeutic option for carefully selected patients. From this vantage, all those who might become involved in this therapy--clinicians, pharmacists, regulators, and patients--could benefit from a clear

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understanding of the evidence that defines its risks and benefits.”⁸

Unfortunately, since Dr. Portenoy's published article in 1996--citing the scientific literature's inability to make definitive conclusions about the risks and benefits of long-term opioid therapy, and advocating opioid therapy for carefully selected patients--there is not any further articles in the literature which would provide for the medical community more recent data that would define more clearly what the risks and benefits are of long-term opioid therapy in this population. That lack of good data has not hindered the enthusiasm of Purdue's marketing and promotion. Never has long term opioid therapy received such promotion--direct and indirect--by the pharmaceutical industry, as mentioned above. And never have the primary care physicians--whose back-ground in pain and addiction issues have admittedly been sub-optimal--been so targeted in the promotion of an opioid as they have by Purdue Pharma and OxyContin. The success of the promotional campaign was reflected in the fact that from 1996 to 2000, the use of other commonly used opioids (codeine, hydrocodone, morphine, and hydromorphone) grew 23% while OxyContin prescriptions dispensed during the same period increased by over 1800%.⁹ The fact that there are no studies in the medical literature demonstrating clear-cut superiority over older preparations such as sustained release morphine makes the promotion and marketing an even greater commercial success for Purdue Pharma.

⁸ Portenoy RK "Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective" J Law Med Ethics 1996 Winter;24(4): 296-309

⁹ statistics, DEA, Office of Diversion Control

Personal Conclusions

1. I would re-iterate that I feel there are at least three major factors involved in the OxyContin abuse epidemic--physician mis-prescribing and over-prescribing; the alarming prevalence of prescription drug abuse in this country; and the promotion and marketing practices of the maker of the drug, Purdue Pharma.
2. Clearly most of the regions of the country that are most affected by the OxyContin abuse epidemic have been the areas of the country where it was simply most available, i.e., where it was prescribed in unusually large amounts.¹⁰ This re-inforces the old observation that if a drug can be abused, it will be abused. And simply, by extension, if an abusable drug is widely available, it will be widely abused.
3. I would hope that several concrete changes can come out of what has been learned from the OxyContin abuse epidemic.
 - (A) It would be my hope that there is a change in the regulations that govern the pharmaceutical industry's marketing and promotional practices. Just as there is a very real difference between non-controlled drugs and controlled drugs, there needs to be a very real difference in regulations for how pharmaceutical companies can promote and market controlled drugs versus non-controlled drugs. The existing regulations have not served the public health well.
 - (B) Hopefully, with available technology, it would be a standard in the pharmaceutical industry that any marketed opioid would need to be formulated so as to minimize the abuse potential--as in the Talwin /NX story or with Purdue's current efforts to re-formulate sustained release oxycodone with naltrexone. It can be done with available technology, it will be done, and hopefully this will become an expectation and standard for the marketing of any opioid in the future.

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¹⁰ US map of OxyContin consumption by state, DEA, Office of Diversion Control

“Partners Against Pain”

On the “Partners Against Pain” web-site sponsored by Purdue Pharma, there is frequent mis-representation of facts that--when taken as a whole--tend to falsely over-sell the benefits and trivialize the risks in the use of opioids for chronic non-malignant pain. Examples follow.

From-- “Patient/Caregiver” menu

“There are 75 million Americans living with pain, although pain management experts say they don’t have to. And the statistics on the cost of pain in America are alarming.”3 paragraphs later..”With the treatments available today, experts say we do not have to live in pain. An array of effective therapies, ranging from relaxation and physical therapies, to prescription pain medications, such as opioid analgesics, can help meet the needs of patients who suffer from various degrees of pain.”

Reality: Opioids are the strongest pain medication available and can alleviate severe pain effectively for many patients. Opioids do not eliminate pain. ---For medication treatment of pain, it would be customary of good medical practice to use a step approach, beginning with non-controlled drugs and, in quite select circumstances, advance to opioids if needed for severe pain.

“In addition, education programs such as Partners Against Pain, play a central role in offering the latest information on pain treatment at the grassroots level.

“Neil Irick, M.D., a noted pain expert in Indianapolis, added ‘Educational efforts such as Partners Against Pain, which inform patients and physicians about the latest developments in pain management, coupled with the new JCAHO standards, form the cornerstone of providing all patients with the very best pain care available, regardless of where they are being treated.’”

Reality: The above gives false reassurance to the patient and caregiver that this is a reliable, non-biased, non-commercial educational site. Dr. Irick has been a paid speaker for Purdue including being featured in promotional videos for Purdue.

(cont.)--Patient/Caregiver

Under 'Pain Killers'

"Recently, however, pain has begun to emerge as a treatable entity in its own right with doctors who specialize in pain management. There are also several methods for enhanced medication delivery including the now ubiquitous patient controlled analgesia (PCA), transdermal opioid patches, and time-release opioids that can be taken as few as two times a day. Another avenue pain specialists pursue is to try 'adjuvant' medications which are approved for uses other than pain but are effective in treating pain (e.g., epilepsy drugs, clonidine). Despite these advances, pain is often left untreated or undertreated for long periods of time before patients find an appropriate doctor and adequate treatment. Unfortunately, pain that is chronically untreated or undertreated may lead to further complications such as poor healing, depression, and immunosuppression. .."

Reality: A stepped approach for pain medication has been the standard in medicine, beginning with drugs with the least potential side effects and progressing if needed in certain patients to controlled drugs, opioids. The patient or caregiver reading the above would not get an accurate view of the customary approach to medication treatment of chronic pain.

From the "Professional Education" menu

"Opioids for Chronic Nonmalignant Pain"

"Recent studies (mostly case studies) have shown that chronic pain patients can take opioids on a long-term basis with favorable results. These studies show that pain reduction was better in patients who used morphine while their functional and cognitive status remained the same. Additionally, with acceptable compliance, patients showed an improvement in pain control which led to an increased amount of activity without excessive tolerance to the selected opioid. It is important for the health care practitioner to keep in mind that some patients may not experience complete relief. It is imperative that physicians inform their patients about their responsibilities when they are prescribed opioids for pain management. The author suggests the use of an agreement form which makes the patient's responsibilities unambiguous."
(Belgrade MJ. Postgraduate Medicine 1999; 106(6): 115-124)

Reality: Going directly to the original article, on finds that Belgrade indicates that it is a "new myth" that 'Addiction almost never occurs when opioids are used for pain control.' He goes on to say that "Although opioids themselves may not cause addiction, the high prevalence of addiction in the general population and the even higher comorbidity of addictive disorders with psychiatric illness mean that a substantial minority of patients with chronic pain treated with opioids display problem behavior that make opioid management arduous, if not impossible. The proportion of problem cases appears to be 10-15% of patients with chronic pain selected for opioid maintenance analgesia."

(cont.) "Professional Education"

from "Opioid analgesia" an essential tool in chronic pain"

"Opioid therapy in chronic malignant and non-malignant pain is beneficial and safe for most people. This article suggests that by following a few basic guidelines, physicians can help patients in pain realize that pain is avoidable."

Reality: These statements over-state the benefits and falsely under-estimate the risks of opioids for chronic non-malignant pain.

from "Opioids and Back Pain: The Last Taboo"

"When will we recognize the role of opioids in chronic back pain? That's a question that more and more medical professionals are asking, as the media focuses new attention on the sad fact that back pain remains poorly controlled."

"Responsibly used, opioids can improve care for selected patients with back pain. But many people still have the out-dated attitude that opioids are taboo in back pain because they 'create' addicts. While opioids can be abused and may be habit forming, clinical experience shows that 'addiction' to opioids legitimately used in the management of pain is very rare.....in trials in almost 25,000 patients with no history of drug dependence, there were only 7 cases of iatrogenic drug addiction."

Reality: Tracing back to original literature, the above figure comes from 3 separate studies summarized below.

- (1) not a study, but a letter to the editor NEJM by J. Porter and H. Jick, 1980, Jan 10; 302(2): 123--reported that of 11,882 patients who received at least one narcotic preparation while hospitalized, there were only four cases of reasonably well documented addiction

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- (2) Perry S. "Management of Pain during Debridement: a Survey of US Burn Units" Pain 13 (1982) 267-280
 --a questionnaire survey of 151 US burn units, regarding analgesic practices for debridement
 --10,000 patients--"not one case of actual iatrogenic addiction could be documented. The 22 patients reported to abuse drugs after discharge all had a prior history of drug abuse"
- (3) Medina J. "Drug Dependency in Patients with Chronic Headaches" Headache, March, 1977, 12-14
 --review of 2,369 patients seen in their clinic with headaches 1975-1976--only 62 patients were actually included in the study; of these only 23 were taking narcotics (propoxyphene or codeine) and of the 23, three were felt to be abusers of their medication

Reality: These studies are quoted on the web site, in literature given to physicians (eg, "Dispelling the Myths about Opioids"), and in literature given to patients who take OxyContin. The reality is that these citations are all in patients who have been exposed to opioids in the acute care pain situation, most hospitalized. They do not give a meaningful assessment of the risks of addiction for patients taking opioids for chronic non-malignant pain.

Dr. Russell Portenoy, an expert of international eminence and an advocate for opioid therapy in very selected patients with chronic non-malignant pain, in reviewing these studies stated "It must be emphasized, however, that neither this observation nor any of the data described previously directly assesses the risk of addiction among chronic nonmalignant pain patients administered opioids for prolonged periods." Portenoy RK "Chronic opioid therapy in nonmalignant pain" J Pain Symptom Manage 1990 Feb;5(1 suppl): S46-62

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Personal Conclusions:

The above review of Purdue Pharma's "Partners Against Pain" website does not purport to be a comprehensive review. However, what is reviewed, I would conclude, does reflect that Purdue through this website has for physicians and patients over-sold the benefits of opioid therapy for chronic non-malignant pain, while providing false reassurance about what the real risks are of addiction for patients taking opioids for chronic non-malignant pain.

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