July 19, 2010

Margaret A. Hamburg, M.D.
Commissioner
United States Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Citizen Petition re: Misleading Claims Concerning OxyContin

Dear Dr. Hamburg:

We are concerned citizens who have experienced firsthand the devastating consequences of prescription drug abuse. We hereby petition the Food and Drug Administration (FDA) pursuant to 21 CFR 10.30 and under 21 USC § 355 to issue a public statement clarifying that there is inadequate clinical evidence to support recent media reports that the newly FDA-approved, reformulated OxyContin is less addictive or less abusable than the traditional OxyContin formulation or other extended-release oxycodone medications.

Statement of Grounds

The FDA on April 5 approved for commercialization Purdue Pharma's new version of the Schedule II pain reliever OxyContin (controlled-release oxycodone hydrochloride). The new OxyContin, which will replace the currently marketed product, is formulated in a manner intended to make more difficult the extraction of the active ingredient for purposes of abuse.

Based upon the information made available to the public by Purdue and FDA at the Advisory Committee meeting on September 24, 2009, Purdue has not conducted any in vivo studies to determine whether this new formulation in fact reduced in any way the potential for abuse of the product, and FDA did not require it to do so. The only studies that Purdue conducted in support of the approval, apart from establishing the bioequivalence of the old and new formulations of OxyContin, were in vitro studies to determine the difficulty of extracting the active ingredient from the formulation. Ultimately, the test of abuse deterrence is not in the test-tube, rather in human reaction. The Centers for Disease Control and Prevention (CDC) reports that opioid abuse is a distinct risk among the teen population. These are non-addicted abusers for whom a baseline understanding – in vivo studies – helps us gauge the potential of deterrence.

Just three months before granting approval of this new OxyContin formulation, FDA released a Draft Guidance on the Assessment of Abuse Potential of Drugs. This guidance sets forth a detailed program of in vitro and in vivo studies designed to evaluate abuse potential. Without explanation, FDA granted approval of the new OxyContin without requiring Purdue to comply with the terms of the disseminated guidance. This hasty approval occurred despite the fact that OxyContin perhaps could be the most abused product ever approved by FDA.

The fact that Purdue did not request – and FDA did not permit – any language in the product label stating that the new formulation is in any way abuse resistant does not mitigate the public perception that the new formulation is indeed abuse resistant. At this time of concern about public health risk, government agencies such as CDC and FDA have been beacons of information and direction.

The recently approved OxyContin reformulation remains a Schedule II Controlled Substance with a high-level abuse potential. OxyContin has a long and widespread history of abuse, according to the National Drug Intelligence Center, and prescribers should exercise great care in determining whether prescribing the new formulation is appropriate for their patients.

Despite clear absence of any scientific foundation and directly contrary to what FDA permitted Purdue to say, the public statement issued by the FDA upon approval of the reformulated OxyContin claimed that the medication "***will likely result in less abuse*** by snorting or injection" and further claimed that, "*the new formulation of OxyContin* ***reduces the likelihood that this drug will be misused and abused,*** *although it can not completely eliminate this possibility*" (emphasis provided). Along with these unfounded affirmative claims about the reduced abusability of reformulated OxyContin, the FDA release acknowledged that the agency will not in fact "*know if the new version of OxyContin is more resistant to drug misuse and abuse*" until after Purdue Pharma "***conduct[s] a post-marketing study*** *to determine the impact of the new formulation on the use and misuse of OxyContin*" (emphasis provided).

Significantly, the press release issued by Purdue Pharma makes no such claims of reduction in abuse or misuse. Indeed, Purdue Pharma's release acknowledges that, "*there is no evidence that the reformulation of OxyContin is less subject to misuse, abuse, diversion, overdose or addiction*" (emphasis in original). While FDA appears to have restricted significantly what it permitted Purdue to say about its reformulated product, the conclusory claims about the addictiveness and abusability of reformulated OxyContin in subsequent news reports are unproven and misleading. In short, in issuing its public statements regarding the new OxyContin formulation, FDA has not acted in accordance with its own guidance and policies. Nonetheless, its action will be viewed by prescribers as the authoritative statement on the abuse liability of the new OxyContin formulation.

Predictably, numerous media reports concerning FDA approval of the reformulated OxyContin contain gross misstatements that could mislead prescribers and the public as to product risks, especially in the context of addiction and abuse. Several such news reports included quotations from Bob Rappaport, M.D., director, Division of Anesthesia and Analgesia Products in the FDA Center for Drug Evaluation and Research. An article headlined, "Controlled-Release OxyContin Approved as Rx ODs Spike," posted online by *Pharmaceutical Executive* on April 7, cited unsupported abuse-deterrent effects of the new formulation, reporting that the new version "adds **fail-safe** mechanisms to keep users from crushing the drug in an effort to inject or snort" (emphasis provided). The full text of this article is attached. Headlines throughout the trade press accounts of the new product approval reinforce this incorrect perception (emphasis provided):

- *About.com:* "FDA Okays **Less Addictive** OxyContin," available at http://usgovinfo.about.com/b/2010/04/14/fda-okays-less-addictive-OxyContin.htm

- *DrugAddictionTreatment.com:* "OxyContin **Addiction Addressed** by Tablet Redesign," available at http://www.drugaddictiontreatment.com/types-of-addiction/prescription-drug-addiction/OxyContin-addiction-addressed-by-tablet-redesign/

- *MedPage Today:* "FDA Okays **Anti-Abuse** Oxycodone," available at http://www.medpagetoday.com/ProductAlert/DevicesandVaccines/19409

- *Scrip News:* "Purdue's **abuse-resistant** OxyContin approved in US," full text below

- *BMI Industry Insights,* "Industry Trend Analysis - New OxyContin Formulation **Approved To Limit Abuse,**" full text below

Prompt FDA action to clarify its claims regarding the abusability and addictiveness of the reformulated OxyContin is now critical and necessary to prevent a repetition of the similar cycle of misleading claims and marketing of the original OxyContin by Purdue Pharma, along with the epidemic rates of abuse and addiction that followed.

When the original OxyContin was first approved in 1995, FDA allowed Purdue Pharma to state that the time-release OxyContin formulation *"is believed to reduce"* its potential to be abused. As part of its marketing effort, Purdue sales representatives told doctors falsely that this statement, rather than simply stating a theory or expectation, meant that OxyContin in fact had a lower potential for addiction or abuse than other pain relievers. These unproven claims, combined with the reality that physicians had been looking for a therapy with an ability to treat pain and better manage risk, OxyContin sales skyrocketed, topping $1 billion by 2001 and jumping nearly six-fold between 1997 and 2005. These massive sales figures were accompanied by widespread reports of abuse and addiction that belied Purdue's marketing claims, at first from rural areas but subsequently spreading both geographically and demographically.

The U.S. Drug Enforcement Administration estimates that by 2008, some 4.8 million people in the U.S. had used OxyContin for a nonmedical purpose at least once. The American Poison Control Centers reported 15,069 case mentions and 7,528 single exposures, involving 13 deaths, related to oxycodone in 2007 alone. From 1998 to 2000, the number of people in the U.S. entering an emergency room because of misusing OxyContin rose 108 percent, and intensified thereafter.

Ultimately, Purdue Pharma and three former executives pleaded guilty in Federal court to felony and misdemeanor criminal charges that they *"misbranded"* OxyContin by fraudulently marketing it for six years as a drug that was less addictive and less prone to abuse because of its time-release formula. The company paid $634 million in fines, the third-highest ever for a drug manufacturer in such a case, and the three executives, including its former president and top attorney, paid an additional $34.5 million in fines.

Now, through FDA's press release, the public has once again received unsubstantiated and inaccurate information concerning the abusability and addictiveness of the reformulated OxyContin, in turn raising the danger that the medical community and the public once again will believe the "new" OxyContin is significantly safer than before. This misperception presents a grave and significant risk to the public health and must be corrected.

Actions Requested

We respectfully request that FDA issue a public statement clarifying that there is insufficient in vivo clinical data to support news reports or other claims that the reformulated OxyContin carries less risk of abuse or addiction than the traditional OxyContin formulation or other extended-release oxycodone medications. FDA should clarify that Purdue Pharma has conducted no human studies to evaluate the behavioral abuse and addiction reaction to the new OxyContin, and should counter early media reports making clear there is no basis to conclude reformulated OxyContin is *"less addictive"* in any way, *"limits abuse"* in any respect, or is *"fail-safe"* or *"abuse resistant"* as compared with the original formulation.

Given Purdue Pharma's history of marketing and misbranding, it is critical that the general public and the medical community not be misled into believing without data that the new OxyContin is any safer that the previous formulation. We further request that the FDA direct Purdue Pharma to release a public statement to similar effect, making clear that there is insufficient clinical data to support news reports or other claims that the reformulated OxyContin is less addictive or less abusable than the current OxyContin formulation or other extended-release oxycodone medications.

Environmental Impact

The actions requested in this petition will not have an impact on the environment.

Certification

The signatories to this petition certify that, to the best of our knowledge and belief, this petition includes all information and views upon which this petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Thank you for your attention to this important public health matter. We look forward to your prompt written reply and responsive actions.

Sincerely,

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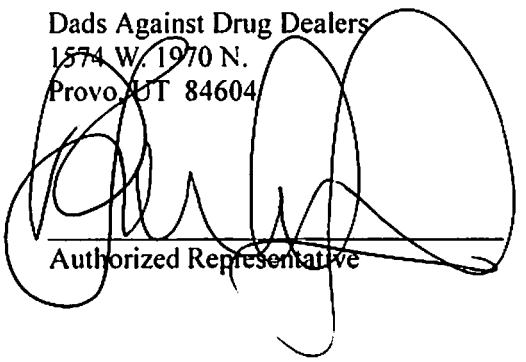

Authorized Representative

Attachments: Three news articles
FDA news release
FDA frequently asked questions
Purdue Pharma news release

Controlled-Release OxyContin Approved as Rx ODs Spike
PharmaExec.com
April 7, 2010

FDA, on Monday, approved a new formulation of the painkiller OxyContin (oxycodone) that's designed to curtail the abuse typically associated with the opioid.

Manufactured by Purdue Pharma, OxyContin has had a history of misuse, going as far as being dubbed Hillbilly Heroin on the street. The new version builds on the current extended release formulation, and adds fail-safe mechanisms to keep users from crushing the drug in an effort to inject or snort it.

That said, FDA still believes that abusers will be able to get high by just taking a larger quantity of the drug.

"Although this new formulation of OxyContin may provide only an incremental advantage over the current version of the drug, it is still a step in the right direction," stated Bob Rappaport, director of the Division of Anesthesia and Analgesia Products in the FDA's Center for Drug Evaluation and Research. "As with all opioids, safety is an important consideration," he said. "Prescribers and patients need to know that its tamper-resistant properties are limited and need to carefully weigh the benefits and risks of using this medication to treat pain."

In related news, the American Journal of Preventative Medicine released a study, on Tuesday, stating that the number of hospitalizations in the US due to overdoses of opioids and sedatives ballooned 65 percent from 1999 to 2006.

Methadone and benzodiazepine overdoses or poisoning increased 400 and 39 percent, respectively. While hospitalization due to overdose of barbiturates and antidepressants dropped 41 and 13 percent.

"Deaths and hospitalizations associated with prescription drug misuse have reached epidemic proportions," stated lead author, Jeffrey H. Coben of the West Virginia University School of Medicine. "It is essential that health care providers, pharmacists, insurance providers, state and federal agencies, and the general public all work together to address this crisis. Prescription medications are just as powerful and dangerous as other notorious street drugs, and we need to ensure people are aware of these dangers and that treatment services are available for those with substance abuse problems."

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Purdue's abuse-resistant OxyContin approved in US
Scrip News
April 7, 2010
By Katie McQue

The US FDA has approved Purdue Pharma's reformulation of OxyContin (oxycodone HCl controlled-release 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg tablets) that has been designed to be less susceptible to misuse and abuse. It is indicated for the management of moderate-to-severe pain where a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

The company said it would start shipping the product to distributers and pharmacies during the third quarter of this year, at which time it will stop shipping its original formulation of OxyContin. To distinguish the appearance of its new product, Purdue has marked an "OP" on the tablet, rather than the "OC" on the currently available tablets. It added that the 60mg and 80mg doses are slightly larger in size than those currently available.

The new OxyContin formulation is intended to prevent immediate access to the full dose of oxycodone in a tablet via cutting, chewing or breaking. Additionally, attempts to dissolve the tablets in liquid result in a gum-like substance that cannot be drawn up into a syringe or injected.

To gain approval, the company had to prove that the new formulation is bioequivalent to the original.

Notably, the company and the FDA both stress that there is no evidence that the new formulation is less subject to misuse, abuse, diversion, overdose or addiction than the original formulation.

"Although this new formulation of OxyContin may provide only an incremental advantage over the current version of the drug, it is still a step in the right direction," said Dr Bob Rappaport, director of the division of anesthesia and analgesia products in the FDA's Center for Drug Evaluation and Research.

The product has appeared before two FDA panels meetings. At the first in May 2008 the agency's experts said the new product was unlikely to reduce abuse or diversion, and may even increase misuse (scripnews.com, 7 May 2008M). The second meeting, last September, however, was successful and the product was endorsed in a 14 to four vote.

Despite this, the panellists who voted in favour expressed reservations and said they recommended approval only because the new formulation appeared no more susceptible to abuse and manipulation than the old one, and the new version may provide a small, incremental advance in safety (scripnews.com, 25 September 2009).

The product will be covered under the class-wide REMS being developed for long-acting opioids and immediate-release methadone. It contains a Medication Guide, Elements to Assure Safe Use, such as healthcare provider training and a timetable for submitting assessments of the REMS.

Purdue Pharma will also be required to conduct a postmarket study to collect data on the extent to which the new formulation reduces abuse and misuse of the opioid.

Competitors
Other players in the abuse-resistant opioid field include King Therapeutics and Pain Therapeutics. Together, they have developed Remoxy (oxycodone), which is formulated as a thick liquid in a hard capsule, which is expected to be re-submitted, after an unsuccessful filing, in the middle of this year (

scripnews.com, 8 July 2009), and Acurox (oxycodone plus niacin), which received a US FDA complete response letter last year (scripnews.com, 3 July 2009).

King received a US approval for its abuse-resistant opioid analgesic Embeda (morphine sulphate plus naltrexone) in August. It was later rapped by the FDA for disseminating misleading information about the product (scripnews.com, 23 October 2009).

Pain has two more abuse-resistant opioid analgesic candidates in its early-stage clinical pipeline, PTI-202 and PTI-721, which are also licensed to King.

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Industry Trend Analysis - New OxyContin Formulation Approved To Limit Abuse
BMI Industry Insights - Pharma & Healthcare, Americas
April 9, 2010

The US Food and Drug Administration (FDA) has approved a new formulation of Purdue Pharma's drug OxyContin (oxycodone). The value-added analgesic will help the pharmaceutical company maintain its portfolio despite pricing, innovation and regulatory pressures. It is BMI's view that drugmakers will increasingly use life-cycle management tactics, such as the launch of new formulations of previously patented drugs.

OxyContin is a powerful opioid painkiller used to treat moderate to severe pain and is the top-selling prescription painkiller in the US. It had sales of US$2.5bn in 2008, an increase of 140% over the previous year, according to data collected by healthcare information company Verispan.

When used correctly, OxyContin is intended to provide slow relief to symptoms associated with cancer, back pain or arthritis over a 12-hour period. As a result, the tablets can be subject to abuse by being crushed and snorted, chewed, or mixed with water and injected - eliminating the time-release factor and allowing for a quick and intense rush to the brain. The more serious short-term risk associated with the analgesic is respiratory depression which could lead to death.

Purdue Pharma have attempted to bypass this substance abuse by including a plastic-like coating, which it hopes will prevent users from crushing, cutting, chewing or dissolving the tablets. Despite this, the drug can still be abused by ingesting more tablets than the recommended dose. The FDA's director of the division of anaesthesia and analgesia products, Bob Rappaport, admitted that the new formulation may only provide 'only an incremental advantage' over the current version but stressed that it was a 'step in the right direction'.

BMI believes that while the drug is an improvement on the previous formulation, it is likely to have only limited effect as a deterrent. Additionally, it does not decrease the chance of developing an addiction in cases where the tablets are prescribed by a doctor. Despite this, BMI welcomes the attempt to fight abuse of the prescription market as it is a major problem in the US, with 5.2mn Americans using prescription painkillers in an inappropriate manner in 2007.

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PURDUE

STATEMENT OF PURDUE PHARMA L.P. REGARDING FDA'S APPROVAL OF REFORMULATED OXYCONTIN® (OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

April 5, 2010 - The U.S. Food and Drug Administration (FDA) approved Purdue Pharma L.P.'s New Drug Application for a reformulation of OxyContin® (oxycodone HCl controlled-release) Tablets.

The reformulation has met FDA criteria for bioequivalence to the original formulation, which means there is no significant difference in the rate and extent of absorption of the therapeutic ingredient.

While similar in appearance to the original formulation, the reformulated tablets have a different marking ("OP") than the currently marketed tablets (marking "OC") and the 60 mg and 80 mg tablets are slightly larger in size than the currently marketed tablets.

Purdue elected to reformulate OxyContin® to be bioequivalent to the original formulation and in an effort to make the tablet more difficult to manipulate for the purpose of intentional misuse and abuse, however, there is no evidence that the reformulation of OxyContin is less subject to misuse, abuse, diversion, overdose or addiction.

OxyContin® continues to be a CII controlled substance with all the attendant risks of Schedule II opioids, specifically that the drug has a high potential for abuse. Use, misuse, or abuse of the drug may lead to physical dependence or addiction (addiction is sometimes referred to as "psychological dependence"). In addition, alteration of the tablet in any manner poses significant risks of overdose and death. The Full Prescribing Information contains warnings about the potential for abuse, diversion, overdose and addiction, including a boxed warning (see below).

Indications and Usage
OxyContin® is a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Usage
OxyContin® is not intended for use on an as-needed basis.

As used here, "moderate" and "moderate to severe" pain do not include commonplace and

ordinary aches and pains, pulled muscles, cramps, sprains, or similar discomfort.

OxyContin® is not indicated for the management of pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OxyContin® is indicated for postoperative use following the immediate post-operative period only if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. (See American Pain Society guidelines.)

OxyContin® is not indicated for pre-emptive analgesia (preoperative administration for the management of postoperative pain).

OxyContin® is not indicated for rectal administration.

Important Safety Information
OxyContin® is contraindicated in patients who have significant respiratory depression, patients who have or are suspected of having paralytic ileus, patients who have acute or severe bronchial asthma, and patients who have known hypersensitivity to any of its components or the active ingredient, oxycodone.

Opioid analgesics have a narrow therapeutic index in certain patient populations, especially when combined with CNS depressant drugs, and should be reserved for cases where the benefits of opioid analgesia outweigh the known risks of respiratory depression, altered mental state, and postural hypotension. Use low initial doses of OxyContin® in patients who are not already opioid-tolerant, especially those who are receiving concurrent treatment with muscle relaxants, sedatives, or other CNS active medications.

Serious adverse reactions which may be associated with OxyContin® Tablet therapy in clinical use are respiratory depression, apnea, respiratory arrest, and circulatory depression, hypotension, or shock. The most common adverse reactions (>5%) include: constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, asthenia, and sweating.

REMS
Working with the FDA, Purdue has developed a Risk Evaluation and Mitigation Strategy (REMS) for OxyContin® Tablets. The OxyContin REMS includes a Medication Guide, Elements to Assure Safe Use, such as healthcare provider training and a timetable for submitting assessments of the REMS.

Product Shipment
The Company expects to begin shipping all dosage strengths of the reformulated product (10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg) to distributors and pharmacies during the third quarter of 2010, at which time Purdue will cease shipping the original formulation.

"We will work with distributors and pharmacies for a smooth transition to the reformulation

that will maintain product supply and protect patient access," said John H. Stewart, President and CEO of Purdue Pharma L.P.

About Purdue Pharma L.P.
Purdue Pharma L.P. and its associated U.S. companies are privately-held pharmaceutical companies known for pioneering research on persistent pain. Headquartered in Stamford, CT, Purdue Pharma is engaged in the research, development, production, and distribution of both prescription and over-the-counter medicines and hospital products. Additional information about Purdue can be found at www.purduepharma.com.

The professional product labeling for OxyContin® Tablets contains the following **boxed warning:**

WARNING: IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE

OxyContin contains oxycodone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. (9)

OxyContin can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. (9.2)

OxyContin is a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)

OxyContin is not intended for use on an as-needed basis. (1)

Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

OxyContin 60 mg and 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for use in opioid-tolerant patients, as they may cause fatal respiratory depression when administered to patients who are not tolerant to the respiratory-depressant or sedating effects of opioids. (2.7)

Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving

opioids should be routinely monitored for signs of misuse, abuse and addiction. (2.2)

OxyContin must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved. Taking cut, broken, chewed, crushed or dissolved OxyContin tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone. (2.1)

The concomitant use of OxyContin with all cytochrome P450 3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir) may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse effects and may cause potentially fatal respiratory depression. Patients receiving OxyContin and a CYP3A4 inhibitor should be carefully monitored for an extended period of time and dosage adjustments should be made if warranted (7.2).

Full prescribing information for OxyContin is available at http://www.purduepharma.com/pressroom/news/OxycontinPI.pdf.

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FDA NEWS RELEASE

For Immediate Release: Apr. 5, 2010
Media Inquiries: Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Approves New Formulation for OxyContin

The U.S. Food and Drug Administration today approved a new formulation of the controlled-release drug OxyContin that has been designed to help discourage misuse and abuse of the medication.

OxyContin is made to slowly release the potent opioid oxycodone to treat patients who require a continuous, around-the-clock opioid analgesic for management of their moderate to severe pain for an extended period of time. Because of its controlled-release properties, each OxyContin tablet contains a large quantity of oxycodone, which allows patients to take their drug less often. However, people intent on abusing the previous formulation have been able to release high levels of oxycodone all at once, which can result in a fatal overdose and contributes to high rates of OxyContin abuse.

The reformulated OxyContin is intended to prevent the opioid medication from being cut, broken, chewed, crushed or dissolved to release more medication. The new formulation may be an improvement that may result in less risk of overdose due to tampering, and will likely result in less abuse by snorting or injection; but it still can be abused or misused by simply ingesting larger doses than are recommended.

"Although this new formulation of OxyContin may provide only an incremental advantage over the current version of the drug, it is still a step in the right direction," said Bob Rappaport, M.D., director of the Division of Anesthesia and Analgesia Products in the FDA's Center for Drug Evaluation and Research.

"As with all opioids, safety is an important consideration," he said. "Prescribers and patients need to know that its tamper-resistant properties are limited and need to carefully weigh the benefits and risks of using this medication to treat pain."

According to the U.S. Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health, approximately half a million people used OxyContin non-medically for the first time in 2008.

The manufacturer of OxyContin, Purdue Pharma L.P., will be required to conduct a postmarket study to collect data on the extent to which the new formulation reduces abuse and misuse of this opioid. The FDA is also requiring a REMS (Risk Evaluation and Mitigation Strategy) that will include the issuance of a Medication Guide to patients and a requirement for prescriber education regarding the appropriate use of opioid analgesics in the treatment of pain.

Purdue Pharma is based in Stamford, Conn.

OxyContin - Questions and Answers

(4/5/2010)

The U.S. Food and Drug Administration has approved a new formulation of the controlled-release drug OxyContin. This new formulation is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose.The new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone.

The following question and answers provide some additional background information on OxyContin, the misuse and abuse of this drug, and the significance of this new technology.

What is OxyContin?

How is OxyContin used to treat pain?

Why is OxyContin abused?

What does the new formulation of OxyContin accomplish? Does it decrease the likelihood that this drug will be misused and abused?

How will FDA know if the new version of OxyContin is more resistant to drug misuse and abuse?

What is OxyContin?

OxyContin is a prescription narcotic pain reliever that was approved by FDA in 1995. It is manufactured by Purdue Pharma LP, and its active ingredient is oxycodone, a derivative of opium.

How is OxyContin used to treat pain?

OxyContin is made to slowly release the potent opioid oxycodone to treat patients who require around-the-clock medical management with an opioid analgesic for their moderate to severe pain. Because of its controlled-release properties, each OxyContin tablet contains a large quantity of oxycodone, which allows patients to take their drug less often—a distinct benefit for patients who are in chronic pain.

Why is OxyContin abused?

The primary reason OxyContin is abused is that this drug, like all opioid narcotics, can produce euphoria (a sense of well-being). Euphoria is the primary reason why people use opioids non-medicinally. Chronic non-medicinal use of euphoric-producing drugs can lead to addiction and dependence.

The wide availability of OxyContin, is secondary reason why this drug is popular to use non-medicinally. Although an individual would need a prescription to legally purchase and use OxyContin medicinally, this drug can be easily obtained through illicit channels. The high volume of OxyContin supply available to the public, and the discrepancy between the fair and black market value of the medicine, contributes to diversion, illicit sale, and abuse of OxyContin.

The rates of OxyContin misuse and abuse remain high—in 2008, the number of new nonmedical users of OxyContin aged 12 or older was approximately half a million.[1]

What does the new formulation of OxyContin accomplish? Does it decrease the likelihood that this drug will be misused and abused?

Over time, individuals have learned effective ways to tamper with OxyContin's controlled-release technology. Tampering with the tablet, via cutting, chewing, breaking, or dissolving, can be very dangerous because it releases high levels of oxycodone all at once.

There have been reports of inadvertent overdose with OxyContin after health care practitioners crushed the drug in order to administer it to patients who could not swallow the tablet.

Tampering with tablets is also popular among individuals seeking OxyContin's euphoric properties. By crushing and snorting, or dissolving and injecting, individuals received a much higher and immediate dose of oxycodone than they would if they swallowed the tablet whole.

The reformulated version of OxyContin is intended to prevent immediate access to the full dose of oxycodone via cutting, chewing, or breaking the tablet. Attempts to dissolve the tablets in liquid result in a gummy substance that cannot be drawn up into a syringe or injected. The new formulation of OxyContin reduces the likelihood that this drug will be misused and abused, **although it can not completely eliminate this possibility**.

The new formulation can still be abused or misused and result in overdose simply by ingesting or administering it in higher than recommended doses. Health care professionals need to remind their patients of the risks associated with using OxyContin not-as-directed.

How will FDA know if the new version of OxyContin is more resistant to drug misuse and abuse?

FDA is requiring Purdue Pharma LP to conduct a post-marketing study to determine the impact of the new formulation on the use and misuse of OxyContin. Additionally, FDA is requiring the manufacturers to follow a Risk Evaluation and Mitigation Strategy (REMS) for this product, which will include the issuance of a Medication Guide to all patients who will use this product

and a requirement for prescriber education on the appropriate use of opioid analgesics in the treatment of pain.

References

1. Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434) Rockville, MD.