

10491

MEDIWATCH

Purdue Pharma L.P.

FDA Approved 11/08/93

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

Mfr report #	2013880
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)					
1. Patient identifier REDACTED	2. Age at event 33 YEARS or DOB:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin DR Tablets, 80 mg (oxycodone hydrochloride)					
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route #1 80 MG SEE TEXT FO		3. Therapy dates (if unk, give dur) #1 - 7/2001 (STOP'D)			
1. DD Adverse Event and/or <input type="checkbox"/> Product problem				6. Diagnosis for use (indication) #1 NON-NALLERANT PAIN		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A			
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> (mo/day/yr) <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent pers damage <input type="checkbox"/> other:		8. Event reappeared after reintroduction #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A			
3. Date of event 7/1/2001		4. Date of this Rept 11/16/2001		6. Lot # (if known) #1 UNKNOWN		7. Exp. Date #1			
5. Describe event or problem A 33-YEAR-OLD FEMALE PATIENT EXPERIENCED A GRAND MAL SEIZURE ON 01JUL01, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 80 MG TABLETS FOR PAIN ASSOCIATED WITH REFLEX SYMPATHETIC DYSTROPHY. APPROXIMATELY THREE YEARS AGO, THE PATIENT BEGAN TAKING OXYCONTIN 10 MG TABLETS. ON UNSPECIFIED DATES, THE DOSE OF OXYCONTIN WAS INCREASED 20 MG TABLETS AND THEN TO 40 MG TABLETS. ON AN UNSPECIFIED DATE, THE DOSE OF OXYCONTIN WAS AGAIN INCREASED TO THREE 80 MG TABLETS THREE TIMES A DAY. THE PATIENT STATED THAT SHE BELIEVED THE TABLETS WERE TO BE TAKEN AS NEEDED. ON 01JUL01, THE PATIENT EXPERIENCED "SMALL SEIZURES ALL DAY LONG, LASTING 10-15 SECONDS." THAT NIGHT, SHE EXPERIENCED A GRAND MAL SEIZURE. THE PATIENT WAS TAKEN TO THE EMERGENCY ROOM AND SUBSEQUENTLY HOSPITALIZED. THE PATIENT RELATED THAT THE RESULTS OF AN EEG (ELECTROENCEPHALOGRAM) WERE "EXTREMELY ABNORMAL." ON 08JUL01, THE PATIENT WAS DISCHARGED FROM THE HOSPITAL. AN UNSPECIFIED DOSE OF DILANTIN (PHENYTOIN) WAS PRESCRIBED TO TREAT THE SEIZURES. OXYCONTIN WAS DISCONTINUED. THE PATIENT IS CURRENTLY TAKING METHARONE FOR HER PAIN. THE PATIENT RELATED THAT SHE CONTINUES TO EXPERIENCE SMALL SEIZURES AND RECENTLY, THE RIGHT SIDE OF HER MOUTH DROOPS AND SHE HAS STARTED DROOLING. REPORTERLY, THE PHYSICIAN ATTRIBUTED THE SEIZURES TO OXYCONTIN. NO FURTHER INFORMATION WAS PROVIDED. **FOLLOW UP INFORMATION RECEIVED ON 06NOV01 FROM THE PATIENT VIA A TELEPHONE CONVERSATION, REVEALED SHE WAS HOSPITALIZED FOR EIGHT DAYS AND IS NOW ON "QUITE A BIT OF DILANTIN."				9. NDC # for prod problems only -				10. Concomitant medical products and therapy dates UNKNOWN	
D. ALL MANUFACTURERS									
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431				2. Phone number (203) 588-8000		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> others			
4. Date Rec'd by Mfr. 11/06/2001				5. CA/NOA# 20-553		IND#			
6. If IND, protocol #				IND#		PLA#			
7. Type of report (check all that apply) <input type="checkbox"/> 35-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 310-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input checked="" type="checkbox"/> follow-up				pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes		8. Adverse event term(s) CONVULS GRAND MAL			
8. Mfr. report number 2013880									
E. INITIAL REPORTER									
1. Name, address & phone # REDACTED									
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no		3. Occupation		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> junk					
MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event. Facsimile Form 3300A									

8003052982

#10756

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	2014990
UF/Dist report #	
FDA Use Only	

ADVERSE EVENT REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

1. Identifier CTED	2. Age at event 42 YEARS or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event	and/or	<input type="checkbox"/> Product problem
2. Is attrib. to event	<input type="checkbox"/>	disability
3. Mth (mo/day/yr)	<input type="checkbox"/>	congen anomaly
4. Life-threatening	<input type="checkbox"/>	required intervention to prevent perm damage
5. Hospitalization -	<input type="checkbox"/>	other:
6. Fatal or prolonged	<input type="checkbox"/>	

3. Date of event	6/2001	4. Date of this Rept	12/07/2001
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5. Describe event or problem

A 42-YEAR-OLD FEMALE PATIENT EXPERIENCED A BOWEL OBSTRUCTION LEADING TO HOSPITALIZATION ON AN UNSPECIFIED DATE, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 20 MG TABLETS FOR POST-OPERATIVE PAIN. AT THE END OF JUNE, THE PATIENT BEGAN TAKING OXYCONTIN 20 MG EVERY 8 HOURS FOLLOWING ABDOMINAL SURGERY. AFTER TAKING OXYCONTIN FOR APPROXIMATELY 3 OR 4 DAYS, THE PATIENT DEVELOPED A BOWEL OBSTRUCTION AND SHE WAS HOSPITALIZED FOR 12 DAYS. OXYCONTIN WAS DISCONTINUED DURING THE HOSPITAL STAY. A FEW MONTHS LATER, THE PATIENT TOOK OXYCONTIN 20 MG EVERY 8 HOURS AGAIN FOR BURSTITIS IN THE SHOULDER. AFTER TWO DOSES THE PATIENT EXPERIENCED NAUSEA, VOMITING AND HEADACHES. OXYCONTIN WAS DISCONTINUED. THE SYMPTOMS ABATED. NO FURTHER INFORMATION WAS PROVIDED.

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)		
#1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride)		
2. Dose, frequency & route		3. Therapy dates (if unk, give dur)
#1 20 MG q8h po		#1 6/2001 (STOP'D)
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced
#1 NON-MALIGNANT PAIN		#1 OQyes <input type="checkbox"/> Ino <input type="checkbox"/> N/A # <input type="checkbox"/> Yes <input type="checkbox"/> Ino <input type="checkbox"/> N/A
6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction
#1 UNKNOWN	#1 UNKNOWN	
9. NDC # for prod problems only		
#1 <input type="checkbox"/> Yes <input type="checkbox"/> Ino <input type="checkbox"/> N/A # <input type="checkbox"/> Yes <input type="checkbox"/> Ino <input type="checkbox"/> N/A		
10. Concurrent medical products and therapy dates		
UNKNOWN		

G. ALL MANUFACTURERS

1. Contact office - name/address		2. Phone number (203) 588-8000
Purdue Pharma L.P. 1 STANFORD FORUM STAMFORD, CT 06901-3431		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
4. Date Rec'd by Mfr - 11/29/2001	5. (AN)OA# 20-553	
6. If INO, protocol #	INO#	
7. Type of report (check all that apply)	PLA#	
<input type="checkbox"/> 15-day <input type="checkbox"/> 10-15-day <input type="checkbox"/> 10-day <input type="checkbox"/> Iperiodic	pre-1958 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product	
8. Adverse event term(s)	OBSTRUCT INTENT NAUSEA VOMIT HEADACHE	
9. Mfr. report number 2014990		

E. INITIAL REPORTER

1. Name, address & phone #			
REDACTED			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no		<input type="checkbox"/> Yes <input type="checkbox"/> Ino <input checked="" type="checkbox"/> Junk	

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/DATA: UNKNOWN

7. Other relevant history, including prexist. med. conditions

ABDOMINAL SURGERY, BURSTITIS IN THE SHOULDER

MED INFI ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003053282

MEDWATCH

Purdue Pharma L.P.

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

Mfr report #	2012218
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION

1. Patient Identifier REDACTED	2. Age at event 58 YEARS	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 111 lbs 111 kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. DCI Adverse Event and/or <input type="checkbox"/> Product problem	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	

3. Date of event	4. Date of this Rept 02/05/2002
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5. Describe event or problem

A 58-YEAR-OLD MALE PATIENT EXPERIENCED "URINARY PROBLEMS" ON AN UNSPECIFIED DATE, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 10 MG AND 20 MG TABLETS FOR PAIN ASSOCIATED WITH FIBROMYALGIA. IN 1998, THE PATIENT BEGAN TAKING OXYCONTIN 40 MG EVERY 8 HOURS (20 MG DAILY). OXYCONTIN 10 MG, AS NEEDED, WAS PRESCRIBED FOR BREAKTHROUGH PAIN. IN APPROXIMATELY FEB01, THE DOSE OF OXYCONTIN WAS INCREASED TO 150 MG A DAY (2 X 20 MG AND 1 X 10 MG EVERY 8 HOURS). ON AN UNSPECIFIED DATE, THE PATIENT EXPERIENCED URINARY PROBLEMS (DESCRIBED AS URGENCY TO URINATE, DIFFICULTY IN GETTING STARTED, PAIN UPON URINATION, INTERMITTENT FLOW). THE PHYSICIAN WAS CONSULTED. THE PATIENT WAS ADVISED TO CONTINUE OXYCONTIN. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/laboratory data, including dates RELEVANT TESTS/LAB DATA: UNKNOWN
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7. Other relevant history, including preexist. med. conditions
HEPATITIS C (1997); CHEMOTHERAPY (1998)

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin ER Tablets, 10 mg (oxycodone hydrochloride) #2 OxyContin ER Tablets, 20 mg (oxycodone hydrochloride)

2. Dose, frequency & route #1 70 MG Q8H PO #2 40 MG Q8H PO	3. Therapy dates (if unk, give dur) #1 7/2001 (CONTIN) #2 2/2001 (CONTIN)
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4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #2 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No
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6. Lot # (if known) #1 UNKNOWN #2 UNKNOWN	7. Exp. Date #1 #2	8. Event reappeared after reintroduction #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No
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9. NDC # for prod problems only - - -	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No
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10. Concomitant medical products and therapy dates
PROZAC (FLUOXETINE) (CONTIN), CARDURA (NITAZOSIN) (CONTIN), AMBIEN (ZOLPIDEM TARTRATE) (CONTIN), FLENEREL (CYCLOBENZAPRINE HCL) (CONTIN)

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	2. Phone number (203) 588-8000	3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
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4. Date Rec'd by Mfr. 05/02/2001	5. (A)IND# 20-553
6. If IND, protocol #	IND# PLA#

7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 170-day (X) periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	8. Adverse event term(s) URIN URGENCY DYSURIA URIN IMPAIRED
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9. Mfr. report number 2012218

E. INITIAL REPORTER

1. Name, address & phone # REDACTED

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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MED INFO ASSOC
Facsimile Form 3300A
Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

8003055069

A. PATIENT INFORMATION

1. Patient identifier
 2. Age at event 67 YEARS
 3. Sex Male
 4. Weight 180 lbs or 82 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product problem
 2. Outcomes attrib. to event
 death
 life-threatening
 hospitalization - initial or prolonged
 disability
 congen anomaly
 required intervention to prevent perm damage
 other:

3. Date of event
 4. Date of this Rept 02/05/2002

5. Describe event or problem

A 67-year-old male patient experienced extreme fatigue, sleepiness, abdominal pain, diarrhea, and an upset stomach on an unspecified date while taking OxyContin (controlled-release oxycodone hydrochloride) for intractable pain related to degenerative arthritis. Reportedly, on an unspecified date, the patient started taking OxyContin 40 mg every eight to twelve hours and after a few days, the patient complained of extreme fatigue and sleepiness. The physician changed the dose of OxyContin to 10 mg every eight to twelve hours and the patient had good pain relief; and the fatigue and the sleepiness went away. After several days on this dose, the patient began to experience abdominal pain and diarrhea. The patient stated that he felt that his "ulcer was recurring." The gastrointestinal physician prescribed Nexium (esomeprazole magnesium) but the gastrointestinal symptoms did not improve. The patient discontinued OxyContin on his own and the gastrointestinal symptoms went away. After a few days, the patient started OxyContin again and the gastrointestinal symptoms recurred. OxyContin was discontinued by the physician. This case was reported by a physician in the United States of America. Additional information to be requested.

6. Relevant tests/laboratory data, including dates

Relevant Tests and Laboratory Data: UNKNOWN

7. Other relevant history, including preexist. med. conditions

UNKNOWN

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)
 #2 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride)

2. Dose, Frequency & route
 #1 40 MG Q8-12H PO
 #2 10 MG Q8-12H PO
 3. Therapy dates (if unk, give dur)
 #1 UNKNOWN (STOP'D)
 #2 UNKNOWN (STOP'D)

4. Diagnosis for use (indication)
 #1 NON-MALIGNANT PAIN
 #2 NON-MALIGNANT PAIN
 5. Event abated after use stopped or dose reduced
 #1 [X]yes []no []N/A
 #2 [X]yes []no []N/A

6. Lot # (if known)
 #1 UNKNOWN
 #2 UNKNOWN
 7. Exp. Date
 #1
 #2

8. Event reappeared after reintroduction
 #1 [X]yes []no []N/A
 #2 [X]yes []no []N/A

9. NDC # for prod problems only
 -
 10. Concomitant medical products and therapy dates
 UNKNOWN

E. ALL MANUFACTURERS

1. Contact office - name/address
 Purdue Pharma L.P.
 1 STAMFORD FORUM
 STAMFORD, CT 06901-3431
 2. Phone number (203) 588-8000

3. Report Source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date Rec'd by Mfr. 06/14/2001
 5. (A)NDA# 20-555
 6. If IND, protocol #
 IND#
 PLAN#

7. Type of report (check all that apply)
 15-day
 115-day
 110-day DX/periodic
 initial
 follow-up #
 pre-1938 []yes
 OTC []yes
 product

8. Adverse event term(s)
 SOMNOLENCE
 ASTHENA
 PAIN ABDO
 DIARRHEA
 NAUSEA

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?
 yes [] no
 3. Occupation
 PHYSICIAN
 4. Initial reporter also sent report to FDA
 yes []no [X]unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

FDA MEDICAL PRODUCTS REPORTING PROGRAM

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Mfr report #	2013096
UF/Dist report #	
FRA Use Only	

A. PATIENT INFORMATION

Patient identifier REDACTED	2. Age at event 50 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or Product problem

2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization <input type="checkbox"/> initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____
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3. Date of event 6/1/2001 4. Date of this Rept 02/05/2002

5. Describe event or problem

A 50-YEAR-OLD FEMALE EXPERIENCED WITHDRAWAL SYMPTOMS IN JUNE 01, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 80 MG TABLETS FOR BACK PAIN. IN 1999, THE PATIENT BEGAN TAKING OXYCONTIN 40 MG TWICE A DAY. ON AN UNSPECIFIED DATE, THE DOSE WAS INCREASED TO 40 MG THREE TIMES A DAY. LORCET (HYDROCODONE BITARTRATE/APAP), AS NEEDED, WAS PRESCRIBED FOR BREAKTHROUGH PAIN. IN APRIL 01, THE DOSE OF OXYCONTIN WAS INCREASED TO 80 MG THREE TIMES A DAY. AT THE SAME TIME, LORCET WAS DISCONTINUED. OXYIR (IMMEDIATE-RELEASE OXYCODONE HYDROCHLORIDE) 5 MG, TWICE A DAY, WAS PRESCRIBED FOR BREAKTHROUGH PAIN. ON AN UNSPECIFIED DATE, THE PATIENT MOVED TO ANOTHER STATE. SHE FINISHED THE PRESCRIPTIONS FOR OXYCONTIN AND OXYIR BEFORE SHE COULD LOCATE A NEW PHYSICIAN. IN EARLY JUNE 01, THE PATIENT EXPERIENCED WITHDRAWAL SYMPTOMS (DESCRIBED AS LOSS OF APPETITE, DIARRHEA, BLURRED VISION, "BIG PUPILS", SHAKING, CAN'T STAND UP). THE SYMPTOMS PERSIST. REPORTEDLY, ON 21 JUNE 01, THE PATIENT HAS AN APPOINTMENT WITH A PAIN MANAGEMENT PHYSICIAN. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/Laboratory data, including dates
RELEVANT TESTS/DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions
HEPATITIS C, 3 BLADDER SURGERIES; 1987 AUTOMOBILE ACCIDENT "NEARLY KILLED ME"

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labelor, if known)
#1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)
#2 OXYIR Capsules (oxycodone hydrochloride)

2. Dose, frequency & route #1 80 MG TID PO #2 5 MG BID PO	3. Therapy dates (if unk, give dur) #1 4/2001 - 6/2001 (STOP'D) #2 4/2001 - 6/2001 (STOP'D)
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4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #2 NON MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no (XIN/A) #2 <input type="checkbox"/> yes <input type="checkbox"/> no (XIN/A)
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6. Lot # (if known) #1 UNKNOWN #2 UNKNOWN	7. Exp. Date #1 #2	8. Event reappeared after reinstitution #1 <input type="checkbox"/> yes <input type="checkbox"/> no (XIN/A) #2 <input type="checkbox"/> yes <input type="checkbox"/> no (XIN/A)
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9. NDC # for prod problems only
- -

10. Concomitant medical products and therapy dates
UNKNOWN

D. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06961-3431	2. Phone number (203) 588-8000
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4. Date Rec'd by Mfr. 06/15/2001	5. (A)NDA# 20-555	3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic DQ Init <input type="checkbox"/> follow-up # _____	pre-1938 <input type="checkbox"/> Iyes DTC <input type="checkbox"/> Iyes product <input type="checkbox"/> Iyes	

8. Adverse event term(s)
WITHDRAW SYND
ANOREXIA
DIARRHEA
AMBLYOPIA
MYDRIASIS
(CONTINUED)

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no (X)unk
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MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003055824

Q8. ADVERSE EVENT TERMS (continued)

TREMOR
ASTHENIA

MEDWATCH

Purdue Pharma L.P.

Mfr report # 2013113

UF/Dist report #

FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

1. Patient identifier REDACTED	2. Age at event 43 YEARS or DOB:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or Product problem

Outcomes attrib. to event disability
 death congen anomaly
 life-threatening required intervention
 hospitalization - to prevent perm damage
 initial or prolonged other:

3. Date of event 4/7/2000 4. Date of this Rept 02/05/2002

5. Describe event or problem

A 43-year-old female patient (unknown race) experienced edema of bilateral legs, neurogenic bladder, weight gain, constipation, bloating, urinary retention, bowel and urinary incontinence, "ghost" tablets appeared in her stool, and lack of drug effect while taking OxyContin (controlled release oxycodone hydrochloride) 80mg 3times a day for approximately 11 months. These symptoms were experienced in April 2000. Prior to this dose she was on OxyContin 40mg bid x 2 months. She was evaluated by her primary physician, and she states that she had retained 800cc of urine after being tested. The physician did not treat her symptoms at that time. In June 2000, she complained of bleeding and infrequent urination, so she revisited her physician and she was treated with a foley catheter for 6 weeks, was referred to a urologist and did self catheterization at home. Over several months her weight increased from 112lbs to 153lbs. She was then treated with Lasix (furosemide) and potassium for 6 months. She experienced constipation for 1 year. The OxyContin was then decreased by 2 pills every day on 01JUN01. Her symptomology improved when the dose of OxyContin was decreased to 40mg daily. Her analgesia medication was also decreased and she is on an additional pain medication. This case was reported by a consumer in the United States or America.

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/LABORATORY DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions

UNKNOWN

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)

#1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)

2. Dose, frequency & route 3. Therapy dates (if unk, give dur)

#1 80 MG 5/DAY PO #1 11 MONTHS (REDUCED)

4. Diagnosis for use (indication) 5. Event abated after use stopped or dose reduced

#1 UNKNOWN #1 Yes No N/A

6. Lot # (if known) 7. Exp. Date

#1 UNKNOWN #1 Yes No N/A

9. NDC # for prod problems only

#1 Yes No N/A

10. Concomitant medical products and therapy dates

LASIX (FUROSEMIDE), POTASSIUM

E. ALL MANUFACTURERS

1. Contact office - name/address 2. Phone number (203) 588-8000

Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431

3. Report Source (check all that apply)

foreign study literature consumer health professional user facility company representative distributor other:

4. Date Rec'd by Mfr. 06/21/2001 5. (A)NDA# 20-553

6. If IND, protocol # IND# _____

7. Type of report (check all that apply) pre-1938 yes

15-day 115-day 110-day periodic

initial follow-up # _____

8. Adverse event term(s)

EDEMA INCONTIN URIN WEIGHT INC

CONSTIP NO DRUG EFFECT (CONTINUED)

9. Mfr. report number 2013113

E. INITIAL REPORTER

1. Name, address & phone #

REDACTED

2. Health professional? yes no

3. Occupation

4. Initial reporter also sent report to FDA yes no unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

8003055839

GB. ADVERSE EVENT TERMS (continued)

FLATUL
URIN RETENT

MEDWATCH

Purdue Pharma L.P.

Mfr report #	2014216
UF/Diet report #	
FOA Use Only	

MHA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

Patient identifier REDACTED	2. Age at event 47 YEARS or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or 89.3 kgs
---------------------------------------	--	---	---------------------------------

B. ADVERSE EVENT OR PRODUCT PROBLEM

<input checked="" type="checkbox"/> Adverse Event	and/or	<input type="checkbox"/> Product problem
Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event	7/2001	4. Date of this Rept	02/05/2002
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5. Describe event or problem

A 47 year-old male patient experienced abdominal spasms, constipation and urinary retention while taking OxyContin (controlled release oxycodone hydrochloride). The patient has taken OxyContin 40mg q6-8hours since 2/2001 for refractory migraine headaches. Patient experienced intermittent abdominal spasms, constipation and urinary retention every 5-7 days starting in 02/2001. The symptoms last 48-72 hours, abate with self initiated dose reduction, and return with self initiated dose increase. The patient remains on OxyContin therapy. Past medical history includes a blow to the head on an unknown date with resultant refractory migraine headaches. Medications included phenergan (promethazine) 25mg po PRN nausea, celecox (celecoxib hydrochloride) 200 qd, walbutrin (bupropion) SR 150mg qd, dilaudid (hydromorphone) 4mg PRN breakthrough pain, sennokot (sennosides) daily and docusate. This case was reported by a pharmacist in the United States.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexist. med. conditions

Refractory migraine headaches. Past traumatic injury, blow to head.

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)		
2. Dose, frequency & route #1 40 MG q6-8H PO	3. Therapy dates (if unk, give dur) #1 1/29/2001	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
9. NDC # for prod problems only -		

10. Concomitant medical products and therapy dates
PHEBERGAN (PROMETHAZINE), CELEXA (CITALOPRAM HYDROBROMIDE), WELLBUTRIN (BUPROPION), DILAUDID (HYDROMORPHONE), SENNOKOT (SENNOSIDES), DOCUSATE

E. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3451		2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 09/05/2001		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	5. (A) NDA# 20-553 IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic DD Init <input type="checkbox"/> Ifollow-up #	8. Adverse event term(s) PAIN ABDQ CONSTIP URIN RETENT	
9. Mfr. report number 2014216		

E. INITIAL REPORTER

1. Name, address & phone # REDACTED		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHARM D	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003055908

MEDWATCH

Purdue Pharma L.P.

Mfr report #	2014545
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

Patient Identifier DACTED	2. Age at event 73 YEARS	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight (lb) or kgs
-------------------------------------	-----------------------------	---	-----------------------------

B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or Product problem

Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yr) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:
---	---

3. Date of event 8//2001 4. Date of this Rept 02/05/2002

5. Describe event or problem
A 73-year-old female experienced hair loss in the past two months while taking OxyContin (controlled release oxycodone hydrochloride) for back pain. She has been taking OxyContin since APR01. Reportedly, the hair loss has become increasingly worse. She denied any change in diet or hair preparation. She has a history of open heart surgery, rheumatoid arthritis, polymyalgia, and back pain. She visited her physician two days ago and he suggested she go to a pain clinic. This case was reported by a consumer in the United States of America.

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
#1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)

2. Dose, frequency & route #1 40 NG TID PO	3. Therapy dates (if unk, give dur) #1 4/2001 (CONTIN)
---	---

4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
--	--

6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
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9. NDC # for prod problems only
#1 Yes No N/A

10. Concomitant medical products and therapy dates
PRIOLOSEC (OMEPRazole),
DIAZIDE (TRIAMTERENE/HYDROCHLORTHIAZIDE), POTASSIUM CHLORIDE,
ASPIRIN, NITROGLYCERIN,
BECONASE (BECLOMETASONE DIPROPIONATE)

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STANFORD FORUM STANFORD, CT 06901-3431	2. Phone number (203) 588-8000
	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer health <input type="checkbox"/> professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> others

4. Date Rec'd by Mfr. 10/12/2001	5. (A)IND# 20-553
6. If IND, protocol #	IND# PLA#

7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 118-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up	8. Adverse event term(s) ALOPECIA
---	--------------------------------------

9. Mfr. report number
2014545

6. Relevant tests/Laboratory data, including dates
RELEVANT TESTS/LAB DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions
HISTORY OF OPEN HEART SURGERY, RHEUMATOID ARTHRITIS,
POLYMYALGIA, BACK PAIN

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
--	---------------	---

HED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3200A

8003056095

REBWATCH

Purdue Pharma L.P.

Mfr report # 2014600

UF/Dist report #

FDA Use Only

1. MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

1. Patient Identifier: **REDACTED**
 2. Age at event: 38 YEARS
 3. Sex: female male
 4. Weight: 46.2 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or Product problem
 1. death
 2. disability
 3. congen anomaly
 4. required intervention to prevent permanent damage
 5. other:
 6. life-threatening
 7. hospitalization - initial or prolonged

3. Date of event: 10/17/2001
 4. Date of this Rept: 02/05/2002

5. Describe event or problem

A 38-YEAR-OLD FEMALE EXPERIENCED INCREASED PAIN AND A "FUZZY HEAD-WHICH NOT CLEAR" IN OCT01, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 80 MG TABLETS FOR PANCREATIC PAIN. AT THE END OF SEP01, THE PATIENT BEGAN TAKING TWO 40 MG TABLETS EVERY 8 HOURS. ON 17OCT01, THE PATIENT WENT TO PICK UP A NEW PRESCRIPTION FOR OXYCONTIN 40 MG. THE PHARMACY WAS OUT OF 40 MG TABLETS. THE PATIENT WAS DISPENSED 80 MG TABLETS. THE DIRECTIONS WERE TO TAKE 1 TABLET EVERY 8 HOURS. THAT DAY, AFTER TAKING THE FIRST DOSE, THE PATIENT EXPERIENCED INCREASED PAIN. THE NEXT DAY, THE SYMPTOM PERSISTED AND THE PATIENT ALSO EXPERIENCED A "FUZZY HEAD-WHICH NOT CLEAR." THERAPY WITH OXYCONTIN 80 MG CONTINUES AND THE SYMPTOMS PERSIST. THE PATIENT RELATED THAT SHE IS GOING TO TAKE TWO 40 MG TABLETS FROM HER PREVIOUS PRESCRIPTION AT THE NEXT DOSE TO SEE IF THE SYMPTOMS ABATE. THE PHYSICIAN WILL BE CONSULTED.

6. Relevant tests/Laboratory data, including dates
 RELEVANT TESTS/DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions
 PANCREATIC PAIN

G. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)
 2. Dose, frequency & route
 #1 80 MG Q8H PO
 3. Therapy dates (if unk, give dur)
 #1 10/17/2001 - 10/19/2001
 4. Diagnosis for use (indication)
 #1 NON-MALIGNANT PAIN
 5. Event abated after use stopped or dose reduced
 #1 Yes No DN/A
 # Yes No DN/A
 6. Lot # (if known)
 #1 UNKNOWN
 7. Exp. Date
 #1 UNKNOWN
 8. Event reappeared after reintroduction
 #1 Yes No DN/A
 # Yes No DN/A
 9. NDC # for prod problems only
 -
 10. Concomitant medical products and therapy dates
 NEURONTIN (GABAPENTIN) (CONTIN), REGLAN (METOCLOPRAMIDE) (CONTIN), ZOLOFT (SERTRALINE HCL) (CONTIN), PREVACTID (LANSOPRAZOLE) (CONTIN), PERRI-COLACE (DIOCTATE SOD/CASANTHRANOL) (CONTIN)

E. ALL MANUFACTURERS

1. Contact office - name/address
 Purdue Pharma L.P.
 1 STAMFORD FORUM
 STAMFORD, CT 06901-3431
 2. Phone number (203) 598-8800
 3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other
 4. Date Rec'd by Mfr. 10/19/2001
 5. (A)NDA# 20-533
 6. If IND, protocol #
 IND#
 PLA#
 7. Type of report (check all that apply)
 15-day 15-day
 10-day periodic
 initial follow-up #
 8. Adverse event term(s)
 PAIN
 NO DRUG EFFECT
 THINKING ABNORM
 9. Mfr. report number 2014600

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED
 2. Health professional? yes no
 3. Occupation
 4. Initial reporter also sent report to FDA yes no unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

8003056123

MEDWATCH

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

11708

Relays International, Inc.
FDA Facsimile Approval 11-JUN-1989

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

Med report #	USA-2002-0000312
UPDR# report #	
FDA Use Only	

Patient Information

1. Patient identified by name **JACKET**

2. Age at time of event **41 Years**

3. Sex female male

4. Weight **UNK** lbs or **UNK** kgs

Adverse Event or Product Problem

Adverse event or Product problem (e.g., defects/misfunctions)

Outcomes attributed to adverse event (check all that apply)

death

life-threatening

hospitalization - initial or prolonged

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other:

3. Date of event **02/22/2002**

4. Date of this report **04/01/2002**

Describe event or problem

**Acute Pancreatitis (PANCREATITIS)
Gallstones (CHOLELITHIASIS)**

Case Description:
A 41-year female, with a history of hypertension, obesity, gastroesophageal reflux disease and hypertriglyceridemia, developed gallstones and acute pancreatitis leading to hospitalization while taking OxyContin (controlled-release oxycodone hydrochloride) 80-mg Tablets for chronic back pain. The patient started taking OxyContin 20-mg Tablets on 1APR01, at a dose of 20 mg three times a day, for chronic back pain. On an unspecified date in SEP01, the dose was increased to 40 mg (five OxyContin 80-mg Tablets) three times daily. Reportedly, the patient developed gallstones and acute pancreatitis with phlegm requiring hospitalization from 22SEP02 until 09MAR02. Concomitant medications included Oxy IR (immediate-release oxycodone hydrochloride), Flexeril (cyclobenzaprine), Ambien (zolpidem), Ativan (lorazepam), Phenergan (promethazine) and Premerin (conjugated estrogens). This case was

6. Relevant test/laboratory data, including dates
UNKNOWN

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, reproductive dysfunction, etc.)
- #1 Current Condition, **ESSENTIAL HYPERTENSION**
 - #2 Current Condition, **OBESITY**
 - #3 Current Condition, (continued)
 - #4 Current Condition, (continued)
 - #5 Current Condition, **PAIN (CHRONIC BACK PAIN)**

C. Suspect medication(s)

1. Name (give labeled strength & molecule, if known)

1. **OxyContin Tablets 80 mg(OXYC) (continued)**

2. **OxyContin Tablets 20 mg(OXYC) (continued)**

2. Dose, frequency & route used

1. **400 mg tid, Oral**

2. **20 mg, tid, Oral**

3. Therapy dates (if unknown, give duration)

1. **09/--/2001, duration UNK**

2. **02/14/2001 to 09--/2001**

4. Diagnosis for use (indication)

1. **UNK**

2. **NON-MALIGNANT PAIN**

5. Lot # (if known) 7. Exp. date (if known)

1. **UNKNOWN** # 1. **UNK**

2. **UNKNOWN** # 2. **UNK**

6. Event abated after use stopped or dose reduced

1. yes no doesn't apply

2. yes no doesn't apply

8. Event reappeared after reintroduction

1. yes no doesn't apply

2. yes no doesn't apply

10. Concomitant medical products and therapy dates (exclude treatment of event)

Flexeril (CYCLOBENZAPRINE HYDROCHLORIDE) UNK to UNK continued in additional info section...

G. All Manufacturers

1. Contact office - name/address (& mailing site for devices)
Pfizer Pharmaceuticals, P

2. Phone number
+1 203 588-8000

3. Report source (check all that apply)

foreign

study

literature

consumer

health professional

user facility

company representative

distributor

other

4. Date received by manufacturer (required)
03/19/2002

5. (A)NDA # **20-553**

IND #

PLA #

pre-1990 yes

OTC product yes

8. Adverse event term(s)
PANCREATITIS, CHOLELITHIASIS

6. If IND, protocol #

7. Type of report (check all that apply)

2-day 15-day

10-day periodic

initial follow-up #

9. Mfr. report number
USA-2002-0000312

E. Initial reporter

1. Name & address phone #/WH#/Ext

Name and address withheld

2. Health professional? yes no

3. Occupation
Physician

4. Initial reporter also sent report to FDA
 yes no UNK



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

01-MPI-0002 (R-25-02)

8003056379

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

MDI report #	USA-2002-0080512
LPQ/lot, report #	
FDA Use Only	

Page 2 of 2

Additional Information

B5. EVENT DESCRIPTION (cont.)

reported on 15MAR02 by a physician in the United States of America. Additional information is being requested.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
3		Current Condition OTHER DISEASES OF ESOPHAGUS	GASTROESOPHAGEAL REFLUX DISEASE
4		Current Condition OTHER ABNORMAL BLOOD CHEMISTRY	HYPERTRIGLYCERIDEMIA

C1. Name (cont.)

Suspect Medication #1: OxyContin Tablets 80 mg(OXYCODONE HYDROCHLORIDE) CR Tablet
Suspect Medication #2: OxyContin Tablets 20 mg(OXYCODONE HYDROCHLORIDE) CR Tablet

C10. CONCOMITANT MEDICAL PRODUCTS

AMBIEN (ZOLPIDEM TARTRATE) UNK to UNK
ATTIVAN (LORAZEPAM) UNK to UNK
PHENERGAN UNK to UNK
PREMARIN (ESTROGENS CONJUGATED) UNK to UNK
Oxycodone HCL IR Capsules (OXYCODONE HYDROCHLORIDE) IR Capsule UNK to UNK

8003056380

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by users, facilities,
distributors and manufacturers for
MANDATORY reporting

18133
Relays International, Inc.
FDA Electronic Approval 11-JUN-1999

Mfr report #	USA-2002-000010
USINDL report #	
FDA Use Only	

Page 1 of 3

A. Patient information

Age at time of event	59 Years	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
	Date of birth: UNK		

B. Adverse event or product problem

Adverse event and/or Product problem (e.g., defects/malfunction)

Causes attributed to adverse event (check all that apply)

<input type="checkbox"/> disability
<input type="checkbox"/> congestive anomaly
<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
<input checked="" type="checkbox"/> other: Medically Significant

hospitalization - initial or prolonged

3. Date of event (month/year)	1-/2001	4. Date of this report (month/year)	6/5/10/2002
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5. Describe event or problem

RESPIRATORY FAILURE [RESPIRATORY INSUFFICIENCY]
CONDITION AGGRAVATED [CONDITION AGGRAVATED]
PULMONARY CANCER [PULMONARY CARCINOMA]
APNOEA [APNOEA]
COMA [COMA]
PNEUMONIA [PNEUMONIA]
MYOCLONIC JERKING [MUSCLE CONTRACTIONS INVOLUNTARY]
Drug Interaction [DRUG - DRUG INTERACTION]
Carbon Dioxide Retention [HYPERCAPNIA]

Case Description:
A 59-year-old female, with a history of lung cancer, developed respiratory insufficiency leading to hospitalization while taking OxyContin (controlled-release oxycodone hydrochloride) 80 mg three times daily for pain associated with the lung cancer. The patient was also taking "either an oxycodone preparation or Percocet (oxycodone/acetaminophen)" continued in additional info section...

6. Relevant tests/laboratory data, including dates

At the time of hospitalization, partial pressure of carbon dioxide was around 180 and the oxygen was 30.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, reproductive dysfunction, etc.)

#1 1-/1998 to UNK Current Condition, (continued)
#2 Current Condition, (continued)
#3 Current Condition, (continued)
#4 Current Condition, (continued)
continued in additional info section...

C. Suspected medication(s)

1. Name (give labeled strength & manufacturer, if known)	
# 1. OxyContin Tablets 80 mg (OXYC) (continued)	
# 2. VISTARIL (HYDROXYZINE EMBONATE) (continued)	
2. Dose, frequency & route used	
# 1. 80 mg, tid, Oral	3. Therapy dates (if unknown, give duration) (continued)
# 2. UNK mg, (continued)	# 1. 1-/1999 to Ongoing
# 2. UNK	
4. Diagnosis for use (indication)	
# 1. MAJOR PAIN	
# 2. Unknown	
5. Event abated after use stopped or dose reduced	
# 1. <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	# 2. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known) 7. Exp. date (if known)	
# 1. UNKNOWN	# 1. UNK
# 2. Unknown	# 2. UNK
8. Event recurred after reintroduction	
# 1. <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	# 2. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # - for product problems only (if known)	
# 1. <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
# 2. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	

10. Concomitant medical products and therapy dates (exclude treatment of event)

ACETAMINOPHEN W/OXYCODONE Tablet 1-/1998 to 12-/2001
AMITRIPTYLINE (AMITRIPTYLINE) Unknown UNK to UNK
continued in additional info section...

D. All Manufacturers

1. Contact office - name/address (& mailing site for devices)	2. Phone number
Purdue Pharma I.P.	+1 219 588-8000
Owe Stamford Forum Stamford, CT 06901-3431 UNITED STATES	3. Report source (check all that apply)
	<input type="checkbox"/> foreign <input type="checkbox"/> solely <input type="checkbox"/> theatre <input type="checkbox"/> co-owner <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other

4. Date received by manufacturer (month/year)	5. (AINDA # 20-55)
04/29/2002	IND #
6. IFIND protocol #	PLA #
	pre-1038 <input type="checkbox"/> yes
7. Type of report (check all that apply)	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	8. Adverse event term(s)
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	RESPIRATORY INSUFFICIENCY, CONDITION AGGRAVATED, PULMONARY CARCINOMA, APNOEA, COMA, PNEUMONIA, MUSCLE
<input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1	continued in additional info section...
9. Mfr. report number	
USA-2002-000010	

E. Initial reporter

1. Name & address	phone # Withheld
Name and address withheld	

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharmacist	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> UNK



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

10-1999-2002 10-26-11

8003057421

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

FD-302 (Rev. 10-1-80)	USA-2002-000010
1. IRT/MS, report #	
FDA Use Only	

Additional Information:

B5. EVENT DESCRIPTION (cont.)

for breakthrough pain." About two months ago, the patient experienced respiratory failure, pneumonia, was apneic and comatose requiring hospitalization. She was placed on a ventilator for approximately two weeks. At the time of her hospitalization, her partial pressure of carbon dioxide was around 180 and her oxygen was 10. Reportedly, the patient was under continuous positive airway pressure and was taken off the OxyContin and other unparalified medications and received morphine injections. Reportedly, the patient had developed myoclonic jerking movements approximately 8-12 months prior to the hospitalization. Two to three weeks after stopping OxyContin therapy, the myoclonic jerking movements became less pronounced and the patient became responsive, woke up, was as "clear as a bell" and was able to take medications by mouth again. At this point, the physician restarted her on OxyContin 40 mg twice daily and the myoclonic jerking movements had almost completely resolved by the time of the report. The patient is now on high doses of steroids, low dose of amitriptyline, Neurontin (gabapentin) titrated up to 600 mg three times daily, an unidentified selective serotonin reuptake inhibitor, Atarax (hydroxyzine pamoate) as needed and oxycodone as needed for pain. The reporting pharmacist related that the myoclonic jerking movements did not prolong the patient's hospitalization and that the treating physician felt that the myoclonic jerking movements were likely related to the higher dosing of OxyContin and that the respiratory failure was a result of the progression of her lung cancer with no causal relationship to OxyContin. This case was reported by a pharmacist in the United States of America. Additional information is being requested.

***Follow-up information received from the reporting pharmacist on 29APR02 revealed that the causality of the patient's respiratory failure and carbon dioxide retention (hypercarbia) was probably secondary to the patient's long standing history of lung disease and the underlying pneumonia in combination with the patient's other medications, specifically Vistaral (hydroxyzine hydrochloride) and OxyContin. The reporter felt that these factors, plus the chronic use of oxygen, probably led to the patient's respiratory decompensation. The patient has made a full recovery and is currently taking OxyContin 20 qd without any problems. Other current medications include Elavil (amitriptyline) 25, Lorazepam, Paxil (paroxetine) and oxycodone 5 mg q4t prn for pain.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	---/1998	Current Condition MALIGNANT NEOPLASM OF UPPER LOBE, BRONCHUS OR LUNG	Right lung cancer with a mass on her right upper lobe. Diagnosis of cancer in mid 1998. Underwent chemotherapy and radiation resulting in tissue scarring and chronic pain.
2		Current Condition CHRONIC AIRWAYS OBSTRUCTION, NOT ELSEWHERE CLASSIFIED	Long standing chronic obstructive pulmonary disease (COPD).
3		Current Condition CHRONIC AND OTHER PULMONARY MANIFESTATIONS DUE TO RADIATION	Scarring of lung tissue and chronic pain secondary to radiation treatment.
4		Current Condition PNEUMONIA, ORGANISM UNSPECIFIED	Recurrent episodes of pneumonia.
5		Current Condition Carbon Dioxide Retention	Ongoing for many years. Is oxygen dependent. pCO2 is always elevated.
6		Current Condition DEPRESSION	
7		Current Condition ANXIETY STATES	
8		Current Condition Steroid dependent	
9		Allergy PERSONAL HISTORY OF ALLERGY TO MEDICINAL AGENTS	Allergic to penicillin and Clindamycin

8003057422

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute
an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service - Food and Drug Administration

Medication #	USA-2002-0040018
Medical report #	
FDA Use Only	

Page 3 of 3

C1. Name (cont.)

Suspect Medication #1: OxyContin Tablets 80 mg (OXYCODONE HYDROCHLORIDE) CR Tablet

Suspect Medication #2: VISTARIL (HYDROXYZINE EMBONATE) Unknown

C2. Dose, frequency & route used (cont.)

Suspect Medication #2: UNK mg, unk, Unknown

C10. CONCOMITANT MEDICAL PRODUCTS

NEURONTIN (GABAPENTIN) UNK to UNK

SSRI UNK to UNK

ATARAX (HYDROXYZINE HYDROCHLORIDE) Unknown UNK to UNK

CORTICOSTEROIDS Unknown UNK to UNK

G8. ADVERSE EVENT TERMS (cont.)

CONTRACTIONS INVOLUNTARY, DRUG - DRUG INTERACTION, HYPERCAEMIA

8003057423

15-DAY ALERT REPORT MEDWATCH

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting.

12821 12820
Relays International, Inc.
FDA Facsimile Approval: 11-JUN-1999

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

DEU report #	DEU-2002-000092
IRPT# report #	
FDA Use Only	

Patient information			
1. Patient identifier	2. Age at time of event	3. Sex	4. Weight
	UNK	<input checked="" type="checkbox"/> female <input type="checkbox"/> male	211.2 lbs or 96.0 kg
<input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			

Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: Medically Significant
3. Date of event	4. Date of this report
02/-/2002	08/15/2002

5. Describe event or problem

Drug-drug Interaction [DRUG - DRUG INTERACTION]
Quick-value increased [PROTHROMBIN DECREASED]

Case Description:
A female patient was switched from Valoxon to Oxygesic 20mg (indication unknown). Concomitant long-term treatment was cumazim (Falithrom). Due to the switch the Quick-value increased from 20% to 99% (decrease in INR-ratio). After withdrawal of Oxygesic the Quick value returned to normal (25%). This case was reported by a physician in Germany via a company representative.
Additional information is being requested.
***Follow-up information was received on 02.08.2002 from the initially reporting physician in form of an adverse event report.
Additional information concerned patient data, concomitant medication and concurrent diseases. The physician wrote: "During concomitant medication with Valithrom, Oxygesic 20 and Faspertin Quick and INR continued in additional info section..."

6. Relevant test/laboratory data, including date:
NI

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)

#1 Indication, LUMBALGIA (Lumbar syndrome)
#2 Historical Condition, (continued)
#3 Current Condition, (continued)
#4 Current Condition, (continued)
#5 Current Condition, OBESITY (Obesity)

C. Suspect medication(s)		
1. Name (give labeled strength & ml/tablet, if known)		
#1. Oxygesic 20 mg (OXYCODONE) (continued)		
#2. PHENPROCOLOMON (PHENPROCOLOMON) (continued)		
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration)
#1. 20 mg, tid, Oral		#1. 02/-/2002 to 02/-/2002
#2. UNK, unk, Oral		#2. UNK
4. Diagnosis for user (indication)		5. Event related after use stopped or dose reduced
#1. Non-sterile joint pain		#1. <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2. PULMONARY EMBOLISM		
6. Lot # (if known)		7. Exp. date (if known)
#1. UNK		#1. UNK
#2. UNK		#2. UNK
8. Event reappeared after reintroduction		
#1. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		
#2. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply		
9. NDC # - for product problems only (if known)		
10. Concomitant medical products and therapy dates (exclude treatment of event)		
FASPERTIN (METHOCLOPRAMIDE HYDROCHLORIDE) 02/-/2002 to 02/-/2002		
continued in additional information...		

C. A.1 Manufacturers	
1. Contact office - name/address (& mailing site for devices)	2. Phone number
Purdue Pharma I. P.	+1 203 588-8000
One Stamford Forum Stamford, CT 06901-3431 UNITED STATES	3. Report source (check all that apply)
	<input type="checkbox"/> foreign DEU
	<input type="checkbox"/> study
	<input type="checkbox"/> literature
	<input type="checkbox"/> consumer
	<input checked="" type="checkbox"/> health professional
	<input type="checkbox"/> user facility
	<input type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	<input type="checkbox"/> other:
4. Date received by manufacturer	5. (A)NDA #
08/02/2002	20-513
6. RIND, protocol #	IND #
	PLA #
	pre-1038 <input type="checkbox"/> yes
	OTC product <input type="checkbox"/> yes
7. Type of report (check all that apply)	8. Adverse event term(s)
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	DRUG - DRUG INTERACTION, PROTHROMBIN DECREASED
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1	
8. Mfr. report number	
DEU-2002-000092	

E. Initial reporter			
1. Name & address		phone #W#b#d	
Name and address withheld.			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Physician	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> UNK	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to this event.

10-11132/01-12-99-10

8003058879

15-DAY ALERT REPORT

WATCH

FOR MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities, distributors and manufacturers for MANDATORY reporting

12830
Re: IBS International, Inc.

FDA Facsimile Approval 17-JUN-1999

Mr. report #
FDA Use Only
USA-2002-000136
FDA Use Only

Page 1 of 4

1. Patient information

1. Age at time of event: 42 Years
2. Sex: female
3. Weight: UNK lbs
4. Date of event: REDACTED

2. Describe event or problem

versus event and/or Product problem (e.g., defects/malfunctions)

causes attributed to adverse event (all that apply)

death
 life-threatening
 hospitalization - initial or prolonged

disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 Medically Significant

3. Date of event: -/-/1999
4. Date of this report: 08/16/2002

5. Describe event or problem

Drug Addiction (DRUG DEPENDENCE)
Anasarca (EDEMA GENERALISED)
Hypalbuminemia (HYPOPROTEINAEMLIA)
Hypokalaemia (HYPOKALAEMIA)
Malnutrition secondary to metastatic carcinoma (MALNUTRITION)
Back Pain (BACK PAIN)
Abdominal Pain (ABDOMINAL PAIN)
Vomiting (VOMITING)
Urinary Tract Infection (URINARY TRACT INFECTION)
Sinus Infection (SINUSITIS)
Hip Pain (ARTHRALGIA)
Osteoarthritis (ARTHRITIS)
Fever (FEVER)
Toothache (TOOTH ACHE)
Nausea (NAUSEA)

Case Description:
continued in additional info section...

6. Relevant tests/laboratory data, including dates

See Text.

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

#1 09/15/1995 to UNK Current Condition, (continued)
#2 -/-/1998 to UNK Current Condition, (continued)
#3 06/03/1999 to UNK Current Condition, (continued)
#4 -/-/1998 to UNK Current Condition, (continued)
continued in additional info section...

8. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
1. OxyContin Tablets(OXYCODON (continued))
2. OxyFast Concentrate 20 mg/mL (continued)

2. Dose, frequency & route used
1. 40 mg, tid, Oral
2. 5 mg, q6h prn, Oral

3. Therapy dates (if unknown, give duration)
1. 05/-/1999 to Ongoing
2. 05/-/1999 to Ongoing

4. Diagnosis for use (indication)
1. Malignant Pain
2. Malignant Pain

5. Event started after use stopped or dose reduced
1. yes no doesn't apply
2. yes no doesn't apply

6. Event recurred after reintroduction
1. yes no doesn't apply
2. yes no doesn't apply

7. Lot # (if known) 7. Exp. date (if known)
1. Unknown # 1. UNK
2. Unknown # 2. UNK

8. NDC # - for product problems only (if known)

9. Concomitant medical products and therapy dates (exclude treatment of event)

SPIRONOLACTONE (SPIRONOLACTONE) Tablet -/-/1999 to UNK
continued in additional info section...

10. Manufacturer

1. Contact office - name/address (a mailing site for devices)
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431 UNITED STATES

2. Phone number
+1 203 588-8000

3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 clinician
ATTORNEY

4. Date received by manufacturer
08/07/2002

5. (ANDA # 20-553
IND #
PLA #
pre-1938 yes
OTC product yes

6. Adverse event term(s)
DRUG DEPENDENCE, EDEMA GENERALISED, HYPOPROTEINAEMLIA, HYPOKALAEMIA, MALNUTRITION, BACK PAIN, ABDOMINAL PAIN,
continued in additional info section...

11. List of doctors

1. Name & address
Name and address withheld. phone #Withheld

12. Health professional?
 yes no

13. Occupation
Physician

14. Initial reporter also sent report to FDA
 yes no UNK



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

10-1519-2002 1-9-2002

8003058897

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

Manufacturer #	USA-2002-0000136
UPA/Device #	
FDA Use Only	

Page 2 of 4

C. Suspect medication(s)	
1. Name (give labeled strength & manufacturer, if known)	
# 2. OxyIR Capsules 5 mg (continued)	
# 3. ROXICBT (continued)	
2. Dose, frequency & route used	3. Therapy dates (If unknown, give duration)
# 3. 5 mg, prn, Oral	# 3. 12/~/2000 to Ongoing
# 4. 2 tablet, prn, Oral	# 4. Ongoing
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced?
# 5. Malignant Pain	# 5. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
# 6. Malignant Pain	# 6. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known) / Exp. date (if known)	7. Event reappeared after reintroduction?
# 7. Unknown # 3. UNK	# 7. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
# 8. Unknown # 4. UNK	# 8. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
8. NDC # - for product problems only (if known)	
NA	
9. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

107429002 11/2001

8003058898

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

MR report #	USA-2100Z-0000135
UPD/alt report #	
FDA Use Only	

Page 3 of 4

Additional information

B5. EVENT DESCRIPTION (cont.)

An adult female patient has reportedly experienced drug addiction while taking Oxycontin (controlled-release oxycodone hydrochloride) for pain related to cancer. She has been taking OxyContin for a period of two years. No other information was provided. This case was reported by a consumer via an attorney in the United States of America.

***Additional information received on 07AUG02 via an attorney in the form of hospital and medical records revealed that the patient is a 42-year-old female who began taking OxyContin and Roxicet (oxycodone/acetaminophen) in JUN99 for pain associated with a diagnosis of metastatic breast cancer. OxyFast (oxycodone liquid concentrate) was added to her pain regimen in SEP99 and she began taking OxyIR (immediate release oxycodone) for breakthrough pain in DEC00. The patient was diagnosed with bilateral metastatic breast cancer in AUG95. She had bilateral mastectomies performed on 15SEP95, which was followed by several courses of chemotherapy. In DEC98, prior to taking OxyContin, the patient developed recurrent malignant ascites secondary to peritoneal metastasis. Since that time the patient has had an ultrasound guided therapeutic paracentesis performed approximately every 2 weeks to remove fluid from her abdomen. She also experienced nausea, vomiting and abdominal pain which was associated with abdominal distention secondary to ascites. OxyContin therapy was initiated in JUN99. At that time the patient began taking OxyContin 30 mg q12h, in addition to Roxicet (oxycodone/acetaminophen) which she had taken previously. On or about 14SEP99 the patient experienced back pain and accelerated painful swelling of her legs and back. She was admitted to the hospital on 17SEP99 with a diagnosis of anasarca secondary to hypoalbuminemia and metastatic cancer, hypocalcemia, malnutrition and a urinary tract infection. Laboratory tests were significant for a potassium level of 2.9 mmol/L (normal range: 3.6-5.0), total protein of 5.2 gm/dL (normal range: 6.1-8.2), albumin of 1.5 gm/dL (normal range: 3.0-5.0) and an A/G ratio (albumin/globulin) of 0.4 gm/dL (normal range: 1.0-2.2). Results of a urinalysis revealed the presence of >50 white blood cells, 1-5 red blood cells, and was positive for Trichomonas, leukocytes and nitrites. The patient was treated with potassium supplements, Cipro (ciprofloxacin) and morphine sulfate for pain control. She was discharged the next day on 18SEP99. In 2001 the patient began to experience hip pain and the results of an x-ray taken on 21AUG01 noted the presence of osteoarthritis involving both hips. The patient was hospitalized from 31DEC01 to 03JAN02 for pain management after she developed diffuse abdominal pain. She was treated with intravenous fluids and received morphine sulfate via a patient controlled analgesia pump for pain management. She was discharged with instructions to continue taking OxyContin and OxyIR for breakthrough pain. Other events experienced by the patient while taking OxyContin include a sinus infection and a toothache. Currently, the patient is receiving palliative treatment and is under the care of the local hospice. Her dose of OxyContin had been gradually increased over the past 2-3 years and as of 15FEB02 she was taking OxyContin 40 mg q6h and Roxicet, OxyFast .25 ml (5 mg) and/or OxyIR 5 mg q6h for breakthrough pain. The medical records do not contain any information indicating that the patient has become addicted to OxyContin.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	09/15/1995	Current Condition MALIGNANT NEOPLASM OF FEMALE BREAST	Bilateral stage III metastatic breast cancer. Bilateral mastectomies performed on 15SEP95. Chemotherapy initiated.
2	-/-/1998	Current Condition ASCITES	Chronic malignant recurrent ascites. Frequent paracentesis performed.
3	06/03/1999	Current Condition SECOND MALIGNANT NEOPLASM OF RETROPERITONEUM & PERITONEUM	Metastatic carcinoma to abdomen and liver.
4	-/-/1998	Current Condition NAUSEA AND VOMITING	Associated with ascites and metastatic disease.
5	05/-/1999	Current Condition HYPOKALEMIA	
6	05/-/1999	Current Condition EDEMA AND DROPSY	Bilateral lower extremity edema.
7	-/-/1999	Current Condition PAIN	Malignant Pain.
8	03/04/1999	Current Condition LOSS OF WEIGHT	Progressive due to disease progression.
9	05/-/1999	URINARY TRACT INFECTION, SITE NOT SPECIFIED	

8003058899

**Medication and Device
Experience Report
(continued)**

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an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service - Food and Drug Administration

MR report #	USA-2002-000136
UFDAL report #	
	FDA Use Only

Page 4 of 4

C1. Name (cont.)

Suspect Medication #1: OxyContin Tablets(OXYCODONE HYDROCHLORIDE) CR Tablet
Suspect Medication #2: OxyFast Concentrate 20 mg/mL(OXYCODONE HYDROCHLORIDE) Oral Solution
Suspect Medication #3: OxyIR Capsules 5 mg(OXYCODONE HYDROCHLORIDE) IR Capsule
Suspect Medication #4: ROXICET(PARACETAMOL, OXYCODONE HYDROCHLORIDE) Tablet

C10. CONCOMITANT MEDICAL PRODUCTS

LASIX (FUROSEMIDE) Tablet --/1999 to UNK
FLOXIN "ORTEO" (OFLOXACIN) Tablet 07/12/1999 to 07/22/1999
PHENERGAN "WYETH-AYERST" (PROMETHAZINE HYDROCHLORIDE) Tablet --/1999 to UNK
TAGAMET ORAL (CIMETIDINE) Tablet --/1999 to UNK
LORAZEPAM (LORAZEPAM) Tablet UNK to UNK
ATROPINE (ATROPINE) Tablet UNK to UNK
CIPRO (CIPROFLOXACIN HYDROCHLORIDE) Tablet 09/19/1999 to UNK
MORPHINE SULFATE Injectable 09/--/1999 to UNK
K-DUR (POTASSIUM CHLORIDE) Tablet 09/--/1999 to UNK
REGLAN Injectable 01/01/2002 to UNK
METAMUCIL (PSYLLIUM HYDROPHILIC MUCILLOID) Granules 01/01/2002 to UNK
COLACE Tablet 01/01/2002 to UNK
TYLENOL Tablet 01/01/2002 to UNK
HALDOL (HALOPERIDOL) Liquid 08/18/2000 to UNK
DIMETAPP (BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, PHENYLPROPANOLAMINE
HYDROCHLORIDE) Liquid 09/14/2000 to UNK

G8. ADVERSE EVENT TERMS (cont.)

VOMITING, URINARY TRACT INFECTION, SINUSITIS, ARTERALGIA, ARTHRITIS, FEVER, TOOTH ACHES, NAUSEA

10-747-2002 10/20/01

8003058900

EDWATCH

A MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

2960 Pyleys International, Inc.
FDA Facility Approval: 11-JUN-1999

MR report #	USA-2002-0002083
USFDA report #	
FDA Use Only	

Page 1 of 2

1. Identification of event CTE	2. Age at time of event UNK	3. Sex Female	4. Weight UNK lbs or UNK kgs
--	---------------------------------------	-------------------------	---

5. Describe event or product problem
Adverse event and/or Product problem (e.g., defects/malfunctions)

6. Times attributed to adverse event (if all that apply)

life-threatening hospitalization - initial or prolonged

disability congenital anomaly required intervention to prevent permanent impairment/damage other:

3. Date of event (month/year) **UNK**

4. Date of this report (month/year) **09/11/2002**

5. Describe event or problem

**Acute viral Infection (INFECTION VIRAL)
Hallucinations (HALLUCINATION)**

Case Description:
A female, age and race not specified, experienced an acute viral infection and hallucinations on unspecified dates while allegedly taking OxyContin (controlled-release oxycodone hydrochloride) 20 to 40 mg three times daily for back pain. Therapy dates were not specified. Reportedly, on an unspecified date, this female experienced hallucinations of the "moving tree" variety, not "bugs and spiders." The reporting physician related that "After being on OxyContin for several weeks, she was hospitalized for several days for an unrelated acute, viral infection during which time her back pain medications (OxyContin, others not specified) were discontinued. The hallucinations rapidly disappeared. However, upon recovery from the viral infection, her physician continued the OxyContin, and the hallucinations reappeared until she discontinued the medication. There have been no incidents of hallucination since."

6. Relevant test/laboratory data, including dates
UNKNOWN

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

#1 Current Condition, PAIN (Back pain)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

1. OxyContin Tablets 20 mg(OXYC (continued))

2. OxyContin Tablets 40 mg(OXYC (continued))

2. Dose, frequency & route used

1. 20 mg, tid, Unknown

2. 40 mg, tid, Unknown

3. Therapy dates (if unknown, give duration) (month/year to month/year)

1. UNK

2. UNK

4. Diagnosis for use (indication)

1. NON-MALIGNANT PAIN

2. NON-MALIGNANT PAIN

5. Event abated after use stopped or dose reduced

1. yes no doesn't apply

2. yes no doesn't apply

6. Lot # (if known) 7. Exp. date (if known)

1. UNKNOWN # 1. UNK

2. UNKNOWN # 2. UNK

8. Event reappeared after reintroduction

1. yes no doesn't apply

2. yes no doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

UNKNOWN UNK to UNK

D. All Manufacturers

1. Contact office - name/address (& mailing site for devices)

Purdue Pharma L.F.

One Stamford Forum
Stamford, CT 06901-3431 UNITED STATES

2. Phone number
1 203 585-8000

3. Report source (check all that apply)

foreign study physician consumer health professional user facility company representative distributor other:

4. Date received by manufacturer (month/year)

09/03/2002

5. (ANDA # 20-551)

IND #

PLA #

pre-1938 yes

OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day 10-day periodic initial follow-up #

8. Adverse event term(s)

INFECTION VIRAL, HALLUCINATION

9. Mfr. report number
USA-2002 0002083

E. Initial reporter

1. Name & address
Name and address withheld. phone # withheld

2. Health professional? yes no

3. Occupation
Physician

4. Initial reporter also sent report to FDA
 yes no UNK



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

8003059203

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute
an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

FD Form #	USA-2002-0602063
URDA report #	
	FDA Use Only

Page 2 of 2

Additional Information

DC. EVENT DESCRIPTION (cont.)

she has been off OxyContin.* This case was received on 03SEP02 and reported by a physician in the United States of America. Additional information is being requested.

CI. Name (cont.)

Suspect Medication #1: OxyContin Tablets 20 mg(OXYCODONE HYDROCHLORIDE) CR Tablet

Suspect Medication #2: OxyContin Tablets 40 mg(OXYCODONE HYDROCHLORIDE) CR Tablet

15-DAY ALERT REPORT MEDWATCH

38A MEDICAL PRODUCTS REPORTING PROGRAM

Pharmaceutical facilities,
device manufacturers for
Mandatory reporting

13204
Purix International, Inc.
FDA Facility Approval: 11-JUN-1998

13204
USA-2002-002970
FDUse Only

Page 1 of 2

A. Patient information

1. Patient identifier CTED	2. Age at time of event 42 Years	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
5. Date of birth REDACTED			

6. Adverse event
 adverse event
 Product problem (e.g., defects/malfunctions)

7. Causality
 death
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event 02/-/2000	4. Date of this report 11/11/2002
-------------------------------	--------------------------------------

5. Describe event or problem
Anterior Cervical Discectomy (INTERVERTEBRAL DISC DISORDER)
Medicine Ineffective (MEDICINE INEFFECTIVE)
Difficulty Urinating (MICTURITION DISORDER)
Dizziness (DIZZINESS)
Falls (FALL)
Leg Weakness (MUSCLE WEAKNESS)

Case Description:
 A 42-year-old white male patient experienced a fall, leg weakness, an anterior cervical discectomy with fusion, difficulty urinating, dizziness, and a lack of drug effect while taking OxyContin (controlled release oxycodone hydrochloride) in various doses for postoperative back pain. The patient underwent an L4-5 Key Cage Interbody Fusion on 12MAR98 and was prescribed OxyContin 50 mg q 8 hours on 17MAR98 for back pain. He was discharged home on 18MAR98 with OxyContin 50 mg q 8 hours, Ambien (zolpidem) 10 mg hs/prn/ sleep, Milk of Magnesia continued in additional info section...

8. Relevant test/laboratory data, including dates
 See Narrative Text

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 #1 07/15/2097 to UNK Historical Condition, (continued)
 #2 03/12/1998, Procedure, SURGERY (continued)
 #3 Procedure, SURGERY (continued)
 #4 Allergy, (continued)
 #5 Procedure, (continued)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known) #1. OxyContin Tablets (OXYCODON) (continued) #2.		3. Therapy dates (if unknown, give duration) #1. 03/17/1998, duration UNK #2.	
2. Dose, frequency & route used #1. 50 mg, q8h, Oral #2.		4. Diagnosis for use (indication) #1. NON-MALIGNANT PAIN #2.	
6. Lot # (if known) #1. UNKNOWN #2.		7. Exp. date (if known) #1. UNK #2.	
8. Event abated after use stopped or dose reduced #1. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply		5. Event repeated after reintroduction #1. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	

9. Concomitant medical products and therapy dates (exclude treatment of event)
 AMBIEN (ZOLPIDEM TARTRATE) 03/18/1998 to UNK
 MILK OF MAGNESIA (MAGNESIUM HYDROXIDE) 03/18/1998 to continued in additional info section...

G. All Manufacturers

1. Contact office - name/address (& mailing site for devices) Purix Pharma L.P. One Stamford Forum Stamford, CT 06901-3431 UNITED STATES		2. Phone number +1 203 588-8000
4. Date received by manufacturer (month) 10/29/2002		5. (A)NDA # 20-553 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes
6. If IND, protocol #		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input checked="" type="checkbox"/> Other: Attorney
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #		8. Adverse event term(s) INTERVERTEBRAL DISC DISORDER, MEDICINE INEFFECTIVE, MICTURITION DISORDER, DIZZINESS, FALL, MUSCLE WEAKNESS
9. Mfr. report number USA-2002-002970		

E. Initial reporter

1. Name & address Name and address withheld.		phone # withheld
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Physician	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> UNK



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

**Medication and Device
Experience Report
(continued)**

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

Medicine # USA-2002-0002970

LEV001a report # _____

FDA Use Only

Additional Information

B5. EVENT DESCRIPTION (cont.)

(magnesium hydroxide) 20 cc prn/gas pain, Benadryl (diphenhydramine) 50 mg q 8 hours prn/itch, diazepam 5 mg po q 6 hours/muscle spasm, morphine sulfate immediate release 3 mg q 3-4 hours prn/pain, Percocet (oxycodone/apap) 1-2 q 3-4 hours prn/breakthrough pain, and Colace (docusate sodium) 100 mg. In subsequent postoperative visits, the patient continued to complain of pain in the lower back and bilateral legs. Prior to surgery, he was informed that there was a 50% chance that the presurgical pain would resolve. The patient reported that the pain became worse after the surgical procedure. Diagnostic tests were performed which revealed a good alignment of the spine and no displacement of the Ray Cages. On 23SEP98, the physician reported, "after an initial period of improvement, he stumbled while at a funeral and since then has been complaining of severe pain in his back with pain mainly in the right lower extremity." He uses a walker on occasion. OxyContin was increased to 100 mg tid on an unspecified date. The patient also underwent epidural injections consisting of Marcaine (bupivacaine), Depomedrol (methylprednisolone), and xylocaine for pain control. The patient was discharged from a pain service around MAR99 for "prominent irregularities with multiple drug prescriptions," and reported that his primary care physician prescribed his analgesics. On an unspecified date, he experienced leg weakness and a fall in which he claimed to have hurt his neck. In FEB00, he underwent a multi level anterior cervical discectomy with fusion. The patient's past medical history is significant for chronic low back and bilateral leg pain which started on 15JUL97 due to a work related strain, lumbar spondylosis, degenerative disc disease, right knee surgery, left knee arthroscopy, appendectomy, right rotator cuff surgery, and an allergy to Darvon (propoxyphene) that causes dizziness and an unspecified allergy to morphine. The patient was also taking Medrol (methylprednisolone), Lortab (hydrocodone/apap) 2 q 6-8 hours, amitriptyline 50 mg hs, Celebrex (celecoxib) 100 mg bid, Prozac (fluoxetine) q hs, Prilosec (omeprazole), Demerol (meperidine) 100 mg qid, Dalmane (flurazepam) 30 mg hs, and Lipitor (atorvastatin).

H7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	07/15/2097	Historical Condition	CHRONIC LOW BACK PAIN AND BILATERAL LEG PAIN
2	03/12/1998	Procedure SURGERY	L4-5 RAY CAGE INTERBODY FUSION
3		Procedure SURGERY	RIGHT KNEE SURGERY; LEFT KNEE ARTHROSCOPY, APPENDECTOMY; MULTI-LEVEL ANTERIOR CERVICAL FUSION
4		Allergy PERSONAL HISTORY OF ALLERGY TO NARCOTIC AGENT	DARVON [PROPOXYPHENE] CAUSES DIZZINESS AND MORPHINE
5		Procedure ROTATOR CUFF SYNDROME OF SHOULDER AND ALLIED DISORDERS	SURGERY

C1. Name (cont.)

Suspect Medication #1: OxyContin Tablets(OXYCODONE HYDROCHLORIDE) CR Tablet

C10. CONCOMITANT MEDICAL PRODUCTS

UNK
BENADRYL (DIPHENHYDRAMINE HYDROCHLORIDE) 03/18/1998 to UNK
DIAZEPAM (DIAZEPAM) 03/18/1998 to UNK
PERCOCET UNK to UNK
COLACE 03/18/1998 to UNK
MORPHINE SULFATE IR Tablet 03/18/1998 to UNK
MEDROL (METHYLPREDNISOLONE) 09/23/1998 to UNK
LORTAB UNK to UNK
CELEBREX (CELECOXIB) UNK to UNK
PROZAC (FLUOXETINE HYDROCHLORIDE) UNK to UNK
PRILASEC (OMEPRAZOLE) UNK to UNK
DEMEROL (PETHIDINE HYDROCHLORIDE) UNK to UNK
DALMANE (FLURAZEPAM HYDROCHLORIDE) UNK to UNK
LIPITOR (ATORVASTATIN) UNK to UNK

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0000789

UF/OTst report #

1A MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 4

FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier
REDACTED-PRIVACY
 2. Age at event: 40 Years
 or DOB: UNK
 3. Sex: female male
 4. Weight: 140.0 lbs or 63.5 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or Product problem
 Outcomes attrib. to event: death (mo/day/yr), life-threatening, hospitalization - initial or prolonged
 Disability: disability, congen anomaly, required intervention to prevent perm damage, other: med significant

3. Date of event: 02/2002
 4. Date of this Rept: 12/09/2002

5. Describe event or problem
 A 40-year-old female patient experienced drug dependence, shaking, vomiting, and feeling hot and cold in FEB02, while taking OxyContin (controlled-release oxycodone hydrochloride) 80 mg Tablets for pain on the left side of the head near the ear. In 1998, the patient began taking OxyContin 40 mg three times a day. OxyFast (immediate-release oxycodone hydrochloride) solution up to 1.5 ounces, was prescribed for breakthrough pain. The dose of OxyContin was gradually increased to 160 mg every 8 hours. In JUN00, the patient underwent a craniectomy. After the surgery, the dose of OxyContin was decreased to 160 mg (2 x 80 mg) three times a day. OxyFast was continued at the same dose. In FEB02, the patient experienced shaking, vomiting and she felt hot and cold. The patient went to the emergency room. A physician, reportedly, told the patient that she "was on a lethal dose of OxyContin". The patient decided to get off OxyContin and OxyFast and she went to a detoxification center. The patient left the center after 5 days, reportedly, after she saw another patient using OxyContin. The patient entered another detoxification center for 6 days. The patient was given Motrin (ibuprofen) for her pain. On 02MAR02, the patient was discharged from the center. The patient, reportedly, was told "you're okay now". That night, the patient experienced shaking and vomiting. On 12MAR02, the patient went to a pain clinic. The patient was started on Valium (diazepam), Zanaflex (tizanidine HCL),

6. Relevant tests/laboratory data, including dates
 UNKNOWN

7. Other relevant history, including preexist. med. conditions
 #1 (continued)

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 OxyContin tablets 80 mg (OXYCODONE HYDROCHLORIDE)
 #2 OxyFast Concentrate 20 mg/ml (OXYCODONE HYDROCHLORIDE)
 2. Dose, frequency & route
 #1 160 mg, tid, UNKNOWN
 #2 0 oz, daily, oral
 3. Therapy dates (if unk, give dur)
 #1 02/1998 - 02/2002
 #2 02/1998 - 02/2002
 4. Diagnosis for use (indication)
 #1 NON-MALIGNANT PAIN
 #2 NON-MALIGNANT PAIN
 5. Event abated after use stopped or dose reduced
 #1 yes no DK/N/A
 #2 yes no DK/N/A
 6. Lot # (if known)
 #1 UNKNOWN
 #2 UNKNOWN
 7. Exp. Date
 #1 UNKNOWN
 #2 UNKNOWN
 8. Event reappeared after reintroduction
 #1 yes no DK/N/A
 #2 yes no DK/N/A
 9. NDC # for prod problems only
 - - - - -

10. Concomitant medical products and therapy dates
 TEGRETOL
 PROZAC
 (CONT)

G. ALL MANUFACTURERS

1. Contact office - name/address
 Purdue Pharma L.P.
 One Stamford Forum
 Stamford, CT 06911-4651
 2. Phone number
 +1 203 586-0000
 3. Report Source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:
 4. Date Rec'd by Mfr.
 04/18/2002
 5. (A)NDA# 20-553
 ENDA# _____
 PIA# _____
 6. If IND, protocol #
 7. Type of report (check all that apply)
 15-day 15-day
 10-day periodic
 Init follow-up # _____
 8. Adverse event term(s)
 DRUG DEPENDENCE
 WITHDRAWAL SYNDROME
 TREMOR
 VOMITING
 (CONT)
 9. Mfr. report number
 USA-2002-0000789

E. INITIAL REPORTER

1. Name, address & phone #
 Name, address and phone withheld
 2. Health professional?
 yes no
 3. Occupation
 Nurse
 4. Initial reporter also sent report to FDA
 yes no DK/unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

8003060039

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-000789

UF/01st report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 4

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient identifier	2. Age at event	3. Sex	4. Weight	1. Name (give labeled strength & mfr/labeler, if known)			
	or BOB:	<input type="checkbox"/> female <input type="checkbox"/> male	lbs or kg	#			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route			
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				#		3. Therapy dates (if unk, give dur)	
2. Outcomes attrib. to event				#		#	
<input type="checkbox"/> death				<input type="checkbox"/> disability		<input type="checkbox"/> Event abated after use stopped or dose reduced	
(no/day/yy)				<input type="checkbox"/> congen anomaly		# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
<input type="checkbox"/> life threatening				<input type="checkbox"/> required intervention to prevent perm damage		# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
<input type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> other:		8. Event reappeared after reintroduction	
3. Date of event UNKNOWN				4. Date of this Rept 12/09/2002		9. NDC # for prod problems only	
5. Describe event or problem				#		# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
<p>Tegretol (carbamazepine), and Motrin (ibuprofen). The patient experienced headaches and insomnia. Valium was discontinued and the patient was switched to Xanax (alprazolam). The patient related that the constant headaches continue and she still has intermittent hot and cold feelings. The patient has an appointment with a psychiatrist on 19APR02. This case was initially reported by a nurse in the United States of America. Additional information is being requested.</p> <p>***Additional information received 11JUL02 from the patient related that she is 40 years old (not 39 years as previously reported). In FEB08, she began taking OxyContin 80 mg Tablets, 160 mg three times a day, for pain associated with trigeminal neuralgia. The patient was also taking 1 to 2 courses of Oxyfast. The patient related that she had good pain relief from OxyContin for the first three years. In JAN02 and FEB02, the patient experienced decreased pain relief and she craved OxyContin more and more. The physician was consulted. The dose was decreased from 160 mg three times a day to 120 mg three times a day to 90 mg three times a day. The patient related "By then I was climbing the walls and became sick - vomiting/not eating/dehydrated". The patient entered a detoxification center in FEB02. The patient took the last dose of OxyContin on 23FEB02. The patient is currently taking unspecified anti-anxiety tablets, Klonopin (clonazepam) and Zyprexa (olanzapine). The patient related</p>				6. Lot # (if known)		7. Exp. Date	
6. Relevant tests/laboratory data, including dates				#		#	
7. Other relevant history, including preexist. med. conditions				10. Concomitant medical products and therapy dates			
				ROXICODONE			
G. ALL MANUFACTURERS							
1. Contact office - name/address				2. Phone number			
Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431				+1 203 586-8000			
4. Date Rec'd by Mfr.				3. Report Source (check all that apply)			
6. If IND, protocol #				<input type="checkbox"/> foreign			
7. Type of report (check all that apply)				<input type="checkbox"/> study			
<input type="checkbox"/> 15-day <input type="checkbox"/> 30-day				<input type="checkbox"/> literature			
<input type="checkbox"/> 10-day OI periodic				<input type="checkbox"/> consumer			
<input type="checkbox"/> Init <input type="checkbox"/> follow up				<input type="checkbox"/> health professional			
9. Mfr. report number USA-2002-000789				<input type="checkbox"/> user facility			
				<input type="checkbox"/> company representative			
				<input type="checkbox"/> distributor			
				<input type="checkbox"/> other:			
				8. Adverse event term(s)			
				DEHYDRATION			
				ANOREXIA			
				TEMPERATURE CHANGED SENSATION			
E. INITIAL REPORTER							
1. Name, address & phone #							
2. Health professional?							
<input type="checkbox"/> yes <input type="checkbox"/> no							
3. Occupation							
4. Initial reporter also sent report to FDA							
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> junk							

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0000789

UF/BSE report #

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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 3 of 4

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient identifier	2. Age at event or _____ DOB: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lb or kgs	1. Name (give labeled strength & mfr/labeler, if known) #			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route #		3. Therapy dates (if unk, give dur) #	
1. Did Adverse Event and/or <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life threatening <input type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> Product problem <input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other			
2. Date of event UNKNOWN		3. Date of this Rept 12/09/2002		4. Diagnosis for use (indication) #		5. Event abated after use stopped or dose reduced # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
5. Describe event or problem "I'm finally feeling better".				6. Lot # (if known) #		7. Exp. Date #	
				8. Event reappeared after reintroduction # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A		9. NDC # for prod problems only # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
				10. Concomitant medical products and therapy dates			
G. ALL MANUFACTURERS							
1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431				2. Phone number +1 203 508-8000			
4. Date Rec'd by Mfr.				5. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health <input type="checkbox"/> professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:			
6. If IND, protocol #				IND# _____ PLA# _____			
6. Relevant tests/laboratory data, including dates				7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input type="checkbox"/> periodic <input type="checkbox"/> initial <input type="checkbox"/> follow up # _____			
7. Other relevant history, including preexist. med. conditions				8. Adverse event term(s)			
				9. Mfr. report number USA-2002-0000789			
F. INITIAL REPORTER							
1. Name, address & phone #							
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk			

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Facsimile Form 3500A

8003060041

3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

1 SURGERY JUN00 patient had craniectomy

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0000808

UF/Dist report #

FDA Use Only

MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

1. Patient Identifier PHYSICIAN or DOB: UNK	2. Age at event 45 Years	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
--	-----------------------------	---	---------------------------------------

B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or comes attrib. to event death (mo/day/yy) life-threatening <input type="checkbox"/> hospitalization initial or prolonged	<input type="checkbox"/> Product problem <input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input checked="" type="checkbox"/> other: med significant
---	--

5. Date of event UNKNOWN 4. Date of this Rept 12/09/2002

5. Describe event or problem

A 45-year-old male (race unspecified) experienced drug dependence and depression on an unspecified date while taking OxyContin (controlled-release oxycodone hydrochloride) 40 mg tablets q8h for severe neck pain. Reportedly, the patient has been taking OxyContin for the past ten months, starting with 20 mg TID and titrated up to 40 mg q8h. The patient related that five hours after he takes a dose of OxyContin, his body craves OxyContin and he holds off "the best he can". Reportedly, this makes him depressed and he is having difficulty functioning. The patient reported that his doctor has tried to taper him off OxyContin at an unspecified time without success. Significant medical history and concomitant medications are unknown. This case was reported on 23APR02 by a consumer in the United States of America. The reporting consumer did not reveal his address and phone number, but did agree to have his doctor call to speak to Purdue's Medical Division.

6. Relevant tests/laboratory data, including dates

UNKNOWN

7. Other relevant history, including preexist. med. conditions

#1 Current Condition, PAIN

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
#1 OxyContin Tablets 40 mg (OXYCODONE HYDROCHLORIDE)

2. Dose, frequency & route #1 40 mg, q8h, Oral
3. Therapy dates (if unk, give dur) #1 UNKNOWN

4. Diagnosis for use (indication) #1 Non-malignant pain
5. Event abated after use stopped or dose reduced #1 yes no N/A

6. Lot # (if known) #1 Unknown
7. Exp. Date #1 UNKNOWN
8. Event reappeared after reintroduction #1 yes no N/A

9. NDC # for prod problems only #1 yes no N/A

10. Concomitant medical products and therapy dates
UNKNOWN

G. ALL MANUFACTURERS

1. Contact office - name/address
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901 3431
2. Phone number
+1 203 588-8000
5. Report Source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 others

4. Date Rec'd by Mfr. 04/23/2002
5. (A)NDA# 20-55T

6. If IND, protocol #
7. Type of report (check all that apply)
 15-day 15-day
 110-day periodic
 initial follow-up
8. Adverse event term(s)
DRUG DEPENDENCE
DEPRESSION

9. Mfr. report number
USA-2002-0000808

E. INITIAL REPORTER

1. Name, address & phone #
Name, address and phone withheld

2. Health professional? yes no
3. Occupation
Consumer
4. Initial reporter also sent report to FDA
 yes no unk

MED INFO ASSOC: Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
facsimile Form 3500A

8003060054

3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

#	Start/Stop	Cond. Type/Condition	Notes
1		Current Condition	SEVERE NECK PAIN ON AN UNSPECIFIED DATE PAIN

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-000957
UF/Dist report #	
FDA Use Only	

DA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

1. Patient identifier ID-PRIVAC	2. Age at event 48 Years	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
------------------------------------	-----------------------------	---	---------------------------------------

B. ADVERSE EVENT OR PRODUCT PROBLEM

<input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input checked="" type="checkbox"/> other: mod significant

3. Date of event	UNKNOWN	4. Date of this Rept	12/09/2002
------------------	---------	----------------------	------------

5. Describe event or problem
A 48-year-old male (race not specified) experienced dyspepsia while taking OxyContin (controlled-release oxycodone hydrochloride) 80 mg tablets every 6 hours for chronic back pain. Reportedly, the patient has been taking OxyContin for three years. About a year ago, the patient's OxyContin dose was increased to 80 mg and he began to feel sick to his stomach. Therefore, he started "to peel the coatings off of the OxyContin 80 mg tablets" before ingesting so that he would not feel sick to his stomach. No further information was provided. This case was reported on 06MAY02 by a nurse in the United States of America. Additional information is being requested.

6. Relevant tests/laboratory data, including dates	UNKNOWN
--	---------

7. Other relevant history, including preexist. med. conditions	#1 Indication, PAIN IN THORACIC SPINE
--	---------------------------------------

MED INFO ASSOC
Facsimile Form 3500A
Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin Tablets 80 mg (OXYCODONE HYDROCHLORIDE) #	
2. Dose, frequency & route #1 80 mg, q6h, Oral	3. Therapy dates (if unk, give dur) #1 UNKNOWN
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DN/A
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1 UNKNOWN
8. Event reappeared after reintroduction #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DN/A	9. MOC # for prod problems only #
10. Concomitant medical products and therapy dates UNKNOWN	

D. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431	2. Phone number #1 203 588-6000
4. Date Rec'd by Mfr. 05/06/2002	5. (A) NDA# 20-555
6. If IND, protocol #	IND# PLA#
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	8. Adverse event term(s) DRUG ABUSE DYSPEPSIA
9. Mfr. report number USA-2002-000957	

E. INITIAL REPORTER

1. Name, address & phone # Name, address and phone withheld		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Nurse	4. Initial reporter also sent report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> unk

8003060262

3500A Continuation Page

A/. Other relevant history, including preexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

#	Start/Stop	Cond. Type/Condition	Notes
1		Indication PAIN IN THORACIC SPINE	CHRONIC BACK PAIN

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-0001067
UR/Dist report #	
FDA Use Only	

A. MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier #1 PRIVACY	2. Age at event 34 Years or DNR-UNK	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
--	--	---	---------------------------------------

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or comes attrib. to event death life-threatening hospitalization - initial or prolonged	and/or	<input type="checkbox"/> Product problem <input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:
3. Date of event UNKNOWN	4. Date of this Rept 12/09/2002	

b. Describe event or problem

A 54-year-old male, race not specified, experienced a lack of drug effect, abnormal gait, falling, disorientation, insomnia, personality changes, abnormal speech, paranoia, and withdrawal symptoms while taking OxyContin (controlled-release oxycodone hydrochloride) for chronic pain syndrome of unknown etiology. Reportedly, most of his pain is in his legs. The reporting physician related that the patient started taking OxyContin 20 mg every 12 hours on an unspecified date in DEC99 and after two weeks on this dose, he was titrated to 80 mg every 12 hours and after two weeks the dose was increased to 120 mg every 12 hours. On an unspecified date, the patient related that he was unable to work due to severe pain. The physician increased the OxyContin to 120 mg at 7 a.m., 80 mg at 1 p.m., and 80 mg at 8 p.m. On an unspecified date in FEB00, the patient reportedly was still having pain and the physician increased his dose to 160 mg every 12 hours. Reportedly, in OMA00, the dose was increased to 240 mg every 12 hours due to pain. The patient reported that OxyContin was "wearing off, it did not last." On an unspecified date in SEP00, the dose was increased to 320 mg twice daily with 40 mg being taken in between these two doses. Reportedly, by an unspecified date in NOV00, the patient was taking OxyContin 200 mg every 8 hours and by an unspecified date in JAN01, the patient was taking 240 mg of OxyContin every 8 hours. The patient reported that he would occasionally fall down steps and his gait

6. Relevant tests/laboratory data, including dates

Numerous, unspecified tests, from neurologists and rheumatologists.

7. Other relevant history, including preexist. med. conditions

#1 Indication, PAIN

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin Tablets 20 mg (OXYCODONE HYDROCHLORIDE)		
2. Dose, frequency & route #1 20 mg, see text, Oral	3. Therapy dates (if unk, give dur) #1 12/1999, duration UNK	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no D/N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A	
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1 UNKNOWN	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no D/N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A
9. NDC # for prod problems only -		
10. Concomitant medical products and therapy dates UNKNOWN		

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431		2. Phone number +1 203 588-8000
4. Date Rec'd by Mfr. 05/15/2002		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
5. (A) NDA# 20-553	6. If IND, protocol # IND# PLAN#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10 day (K) periodic DD Init <input type="checkbox"/> follow-up #	8. Adverse event term(s) MEDICINE INEFFECTIVE GAIT ABNORMAL FALL CONFUSION (CONF)	
9. Mfr. report number USA-2002-0001067		

E. INITIAL REPORTER

1. Name, address & phone # Name, address and phone withheld			
2. Health professional? DI yes <input type="checkbox"/> no	3. Occupation Osteopathic Physician <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	4. Initial reporter also sent report to FDA	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Form 3500A

8003060356

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0001067

UF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 4

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient Identifier	2. Age at event OR DOB:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) # #			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route # #		5. Therapy dates (if unk, give dur) # #	
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				4. Diagnosis for use (indication) # #		5. Event abated after use stopped or dose reduced # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____		6. Lot # (if known) # #	
3. Date of event UNKNOWN				7. Exp. Date # #		8. Event reappeared after reintroduction # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
4. Date of this Rept (2/09/2002)				9. NDC # for prod problems only # #			
5. Describe event or problem use slightly ataxic. By the end of MAR01, the patient started to become disoriented, he couldn't sleep, had personality changes (harsh, mean), his speech was indecipherable, and he was paranoid. On an unspecified date, the physician began to wear him off the Oxycotin. Reportedly, the patient had withdrawal symptoms at 20 mg twice daily and the dose was increased to 40 mg twice daily. On an unspecified date in MAY01, the patient was admitted to the hospital for his pain management and was treated with physical therapy, occupational therapy, biofeedback and psychiatric counseling. He was discharged four weeks later. The patient was weaned off the Oxycotin and is using Duragesic (fentanyl) patch. Reportedly, the patient is functioning in a different job, and at times does not recall all of the mentioned events. This case was reported on 19MAY02 by a physician via a company representative in the United States of America. Additional information is being requested.				10. Concomitant medical products and therapy dates			
6. Relevant tests/laboratory data, including dates				G. ALL MANUFACTURERS			
7. Other relevant history, including preexist. med. conditions				7. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431		2. Phone number +1 203 588-8000	
				4. Date Rec'd by Mfr.		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
				6. If IND, protocol #		5. IANDA# IND# PLA#	
				7. Type of report (check all that apply) <input type="checkbox"/> 35-day <input type="checkbox"/> 115-day <input type="checkbox"/> 310-day D(Periodic) <input type="checkbox"/> Init <input type="checkbox"/> follow up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product	
				8. Adverse event term(s) INSOMNIA PERSONALITY DISORDER SPEECH DISORDER PARANOID REACTION (CONT)		9. Nfr. report number USA-2002-0001067	
				E. INITIAL REPORTER			
				1. Name, address & phone #			
				2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation	
				4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk			

MED INFO ASSCC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003060357

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-001067

UF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 3 of 4

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient identifier	2. Age at event or DOB:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) # #			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route # #		3. Therapy dates (if unk, give dur) # #	
1. DX Adverse Event and/or <input type="checkbox"/> Product problem				4. Diagnosis for use (indication) # #		5. Event abated after USE Stopped or dose reduced # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A	
2. Outcomes attrib. to event <input type="checkbox"/> death (no/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged				6. Lot # (if known) # #		7. Exp. Date # #	
3. Date of event UNKNOWN				4. Date of this Rpt 12/09/2002		8. Event reappeared after reintroduction # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A	
5. Describe event or problem				9. NDC # for prod problems only # #			
6. Relevant tests/laboratory data, including dates				10. Concomitant medical products and therapy dates			
7. Other relevant history, including preexist. med. conditions				D. ALL MANUFACTURERS			
				1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901 3431		2. Phone number +1 203 588-8000	
				4. Date Rec'd by Mfr.		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company <input type="checkbox"/> representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
				5. (A)NDA#			
				6. If IND, protocol #			
				7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day DX/periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		8. Adverse event term(s) WITHDRAWAL SYNDROME	
				9. Mfr. report number USA-2002-001067			
E. INITIAL REPORTER				1. Name, address & phone #			
				2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation	
						4. Initial reporter also sent report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Junk	

MED INFO ASSOC submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003060358

3500A Continuation Page

A/. Other relevant history, including prexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

1 Indication CHRONIC PAIN SYNDROME OF UNKNOWN ETIOLOGY
PAIN

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-0001088
UF/Dist report #	
FDA Use Only	

MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient Identifier ACTED	2. Age at event 68 Years or DOS: UNK	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin Tablets 20 mg (COXYCODONE HYDROCHLORIDE) #2 OxyContin Tablets 20 mg (COXYCODONE HYDROCHLORIDE)			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route		3. Therapy dates (if unk, give dur)	
Adverse Event and/or <input type="checkbox"/> Product problem				#1 20 mg, q12h, Oral #2 20 mg, q8h, Oral		#1 UNKNOWN #2 UNKNOWN	
comes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent permanent damage <input type="checkbox"/> other:		4. Event abated after use stopped or dose reduced	
3. Date of event UNKNOWN				4. Date of this Rept 12/09/2002		5. #1 <input type="checkbox"/> Yes <input type="checkbox"/> No D/N/A #2 <input type="checkbox"/> Yes <input type="checkbox"/> No D/N/A	
5. Describe event or problem				6. Lot # (if known)		7. Exp. Date	
A 68-year-old female (race unspecified) experienced dehydration, sedation and lack of pain relief while taking OxyContin (controlled release oxycodone hydrochloride) 20 mg, every twelve hours for unspecified pain. Reportedly, the patient began taking OxyContin on an unspecified date and experienced ineffective pain relief. The dose was adjusted from 20 mg every twelve hours to 20 mg every eight hours. Allegedly, the patient then became sedated and dehydrated and required hospitalization on an unspecified date. Reportedly, the OxyContin was discontinued. The reporting physician "doesn't know if the dehydration is due to something else". The patient's medical history and concomitant medications are unknown. This case was reported on 15MAY02 by a physician via a company representative in the United States of America. Additional information is being requested.				#1 UNKNOWN #2 UNKNOWN		#1 UNKNOWN #2 UNKNOWN	
6. Relevant tests/laboratory data, including dates				9. NDC # for prod problems only			
UNKNOWN				-			
7. Other relevant history, including preexist. med. conditions				10. Concomitant medical products and therapy dates			
#1 (continued)				UNKNOWN			
G. ALL MANUFACTURERS							
1. Contact office - name/address				2. Phone number			
Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431				+1 203 588-8000			
4. Date Rec'd by Mfr. 05/14/2002				5. (A) NDA# 20-553			
6. <input type="checkbox"/> IND, protocol #				IND#			
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day (X) periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up				pre-1958 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product			
9. Mfr. report number USA-2002-0001088				8. Adverse event term(s) DEHYDRATION SOMNOLENCE MEDICINE INEFFECTIVE			
3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input checked="" type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:							
E. INITIAL REPORTER							
1. Name, address & phone # Name, address and phone withheld							
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation Physician		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003060395

3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

1 UNKNOWN

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0001378

UF/Diet report #

FDA Use Only

IA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 5

A. PATIENT INFORMATION

1. Patient identifier: **ACTED**
 2. Age at event: UNK
 3. Sex: female male
 4. Weight: UNK lbs or UNK kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

X1 Adverse Event and/or Product problem
 Outcomes attrib. to event:
 death
 life-threatening
 hospitalization - initial or prolonged
 disability
 congen anomaly
 required intervention to prevent perm damage
 other: med significant

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 OxyContin Tablets 10 mg (OXYCODONE HYDROCHLORIDE)
 #2 OxyContin Tablets 10 mg (OXYCODONE HYDROCHLORIDE)
 2. Dose, frequency & route
 #1 10 mg, q12h, Oral
 #2 10 mg, q8h, Oral
 3. Therapy dates (if unk, give dur)
 #1 07/10/2000 - 08/07/2000
 #2 08/07/2000, duration UNK
 4. Diagnosis for use (indication)
 #1 NON-MALIGNANT PAIN
 #2 NON MALIGNANT PAIN
 5. Event abated after use stopped or dose reduced
 #1 Yes No N/A
 #2 Yes No N/A
 6. Lot # (if known)
 #1 UNKNOWN
 #2 UNKNOWN
 7. Exp. Date
 #1 UNKNOWN
 #2 UNKNOWN
 8. Event reappeared after reintroduction
 #1 Yes No N/A
 #2 Yes No N/A
 9. NDC # for prod problems only
 #1
 #2
 10. Concomitant medical products and therapy dates
 UNKNOWN

3. Date of event: UNKNOWN
 4. Date of this report: 12/09/2002

5. Describe event or problem
 A male consumer (race and age not specified) allegedly experienced drug addiction, constipation, depression, anorexia, rash, pruritus, dizziness, nausea, physical pain, withdrawal symptoms, lack of drug effect and mental anguish while taking OxyContin (controlled-release oxycodone hydrochloride) for persistent back pain. Reportedly, the consumer had back surgery in 7/99 to repair ruptured discs. The consumer was prescribed Lorcet Plus (paracetamol/hydrocodone bitartrate) for postoperative pain. Reportedly, the consumer was referred to a pain specialist after he noted that the pain was not subsiding. The pain specialist prescribed OxyContin 10 mg every 12 hours on 10/10/00 for the consumer. On 11/10/00, the consumer's dose of OxyContin was increased to every eight hours for continued complaints of pain. On 06/01/01, the consumer filled two prescriptions for OxyContin, one provided the consumer's regular 30 day supply and the second was for 45 more 10 mg OxyContin tablets. Allegedly while taking OxyContin, the consumer experienced drastic and substantial changes in his actions such as: he was unable to remember conversations and he became withdrawn, groggy and lethargic. The consumer reportedly developed skin rashes and severe itching. The consumer continued to need more and more OxyContin to relieve his pain and would run out of medication early. Reportedly, the consumer would seek alternative means to obtain the extra OxyContin he needed to control his craving. The consumer also

6. Relevant tests/laboratory data, including dates
 UNKNOWN

7. Other relevant history, including preexist. med. conditions
 #1 Procedure, SURGERY
 #2 Indication, PAIN IN THORACIC SPINE

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

G. ALL MANUFACTURERS

1. Contact office - name/address
 Purdue Pharma L.P.
 One Stamford Forum
 Stamford, CT 06901-3431
 2. Phone number
 +1 203 588-8000
 3. Report Source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other: Attorney
 4. Date Rec'd by Mfr.
 06/17/2002
 5. (A)NDA# 20-153
 IND#
 PLA#
 pre 1938 Yes
 OTC Yes
 product
 6. If IND, protocol #
 7. Type of report (check all that apply)
 15-day 15-day
 110-day periodic
 Init follow-up #
 8. Adverse event term(s)
 DRUG DEPENDENCE
 SOMNOLENCE
 SOMNOLENCE
 DEPRESSION
 (CONT)
 9. Mfr. report number
 USA-2002-0001378

E. INITIAL REPORTER

1. Name, address & phone #
 Name, address and phone withheld
 2. Health professional?
 Yes No
 3. Occupation
 Consumer
 4. Initial reporter also sent report to FDA
 Yes No Unk

8003060672

REDWATCH

Purdue Pharma, I.P.

Mfr report # USA 2002 0001378

UF/Diot report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 5

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	2. Outcomes attrib. to event (mo/day/yr) <input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:
--	--

3. Date of event UNKNOWN	4. Date of this Rept 12/09/2002
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5. Describe event or problem

reported experiencing incapacitating dizziness, nausea, major depression, physical pain and mental anguish. The consumer reported that he sought treatment for his addiction by attending out-patient therapy and receiving daily methadone treatments for withdrawal from Oxycodone. No further information was provided. This case was reported on 17JUN02 by a consumer via an attorney in the United States of America. Additional information is being requested.

***Upon further review of the safety database on 04-DEC-02, case USA-2002-0002152, which was previously submitted to the agency, is being deleted from the database because it is a duplicate of this case. All information under case USA-2002-0002152 has been merged into this case (USA-2002-0001378). Any additional information received will be reported under manufacturer report number USA-2002-0001378.

***Regulatory Submission History for the case being deleted was as follows: 04-OCT-02 Initial Internal Use-USA07-OCT-02 Initial Internal Use-MAG

6. Relevant tests/Laboratory data, including dates
7. Other relevant history, including preexist. med. conditions

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) # #

2. Dose, frequency & route # #	3. Therapy dates (if unk. give dur) # #
--------------------------------------	---

4. Diagnosis for use (indication) # #	5. Event abated after use stopped or dose reduced # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A
---	---

6. Lot # (if known) # #	7. Exp. Date # #	8. Event reappeared after reintroduction # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A
-------------------------------	------------------------	--

9. NDC # for prod problems only # #

10. Concomitant medical products and therapy dates
--

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma I.P. One Stamford Forum Stamford, CT 06901-3431	2. Phone number +1 203 588-8000	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
---	------------------------------------	---

4. Date Rec'd by Mfr.	5. (A)NDA#
6. If IND, protocol #	(IND#
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day (X) periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	PLA# pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes

8. Adverse event term(s) AMNESIA RASH PRURITUS DIZZINESS (CONT)
--

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk
---	---------------	--

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003060673

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-000137B

UF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 4 of 5

A. PATIENT INFORMATION			
1. Patient identifier	2. Age at event or DOB:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or		<input type="checkbox"/> Product problem	
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:	
3. Date of event UNKNOWN	4. Date of this Rept 12/09/2002		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexist. med. conditions			

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known) # #	
2. Dose, frequency & route # #	3. Therapy dates (if unk, give dur) # #
4. Diagnosis for use (indication) # #	5. Event abated after use stopped or dose reduced # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I/A
6. Lot # (if known) # #	7. Exp. Date # #
9. NDC # for prod problems only # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I/A	
10. Concurrent medical products and therapy dates	
G. ALL MANUFACTURERS	
1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06907-3431	
2. Phone number +1 203 588 8000	
3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
4. Date Rec'd by Mfr.	5. (A)IND# IND# PL#
6. If IND, protocol #	7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input type="checkbox"/> follow up #
8. Adverse event term(s) ANXIETY	
9. Mfr. report number USA-2002-000137B	

E. INITIAL REPORTER			
1. Name, address & phone #			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	

NFD INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003060675

3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

#	Start/Stop	Cond. Type/Condition	Notes
1	11/22/1999	Procedure SURGERY	BACK SURGERY TO REPAIR RUPTURED DISCS
2		Indication PAIN IN THORACIC SPINE	PERSISTENT BACK PAIN

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA 2002 0001727

UF/Diat report #

FDA Use Only

MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 3

A. PATIENT INFORMATION

1. Patient Identifier **ACTED**
 2. Age at event 57 Years
 3. Sex female
 4. Weight 57.7 lbs or 262.0 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse Event and/or Product problem
 comes attrib. to event disability
 death congen anomaly
 (mo/day/yy) required intervention
 life-threatening to prevent perm damage
 hospitalization - other: med significant
 initial or prolonged

3. Date of event 02/2001 4. Date of this Rept 12/09/2002

5. Describe event or problem
 A female (age and race not specified) allegedly experienced drug addiction, drug abuse, anxiety and emotional distress on unspecified dates while taking OxyContin (controlled-release oxycodone hydrochloride) for an unspecified indication. Dose, frequency, and therapy dates were not specified. Reportedly, this female's medical history is significant for type II diabetes, hypothyroidism, low back pain with degenerative joint disease and anxiety. This case was reported on 16JUL02 by a consumer via an attorney in the United States of America. Additional information is being requested. ***Additional information received on 18SEP07 via an attorney in the form of hospital and medical records reveal that the patient is a 57-year-old white female who experienced depression, anxiety, hallucinations, nightmares and panic attacks while taking OxyContin 40 mg tid for non-malignant pain. The patient began taking OxyContin 40 mg bid on 16JUL01. On 15MAR01 she experienced diarrhea and abdominal discomfort which was diagnosed as recurrent diverticulitis. At this visit she told her physician that she was experiencing pain in the middle of the day and that she was taking an extra dose of OxyContin at night to help her sleep. Given this information, her dose of OxyContin was increased to 40 mg tid on 15MAR01. On 29MAY01 the patient was seen by her physician with complaints of nervousness, anxiety, tremulousness, and nightmares. She claimed that she was very nervous and had been experiencing a lot of stress.

6. Relevant tests/laboratory data, including dates
 UNKNOWN

7. Other relevant history, including preexist. med. conditions
- #1 Current Condition, DIABETES MELLITUS
 - #2 Current Condition, UNSPECIFIED HYPOTHYROIDISM
 - #3 Current Condition, PAIN
 - #4 Current Condition, ANXIETY STATES
 - #5 Current Condition, DEPRESSION
 - #6 Current Condition, ANOREXIA
 - #7 Current Condition, CONSTIPATION
 - #8 Current Condition, CYSTITIS, OTHER
 - #9 Current Condition, OSTEOARTHRITIS

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 OxyContin Tablets 40 mg (OXYCODONE HYDROCHLORIDE)
 2. Dose, frequency & route #1 40 mg, tid, Oral
 3. Therapy dates (if unk, give dur)
 #1 02/16/2001 - 06/07/2001

4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN
 5. Event abated after use stopped or dose reduced
 #1 yes no DK/N/A

6. Lot # (if known) #1 UNKNOWN
 7. Exp. Date #1 UNKNOWN
 8. Event reappeared after reintroduction
 #1 yes no DK/N/A

9. NDC # for prod problems only
 #1 yes no DK/N/A

10. Concomitant medical products and therapy dates
 PAXIL
 XANAX
 (CONT)

G. ALL MANUFACTURERS

1. Contact office - name/address
 Purdue Pharma L.P.
 One Stamford Forum
 Stamford, CT 06901-3431
 2. Phone number
 #1 203 588-8000

3. Report Source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other: ATTORNEY

4. Date Rec'd by Mfr. 07/16/2002
 5. (AINDA# 20-553)
 6. If IND, protocol # IND#
 7. Type of report (check all that apply)
 15-day 15-day
 170-day periodic
 Init follow up
 8. Adverse event term(s)
 DRUG DEPENDENCE
 DRUG ABUSE
 ANXIETY
 EMOTIONAL LABILITY (CONT)

9. Mfr. report number USA-2002-0001727

E. INITIAL REPORTER

1. Name, address & phone #
 Name, address and phone withheld

2. Health professional? yes no
 3. Occupation Physician
 4. Initial reporter also sent report to FDA yes no unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

8003061167

NEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0001727

UF/Diet report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 8

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at event	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. (X) Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event UNKNOWN	4. Date of this Rpt 12/09/2002
--------------------------	--------------------------------

5. Describe event or problem

She admitted to being depressed, feeling down, and not sleeping well. She stopped taking Ambion (zalcipidm tartrate) because she read that "it can cause hallucinations" and she stopped taking Detrol (tolteradine L-tartrate) "because it caused that." Per the physician's notes, she admitted to thinking about suicide and was wondering if its worth doing but never attempted. The patient told her physician that she thought OxyContin was "causing this to her." Her physician informed her that all of her symptoms could be related to OxyContin, however he also felt that her symptoms of depression and panic could be related to the stressful home situation. According to the physician's notes date 06JUN01, the patient insisted and was adamant about stopping OxyContin since she felt that all of her problems, including depression, nightmares, feeling scared and hallucinations, were related to OxyContin. On 06JUN01 OxyContin was discontinued and the patient was placed on Meclizone 20 mg tid prn. Per the physician's progress note dated 14JUN01, the patient was placed on Meclizone "not with the intention of weaning them off, but rather of switching them from one pain medication to the other." The notes also stated that the patient's condition had deteriorated after she started to have problems at home with her son. She began to appear nervous and show signs of "depression more than anxiety or a combination of depression and anxiety

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexist. med. conditions

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)

2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
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4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
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6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction
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9. NDC # for prod problems only	# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
---------------------------------	---

10. Concomitant medical products and therapy dates

AVANDIA
DILACOR XR
(CONT)

G. ALL MANUFACTURERS

1. Contact office - name/address	2. Phone number
----------------------------------	-----------------

3. Report Source (check all that apply)

4. Date Rec'd by Mfr.	5. (A)NDA#
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6. If IND, protocol #	IND#
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7. Type of report (check all that apply)	8. Adverse event term(s)
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C. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
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MED INDU ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003061168

MEDWATCH

Purdue PHARM, L.P.

Mfr report #	USA-2002-0001727
UF/Diet report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 3 of 8

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:
3. Date of event UNKNOWN	4. Date of this Rept 12/09/2002

5. Describe event or problem

pointing toward panic." While taking OxyContin the patient was also treated for a candidiasis skin infection on ZAPROL and for an allergic reaction (hives and swelling) to Augmentin on DIFFROIT. Augmentin was prescribed for the patient on 16JUN01, the same day that the patient began taking OxyContin. The medication was prescribed for bronchitis and the patient failed to inform the physician that she was allergic to penicillin. On 11JUN01, 5 days after discontinuing OxyContin and while taking Methadone 20 mg tid, the patient was admitted to the hospital with a diagnosis of pneumonia. At the time of admission, the patient claimed that she was in "Oxycontin withdrawal." The patient's pneumonia was successfully treated she was discharged on 15JUN01 to psychiatric facility. Per the hospital discharge summary, the patient was advised to seek in-patient psychiatric treatment for problems "concerning her mental status and the presumed problem of methadone." A hospital note dated 14JUN01 revealed that "She indicated that she is very stressed at home and anxious and that she is severely depressed and has been so for over a year." An agreement was reached between the family and the patient that she would be admitted to a psychiatric facility for drug rehabilitation and psychiatric care. On 15JUN01 the patient was transferred from the hospital to an in-patient psychiatric hospital with a diagnosis of major depressive disorder with psychosis and for

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexist. med. conditions

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)

2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
4. Diagnosis for use (indication)	5. Event started after use stopped or dose reduced
6. Lot # (if known)	7. Exp. Date
9. NDC # for prod problems only	8. Event reappeared after reinstitution

10. Concomitant medical products and therapy dates

SYNTHROID
MIRALAK
(CDMT)

D. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901 3431	2. Phone number +1 203 588-8000
3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	

4. Data Rec'd by Mfr.	5. (A)NDA#
6. If IND, protocol #	IND#
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day (X) periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up	8. Adverse event term(s) MONILIASIS NERVOUSNESS DIVER TICULITIS, COLONIC ALLERGIC REACTION (CDMT)
9. Mfr. report number USA 2002 0001727	

E. INITIAL REPORTER

1. Name, address & phone #			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003061169

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-0001727
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 4 of 8

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age at event or NOR	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight (lbs) or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event	UNKNOWN	4. Date of this Rept	12/09/2002
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5. Describe event or problem
opioid detoxification, methadone taper.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexist. med. conditions

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known)	#

2. Dose, frequency & route	#	3. Therapy dates (if unk, give dur)	#
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4. Diagnosis for use (indication)	#	5. Event abated after use stopped or dose reduced	#
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6. Lot # (if known)	#	7. Exp. Date	#	8. Event reappeared after reintroduction	#
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9. NDC # for prod problems only	#	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------------------	---	---

10. Concomitant medical products and therapy dates
COITRIMIN
ATACAMP
(CONT)

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431	2. Phone number +1 203 588-8000
---	------------------------------------

4. Date Rec'd by Mfr.	5. (A)NDA#	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	IND#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input type="checkbox"/> follow-up #	PLA# pre-1930 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product	

8. Adverse event term(s) URTICARIA
9. Mfr. report number USA-2002-0001727

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
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MED INFO ASSOC
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Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

8003061170

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-0001727
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 5 of 8

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient identifier or DOB:	2. Age at event or	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) # #			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route # #		3. Therapy dates (if unk, give dur) # #	
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				4. Diagnosis for use (indication) # #		5. Event started after use stopped or dose reduced # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A	
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:		8. Event reappeared after reintroduction # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A # <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> IN/A	
3. Date of event UNKNOWN		4. Date of this Rept 12/09/2002		6. Lot # (if known) # #		7. Exp. Date # #	
5. Describe event or problem				9. HOC # for prod problems only - -			
				10. Concomitant medical products and therapy dates FLAGYL FORTE CIPRO (CONT)			
G. ALL MANUFACTURERS							
1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901 3431				2. Phone number +1 203 588-8000		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
4. Date Rec'd by Mfr.				5. (A)NDAW IND# PLAW		7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 10-day <input type="checkbox"/> 1 periodic DD Init <input type="checkbox"/> I follow-up #	
6. Relevant tests/Laboratory data, including dates				9. Mfr. report number USA 2002 0001727		8. Adverse event term(s)	
7. Other relevant history, including preexist. med. conditions				E. INITIAL REPORTER			
				1. Name, address & phone #			
				2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003061474

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-0001727
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 6 of 8

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient identifier	2. Age at event or DOB:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) # #			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route # #		3. Therapy dates (if unk, give dur) # #	
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				4. Diagnosis for use (indication) # #		5. Event abated after use stopped or dose reduced # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization <input type="checkbox"/> initial or prolonged				[<input type="checkbox"/> disability [<input type="checkbox"/> congen anomaly [<input type="checkbox"/> required intervention to prevent perm damage [<input type="checkbox"/> others:		8. Event reappeared after reintroduction # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
3. Date at event UNKNOWN		4. Date of this Rept 12/09/2002		6. Lot # (if known) # #		7. Exp. Date # #	
5. Describe event or problem				9. NDC # for prod problems only # #			
6. Relevant tests/laboratory data, including dates				10. Concurrent medical products and therapy dates CARDIZEM CR AMBIEN (CONT)			
				G. ALL MANUFACTURERS			
7. Other relevant history, including preexist. med. conditions				1. Contact office - name/address Purdue Pharma L.P. One Stamford Forum Stamford, CT 06907-3437		2. Phone number +1 203 588-8000	
				3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:			
8. Adverse event term(s)				4. Date Rec'd by Mfr. #		5. (A)NDA# IND# PLA#	
				6. (f IND, protocol #			
9. Mfr report number USA-2002-0001727				7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		8. Adverse event term(s)	
				E. INITIAL REPORTER			
1. Name, address & phone #				2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> junk							

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003061172

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0001727

UF/Diet report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 7 of 8

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
1. Patient identifier	2. Age at event	3. Sex	4. Weight	1. Name (give labeled strength & mfr/labeler, if known)			
	or DOB:	<input type="checkbox"/> female <input type="checkbox"/> male	lbs or kgs	#			
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route			
1. <input checked="" type="checkbox"/> Adverse Event and/or				5. Therapy dates (if unk, give dur)			
<input type="checkbox"/> Product problem				#	#		
2. Outcomes attrib. to event				4. Diagnosis for use (indication)			
<input type="checkbox"/> death				#			
<input type="checkbox"/> life-threatening (mo/day/yy)				5. Event started after use stopped or dose reduced			
<input type="checkbox"/> hospitalization initial or prolonged				# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
3. Date of event UNKNOWN				6. Lot # (if known)			
4. Date of this report 12/09/2002				7. Exp. Date			
5. Describe event or problem				#			
				8. Event reappeared after reintroduction			
				# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
				9. NDC # for prod problems only			
				# <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
				10. Concomitant medical products and therapy dates			
				DETROL			
G. ALL MANUFACTURERS							
1. Contact office - name/address				2. Phone number			
Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-2451				+1 203 588-8000			
4. Date Rec'd by Mfr.				3. Report Source (check all that apply)			
5. (A)NDA#				<input type="checkbox"/> foreign			
6. If IND, protocol #				<input type="checkbox"/> study			
7. Type of report (check all that apply)				<input type="checkbox"/> literature			
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day				<input type="checkbox"/> consumer			
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic				<input type="checkbox"/> health professional			
RX Init <input type="checkbox"/> follow-up				<input type="checkbox"/> user facility			
#				<input type="checkbox"/> company representative			
9. Mfr report number				<input type="checkbox"/> distributor			
USA-2002-0001727				<input type="checkbox"/> other:			
E. INITIAL REPORTER							
1. Name, address & phone #							
2. Health professional?							
3. Occupation							
4. Initial reporter also sent report to FDA							
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk							

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

facsimile Form 3500A

8003061173

3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

#	Start/Stop	Cond. Type/Condition	Notes
1		Current Condition DIABETES MELLITUS	TYPE II DIABETES
2		Current Condition UNSPECIFIED HYPOTHYROIDISM	HYPOTHYROIDISM
3		Current Condition PAIN	LOW BACK PAIN WITH DEGENERATIVE JOINT DISEASE; ; ;
4		Current Condition ANXIETY STATES	ANXIETY
5		Current Condition DEPRESSION	
6		Current Condition OBESITY	MORBID OBESITY
7		Current Condition CONSTIPATION	CHRONIC CONSTIPATION
8		Current Condition CYSTITIS, OTHER	INTERMITTENT BLADDER INFECTIONS
9		Current Condition OSTEOARTHRITIS	DEGENERATIVE JOINT/DISC DISEASE AND CHRONIC LOW BACK PAIN
10		Current Condition ACUTE SINUSITIS	SINUSITIS WITH SINUS HEADACHES
11		Current Condition DIVERTICULA OF COLON	DIVERTICULITIS
12		Current Condition HYSTERIA	PANIC ATTACKS
13		Current Condition ESSENTIAL HYPERTENSION	
14		Current Condition MIXED HYPERLIPIDAEMIA	HYPERLIPIDEMIA
15		Current Condition DISEASES OF ESOPHAGUS	GASTRIC REFLUX DISEASE
16		Historical Condition CARPAL TUNNEL SYNDROME	
17		Historical Condition CHOLECYSTITIS, OTHER	CHOLECYSTECTOMY
18		Historical Condition HEMORRHOIDS	
19	02/16/2001	Current Condition ACUTE BRONCHITIS	Treated with Augmentum



3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

- | # | Start/Stop | Cond. Type/Condition | Notes |
|---|------------|--|-------|
| 1 | | Historical Condition
MAJOR VEHICLE
TRAFFIC ACCIDENT OF
UNSPECIFIED NATURE | |
| 2 | | Indication
OTHER AND
UNSPECIFIED DISORDER
OF JOINT | |

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0002117

HF/Dist report #

FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

Patient identifier REDACTED	2. Age at event 41 Years	3. Sex Female	4. Weight 155.0 lbs or 70.3 kgs
---------------------------------------	-----------------------------	------------------	--

B. ADVERSE EVENT OR PRODUCT PROBLEM

Adverse event and/or Product problem

Outcomes attrib. to event
 death (mo/day/yy)
 life-threatening
 hospitalization - initial or prolonged

disability
 congen anomaly
 required intervention to prevent perm damage
 other: not significant

3. Date of event UNKNOWN 4. Date of this Rept 17/09/2002

5. Describe event or problem

An adult female patient allegedly experienced drug addiction and withdrawal symptoms while taking OxyContin (controlled release oxycodone hydrochloride) from FEB99 through MAR01. Reportedly, the patient was taking OxyContin on an unspecified date prior to FEB99, but was withdrawn due to no anatomical problem. The patient has reportedly undergone medical treatment for her addiction. This case was reported on 04SEP02 by a consumer via an attorney in the United States of America. Additional information is being requested.
 ***Additional information received on 10OCT02 via an attorney, revealed that this is a 41-year-old Caucasian female who was prescribed OxyContin 20, 40 and 80 mg three times a day for chronic back pain from FEB98 (not FEB99 as previously reported) until 20MAR01. She became addicted to OxyContin and was hospitalized from 20MAR01 until 26MAR01 for detox and had to seek follow-up care for continued withdrawal symptoms. No further information was provided.

6. Relevant tests/laboratory data, including dates

NORMAL NERVE CONDUCTION STUDIES

7. Other relevant history, including preexist. med. conditions

#1 Indication, UNSPECIFIED DISORDERS OF BACK

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)

#1 OxyContin Tablets (OXYCODONE HYDROCHLORIDE)

2. Dose, frequency & route 3. Therapy dates (if unk, give dur)

#1 UNK mg, see text, (CONT) #1 02/1998 - 03/2001

4. Diagnosis for use (indication) 5. Event abated after use stopped or dose reduced

#1 NON-MALIGNANT PAIN #1 yes no N/A

6. Lot # (if known) 7. Exp. Date 8. Event reappeared after reintroduction

#1 UNKNOWN #1 UNKNOWN #1 yes no N/A

9. NDC # for prod problems only #1 yes no N/A

10. Concomitant medical products and therapy dates

UNKNOWN

G. ALL MANUFACTURERS

1. Contact office name/address 2. Phone number

Purdue Pharma L.P. +1 203 588-8000

One Stamford Forum 3. Report Source (check all that apply)

Stamford, CT 06901-3431

foreign study literature consumer health professional user facility company representative distributor other: Attorney

4. Date Rec'd by Mfr. 07/04/2002 5. (A)NDA# 20-553

6. IF IND, protocol # IND#

7. Type of report (check all that apply) 15-day 115-day 110-day periodic Init follow-up #

8. Adverse event term(s) DRUG DEPENDENCE WITHDRAWAL SYNDROME

9. Mfr. report number USA-2002-0002117

E. INITIAL REPORTER

1. Name, address & phone #

Name, address and phone withheld

2. Health professional? 3. Occupation 4. Initial reporter also sent report to FDA

yes no lawyer yes no unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

3500A Continuation Page

A7. Other relevant history, including preexist. med. conditions (continued)

#	Start/Stop	Cond. Type/Condition	Notes
1		Indication UNSPECIFIED DISORDERS OF BACK	CHRONIC BACK PAIN

C2. Dose, frequency & route (continued)
#1 unknown, see text, Unknown

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0002455

UF/Dist report #

FDA Use Only

ADVERSE EVENT REPORTING PROGRAM

Page 1 of 2

PATIENT INFORMATION

1. Identifier **UNACTED**
 2. Age at event 31 Years
 3. Sex [] female [X] male
 4. Weight UNK lbs UNK kgs

ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or [] Product problem
 2. Was attrib. to event [] disability [] congen anomaly [] required intervention to prevent perm damage [X] other: med significant
 3. Date of event UNKNOWN
 4. Date of this Rept 12/09/2002

5. Describe event or problem
 A 31-year-old male, race not specified, allegedly experienced drug addiction on an unspecified date while taking OxyContin (controlled-release oxycodone hydrochloride) for pain associated with a broken back. Reportedly, on an unspecified date in JAN99, this male broke his back while on the job, falling 7 feet off a ladder onto a concrete floor. Reportedly, a page from his medical record dated 14.JUL99 revealed that 10-20 mg of OxyContin four times daily and a prn (taken as needed) allowance was prescribed for this male. Another note dated 12.MAY01 revealed that his dose of OxyContin was increased to 120 mg every eight hours. It was reported that the OxyContin was prescribed in "increasing doses making this male more and more dependent on the drug. This case was received via 10SEP02 via the news media in the United States of America.

6. Relevant tests/laboratory data, including dates
 UNKNOWN

7. Other relevant history, including preexist. med. conditions
 #1 Historical Condition, FRACTURE OF VERTEBRAL COLUMN W/ (CONT)

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 OxyContin Tablets (OXYCODONE HYDROCHLORIDE)
 2. Dose, frequency & route #1 UNK mg, see text, (CONT)
 3. Therapy dates (if unk, give dur) #1 UNKNOWN
 4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN
 5. Event abated after use stopped or dose reduced #1 [] yes [] no [X] N/A
 6. Lot # (if known) #1 UNKNOWN
 7. Exp. Date #1 UNKNOWN
 8. Event reappeared after reintroduction #1 [] yes [] no [X] N/A
 9. MOC # for prod problems only #1 [] yes [] no [X] N/A
 10. Concomitant medical products and therapy dates UNKNOWN

G. ALL MANUFACTURERS

1. Contact office - name/address
 Purdue Pharma L.P.
 One Stamford Forum
 Stamford, CT 06901-5431
 2. Phone number +1 203 500-8000
 3. Report Source (check all that apply)
 [] foreign [] study [] literature [X] consumer health [] professional user facility [] company representative [] distributor [X] other: MEDIA
 4. Date Rec'd by Mfr. 09/10/2002
 5. (CA)NDA# 201-951
 6. If IND, protocol # IND# PLA#
 7. Type of report (check all that apply)
 [] 15-day [] 15-day [] 110-day OJ periodic [] initial [] full follow-up #
 pre-1938 [] yes OTC [] yes product [] yes
 8. Adverse event term(s) DRUG DEPENDENCE
 9. Mfr. report number USA-2002-0002455

E. INITIAL REPORTER

1. Name, address & phone #
 Name, address and phone withheld
 2. Health professional? [] yes [X] no
 3. Occupation Journalist
 4. Initial reporter also sent report to FDA [] yes [] no [X] unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

8003062083

3S0DA Continuation Page

A7. other relevant history, including preexist. med. conditions (continued)

Start/Stop Cond. Type/Condition Notes

1 01/--/1999 Historical Condition BROKE HIS BACK FALLING 7 FEET OFF A LADDER ONTO A CONCRETE FLOOR
FRACTURE OF
VERTEBRAL COLUMN W/O
MENTION OF SPIN CORD
INJURY

MEDWATCH

Purdue Pharma L.P.

Mfr report # 990473

UF/Dist report #

FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event or _____ DOB: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____

3. Date of event 8/1/1999	4. Date of this Rept 01/05/2000
---------------------------	---------------------------------

5. Describe event or problem
A male patient experienced intractable hiccups on 01AUG99, while taking OxyContin 80 mg (2 x 40-mg tablets) every 8 hours for back pain. Reportedly, the hiccups were so severe, that the patient went to the emergency room that same day. He was treated with Compazine (prochlorperazine) and was subsequently released. OxyContin was discontinued and the symptom abated three days later, on 03AUG99. On 26SEP99, the patient took one OxyContin 40-mg tablet and again experienced hiccups. OxyContin was discontinued and the symptom abated the next day. Reportedly, the "event doesn't occur when the patient takes a single 20 mg tablet [of OxyContin]." No further information was provided.

6. Relevant tests/laboratory data, including dates
RELEVANT TESTS/DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions
Cervical radiculopathy

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known)	
#1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride) #2 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)	

2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
#1 80 MG Q8H PO #2 40 MG ONCE PO	#1 8/1/1999 - 8/1/1999 (STOP'D) #2 9/26/1999 - 9/26/1999 (STOP'D)

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 BACK PAIN #2 BACK PAIN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A

6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction
#1 UNKNOWN #2 UNKNOWN	#1 #2	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A

9. NDC # for prod problems only	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
---------------------------------	--

10. Concomitant medical products and therapy dates
WELLBUTRIN (BUPROPION), PRIOSECC (OMEPRAZOLE), LAMICTAL (LAMOTRIGINE), FLOMAX (TAMSULOSIN HCL)

G. ALL MANUFACTURERS		
1. Contact office - name/address	2. Phone number (203) 854-7280	3. Report Source (check all that apply)
Purdue Pharma L.P. 100 Connecticut Ave. Norwalk, CT 06850-3590		<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:

4. Date Rec'd by Mfr. 09/28/1999	5. (A)NDA# 20-553
6. If IND, protocol #	IND# _____ PLA# _____
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> init <input type="checkbox"/> follow-up # _____	pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes

8. Adverse event term(s)
HICCUP
9. Mfr. report number 990473

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			

2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHYSICIAN	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report # 990628

UF/Dist report #

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

FDA Use Only

A. PATIENT INFORMATION			
1. Patient name REDACTED	2. Age at event 32 YEARS or DOB	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:	
3. Date of event 11/16/1999	4. Date of this Rept 01/05/2000		
5. Describe event or problem A female patient experienced continuous nausea and vomiting over a two week period in 1999, while taking OxyContin (controlled-release oxycodone hydrochloride) 40 mg every 8 to 12 hours for an unspecified indication. Starting in NOV99, after having been taking OxyContin for approximately six weeks, the patient started experiencing continuous nausea and vomiting for two weeks. A pregnancy test was negative. The patient has been using Phenergan (promethazine) to treat the symptoms. Reportedly, she has had good pain control with OxyContin. The clinical outcome is unknown at this time. Additional information is being requested. ***Additional information received on 09DEC99 from the pharmacist revealed that the patient is a 32-year-old female who began taking OxyContin 40 mg every 8 hours on 16AUG99 (not every 8 to 12 hours in OCT99 as previously reported) for lumbar stenosis. On 16NOV99, the patient experienced continuous nausea and vomiting. Reportedly, the patient was given an unspecified dose of Reglan (metoclopramide) and the symptoms abated. No further information was provided.			
6. Relevant tests/laboratory data; including dates RELEVANT TESTS/DATA: A pregnancy test came back negative.			
7. Other relevant history, including preexist. med. conditions UNKNOWN			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride) #			
2. Dose, frequency & route #1 40 MG Q8H PO #		3. Therapy dates (if unk, give dur) #1 8/16/1999 (CONTIN) #	
4. Diagnosis for use (indication) #1 LUMBAR STENOSIS #		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN #	7. Exp. Date #1 #	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
9. NDC # for prod problems only -			
10. Concomitant medical products and therapy dates ZOLOFT (SERTRALINE HCL) (from 11/10/1999)			
G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 100 Connecticut Ave. Norwalk, CT 06850-3590		2. Phone number (203) 854-7280	
4. Date Rec'd by Mfr. 12/02/1999		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 990628		8. Adverse event term(s) NAUSEA VOMIT	

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHARMACIST	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	990636
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

1. Patient Identifier REDACTED	2. Age at event 52 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 89.8 kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem	
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____

3. Date of event	11/10/1999	4. Date of this Rept	01/05/2000
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5. Describe event or problem

A: 52-year-old female patient experienced leg weakness, inability to walk, and difficulty staying awake on 10NOV99, while taking OxyContin (controlled-release oxycodone hydrochloride) 10 three times daily for pain and Duragesic (fentanyl) patch for chronic pain. The case was reported as follows: "Consumer reports she was hospitalized on 10-NOV-99 for seven days for leg weakness, inability to walk, and difficulty staying awake, while using fentanyl-TTS therapy. The patient also reports starting oxycodone hydrochloride three weeks prior to hospitalization. She states the physician said the events were mostly related to 'too much medication.' During the hospitalization the patient was found to have low blood oxygen, low thyroid function, and her 'heart acted up.' All her medications were discontinued except for the oxycodone w/ acetaminophen and doxepin. During hospitalization she was treated with fentanyl intravenously for five days. Her fentanyl-TTS patch was restarted prior to discharge. The events have resolved." (Mfr. Report Number: _____)

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/DATA: Thyroid studies revealed low thyroid; low blood oxygen.

7. Other relevant history, including preexist. med. conditions

Foreign body removed from lung (1993); "other diseases of the lung, not elsewhere classified."

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
#1 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride) #2 DURAGESIC (FENTANYL) PATCH

2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
#1 10 MG TID PO #2 50 MCG/HR TD	#1 10/1999 - 11/10/1999 (STOP'D) #2 1997 - 11/10/1999 (STOP'D)

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 PAIN #2 CHRONIC PAIN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A

6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction
#1 UNKNOWN #2 UNKNOWN	#1 #2	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A

9. NDC # for prod problems only	10. Concomitant medical products and therapy dates
	NEURONTIN (GABAPENTIN) (1994 to 11/10/1999 (STOP'D)), DOXEPIN HCL (from 10/1999 (CONTIN)), CELEBREX (CELECOXIB) (10/1999 to 11/10/1999 (STOP'D)), DEPAKOTE (VALPROIC ACID) (1994 to 11/10/1999 (STOP'D)), (CONTINUED)

G. ALL MANUFACTURERS

1. Contact office - name/address	2. Phone number
Purdue Pharma L.P. 100 Connecticut Ave. Norwalk, CT 06850-3590	(203) 854-7280
4. Date Rec'd by Mfr.	5. (A)NDA#
12/09/1999	20-553
6. If IND, protocol #	7. Type of report (check all that apply)
	<input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up # _____
9. Mfr. report number	8. Adverse event term(s)
990636	ASTHENIA SONNOLENCE

3. Report Source (check all that apply)
<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input checked="" type="checkbox"/> other:
PHARMACEUTICAL CO.

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	UNKNOWN	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

C10. CONCOMITANT MEDICAL PRODUCTS (continued)

ZANAFLEX (TIZANIDINE HYDROCHLORIDE)
(6/1999 to 11/10/1999 (STOP'D)),
PERCOCET (OXYCODONE/APAP) (CONTIN)

HEDWATCH

Purdue Pharma L.P.

Mfr report #	990638
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 43 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 65.3 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____	
3. Date of event 11/16/1999		4. Date of this Rept 01/05/2000	
5. Describe event or problem A 43-YEAR-OLD FEMALE PATIENT EXPERIENCED CONSTIPATION AND VOLVULUS, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 80 MG, THREE TIMES DAILY, FOR PAIN DUE TO OSTEOARTHRITIS AND OSTEOPOROSIS. THE PATIENT, WHO IS UNDER THE CARE OF A GASTROENTEROLOGIST BECAUSE OF A HISTORY OF "STOMACH PROBLEMS", BEGAN TAKING OXYCONTIN 20 MG FOUR TIMES DAILY IN JUL96, ON HIS ADVICE. IN MAY99, THE DOSAGE WAS INCREASED TO 80 MG THREE TIMES DAILY. ON 16NOV99, THE PATIENT BEGAN EXPERIENCING CONSTIPATION AND SHE CONSULTED A NEW GASTROENTEROLOGIST (SINCE HER REGULAR GASTROENTEROLOGIST WAS ILL). (REPORTEDLY, ABOUT THE SAME TIME, THE PATIENT WAS UNDER A LOT OF STRESS BECAUSE HER HUSBAND HAD SUFFERED A HEART ATTACK.) THE PATIENT HAD A COLONOSCOPY ON 22NOV99 WHICH WAS NEGATIVE. THE NEXT DAY, ON 23NOV99, THE PATIENT DEVELOPED "VOLVULUS" AND THE NEW PHYSICIAN DECREASED THE OXYCONTIN DOSE TO 80 MG TWICE DAILY AND ADDED DARVO CET (PROPOXYPHENE NAPSYLATE/APAP) 650 MG EVERY 6 HOURS TO THE TREATMENT. THE SYMPTOMS CONTINUED AND AFTER A "FEW DAYS" ON THIS REGIMEN, THE PATIENT WAS ADVISED BY HER REGULAR GASTROENTEROLOGIST, TO STOP TAKING DARVO CET AND TO RESUME OXYCONTIN 80 MG THREE TIMES DAILY. ON 29NOV99, THE PATIENT HAD A BARIUM ENEMA. THAT SAME NIGHT, THE NEW PHYSICIAN CALLED THE PATIENT AND ADVISED HER THAT "OXYCONTIN HAD COLLAPSED THE BOWEL." THE PATIENT IS CONTINUING OXYCONTIN 80 MG THREE TIMES DAILY AND SHE IS STARTING TO HAVE BOWEL MOVEMENTS AGAIN. NO FURTHER INFORMATION WAS PROVIDED.			
6. Relevant tests/laboratory data, including dates RELEVANT TESTS/DATA: *22NOV99: COLONOSCOPY NEGATIVE *29NOV99: BARIUM ENEMA (RESULTS UNKNOWN)			
7. Other relevant history, including preexist. med. conditions HISTORY OF STOMACH PROBLEMS, ASTHMA AND "STRESS" (NOV99) ASSOCIATED TO A "HEART ATTACK" HER HUSBAND HAD.			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride) #2 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)			
2. Dose, frequency & route #1 20 MG QID PO #2 80 MG TID PO		3. Therapy dates (if unk, give dur) #1 7/1996 - 5/1999 (STOP'D) #2 5/1999 - 11/23/1999 (REDUC'D)	
4. Diagnosis for use (indication) #1 OSTEOARTHRITIS AND OSTEOPOROSIS #2 OSTEOARTHRITIS AND OSTEOPOROSIS		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> IN/A #2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> IN/A	
6. Lot # (if known) #1 UNKNOWN #2 UNKNOWN		7. Exp. Date #1 UNKNOWN #2	
9. NDC # for prod problems only #1 #2			
10. Concomitant medical products and therapy dates PREVACID (LANSOPRAZOLE) (CONTIN), TYLENOL (ACETAMINOPHEN) (CONTIN), AZNACORT (TRIAMCINOLONE) (CONTIN), DARVO CET-N 100 (PROPOXYPHENE) (from 11/23/1999 (STOP'D))			

G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 100 Connecticut Ave. Norwalk, CT 06850-3590		2. Phone number (203) 854-7280	
4. Date Rec'd by Mfr. 12/01/1999		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# _____ PLA# _____	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up # _____		8. Adverse event term(s) CONSTIP VOLVULUS	
9. Mfr. report number 990638		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	990372
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 45 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 72.5 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____

3. Date of event	4. Date of this Rept 01/05/2000
------------------	---------------------------------

5. Describe event or problem

A: 45-year-old black female developed a rash and experienced dizziness and abdominal burning while taking OxyContin (controlled-release oxycodone hydrochloride), gabapentin and Tegretol (carbamazepine). In May99, the patient was switched from Percocet (oxycodone/APAP) to OxyContin 20 mg every 8 hours for chronic pain. Simultaneously, the patient began treatment for neck spasms, first with gabapentin, which resulted in a rash within 72 hours, and then with Tegretol which caused excessive dizziness by 2 or 3 days. Both events abated once replaced by baclofen. OxyContin therapy continued, and the dose was titrated upward to 40 mg (two 20 mg tablets) every 8 hours and then to 80 mg (two 40 mg tablets) every 8 hours. After the first 80mg dose, the patient experienced an internal, mid-abdominal burning sensation ("not like heartburn"). OxyContin was discontinued and the symptoms abated within 24 hours. The reporting pharmacist determined the events were probably related to OxyContin.

***Follow-up information received on 20SEP99, from the reporting pharmacist revealed that the patient is a 45-year-old black female who began taking OxyContin 80 mg (two 40 mg tablets) every 8 hours for pain on 07JUN99. On 10JUN99, the patient experienced abdominal burning which lasted 20 to 30 minutes. Reportedly, the patient described the event as "bursting into flames." The event resolved on 11JUN99. OxyContin was discontinued on 21JUN99. The reporting pharmacist assessed causality as "definitely" related to OxyContin.

6. Relevant tests/Laboratory data, including dates
RELEVANT TESTS/DATA:NONE

7. Other relevant history, including preexist. med. conditions
Hypertension; depression; motor vehicle accident; neck muscle spasms; manic disorder; migraine; back injury with neuropathic pain.

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)	
2. Dose, frequency & route #1 80 MG Q8H PO	3. Therapy dates (if unk, give dur) #1 6/7/1999 - 6/21/1999 (STOP'D)
4. Diagnosis for use (indication) #1 PAIN	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1 UNKNOWN
8. Event reappeared after reintroduction	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
9. NDC # for prod problems only	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
10. Concomitant medical products and therapy dates GABAPENTIN, TEGRETOL (CARBAMAZEPINE), BACLOFEN, OXYCODONE HCL (from 5/17/1999)	

G. ALL MANUFACTURERS	
1. Contact office - name/address Purdue Pharma L.P. 100 Connecticut Ave. Norwalk, CT 06850-3590	2. Phone number (203) 854-7280
4. Date Rec'd by Mfr. 09/20/1999	5. (A)NDA# 20-553
6. If IND, protocol #	IND# _____ PLA# _____
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input type="checkbox"/> Init <input checked="" type="checkbox"/> follow-up # 1	8. Adverse event term(s) PAIN ABDO DIZZINESS RASH
9. Mfr. report number 990372	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation CLINICAL PHARMACIST	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

15-DAY ALERT REPORT

6839

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200625
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)			
Patient identifier 1	2. Age at event or _____ DOB:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight or _____ lbs or _____ kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride) #		2. Dose, frequency & route #1 80 MG Q8H PO	
B. ADVERSE EVENT OR PRODUCT PROBLEM				3. Therapy dates (if unk, give dur) #1 UNKNOWN		4. Diagnosis for use (indication) #1 CHRONIC PAIN	
<input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A		6. Lot # (if known) #1 UNKNOWN	
Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged				[] disability [] congen anomaly [] required intervention to prevent perm damage <input checked="" type="checkbox"/> other: MEDICALLY SIGNIFICAN		7. Exp. Date #1	
3. Date of event		4. Date of this Rept 10/06/2000		9. NDC # for prod problems only		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	
5. Describe event or problem A pregnant female patient experienced "peculiar eye motions" and lost the baby at 22 weeks of gestation while taking OxyContin (controlled-release oxycodone hydrochloride) 80 mg every eight hours for chronic pain for an unspecified period of time. This case was reported by a nurse in the United States of America via a company representative. No further information was provided.				10. Concomitant medical products and therapy dates UNKNOWN			
6. Relevant tests/laboratory data, including dates Relevant Tests and Laboratory Data: UNKNOWN				G. ALL MANUFACTURERS			
7. Other relevant history, including preexist. med. conditions UNKNOWN				1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
				4. Date Rec'd by Mfr. 09/25/2000		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
				6. If IND, protocol #		5. (A)NDA# 20-553	
				7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up		8. Adverse event term(s) ABORTION EYE DIS	
				9. Mfr. report number 200625			
				E. INITIAL REPORTER			
				1. Name, address & phone # RELATED			
				2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation NURSE	
				4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

Mfr report #	200031
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 63 YEARS	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or 62.5 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:	
3. Date of event	11/20/1999	4. Date of this Rept	02/08/2001
5. Describe event or problem A 63-year-old male patient experienced eyelid swelling on 20NOV99, while taking OxyContin (controlled-release oxycodone hydrochloride) 10 mg three times daily for pain due to lung cancer. The patient began taking OxyContin on 04OCT99, approximately six weeks later, on 20NOV99, the patient experienced eyelid swelling. OxyContin was discontinued 2 days later, on 22NOV99 and the symptom abated. On 12JAN00, OxyContin was restarted and the symptom recurred. Eleven days later, on 21JAN00, OxyContin was discontinued. The clinical outcome is unknown. No further information was provided. ***Additional information received on 17FEB00 from the reporting nurse revealed that the patient is a 63-year-old Caucasian male with metastatic squamous cell carcinoma (unknown primary), who began taking OxyContin 10 mg every 8 hours for pain on 04OCT99. Reportedly, the patient complained of "sinus swelling" and experienced bilateral eyelid swelling. OxyContin was discontinued on 22NOV99 and the symptoms abated. OxyContin was reintroduced at a later date and the symptoms recurred. OxyContin was again discontinued. The patient recovered on an unspecified date. The reporting nurse assessed causality of the event as "probably" related to OxyContin.			
6. Relevant tests/laboratory data, including dates RELEVANT TESTS/DATA: UNKNOWN			
7. Other relevant history, including preexist. med. conditions Metastatic squamous cell carcinoma (unknown primary).			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride) #2 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride)			
2. Dose, frequency & route #1 10 MG Q8H PO #2 10 MG Q8H PO		3. Therapy dates (if unk, give dur) #1 10/4/1999 - 11/22/1999 (STOP'D) #2 1/12/2000 - 1/21/2000 (STOP'D)	
4. Diagnosis for use (indication) #1 PAIN DUE TO LUNG CANCER #2 PAIN DUE TO LUNG CANCER		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN #2 UNKNOWN		7. Exp. Date #1 #2	
9. NDC # for prod problems only		8. Event reappeared after reintroduction #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
10. Concomitant medical products and therapy dates DEXAMETHASONE, ISORDIL (ISOSORBIDE), LASIX (FUROSEMIDE), SULINDAC			

G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
4. Date Rec'd by Mfr. 01/27/2000		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 200031		8. Adverse event term(s) EDEMA FACE	

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation NURSE	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

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Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200286
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 36 YEARS REDACTED	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or 84 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (no/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:	
3. Date of event	4. Date of this Rept 02/08/2001		
5. Describe event or problem A 36-year-old male experienced extreme nausea and pain in his stomach on an unspecified date while taking Oxycontin (controlled-release oxycodone hydrochloride) 160 mg every six hours for back pain. Reportedly, the patient had an automobile accident on an unspecified date and therapy with Oxycontin started on 01JAN99. The reporting pharmacist informs that the patient has experienced extreme nausea and pain in his stomach when taking tablets from lots 3S21 (expiration date 2/2003) and 4L41 (expiration date 3/2004). Reportedly, therapy with Oxycontin continues. This case was reported by a pharmacist in the United States. No further information was provided.			
6. Relevant tests/laboratory data, including dates Relevant Tests and Laboratory Data: UNKNOWN			
7. Other relevant history, including preexist. med. conditions Additional information received 14JUL00 indicates the patient is sensitive to NSAIDs (non-steroidal antiinflammatory drugs).			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride) #2 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)			
2. Dose, frequency & route #1 160 MG Q6H PO #2 160 MG Q6H PO		3. Therapy dates (if unk, give dur) #1 1/1/99-UNKNOWN #2 UNKNOWN	
4. Diagnosis for use (indication) #1 BACK PAIN #2 BACK PAIN		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	
6. Lot # (if known) #1 3S21 #2 4L41	7. Exp. Date #1 02/01/2003 #2 03/01/2004	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	
9. NDC # for prod problems only - -			
10. Concomitant medical products and therapy dates VALIUM (DIAZEPAM) (from 6/14/1999)			

G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
4. Date Rec'd by Mfr. 05/18/1999		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 200286		8. Adverse event term(s) PAIN ABDO NAUSEA	

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? DC yes <input type="checkbox"/> no	3. Occupation PHARMACIST	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> junk	

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MEDWATCH

Purdue Pharma L.P.

Mfr report #	200350
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 45 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 48.9 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____	
3. Date of event	5/20/2000	4. Date of this Rept	02/08/2001
5. Describe event or problem A female patient experienced intractable nausea while taking OxyContin (controlled-release oxycodone hydrochloride) for three months for an unspecified indication. Dose, strength and specific therapy dates were not specified. The reporting physician related that anti-emetics did not help the condition. The patient was switched to Duragesic (fentanyl) and the symptom abated. This case was reported by a physician in the United States via a company representative. No further information was provided. ***Additional information received on 17OCT00 from the reporting physician revealed that the patient is a 45-year-old Caucasian female who experienced severe constipation (not nausea as previously reported) on 20MAY00, while taking OxyContin 10 mg two to three times daily for chronic pain. Reportedly, the dose was gradually increased over several weeks to 60 mg/day. On 20MAY00, the patient experienced severe constipation "in spite of [a] very aggressive bowel program with Senokot [sennosides], Pericolace [docusate sodium], Citrucel [methylcellulose], ExLax [phenolphthalein] and increased fluids." OxyContin was discontinued on 12JUN00 and the patient symptom abated. The reporting physician assessed causality of the event as "probably" related to OxyContin.			
6. Relevant tests/laboratory data, including dates Relevant Tests and Laboratory Data: UNKNOWN			
7. Other relevant history, including preexist. med. conditions Chronic hip and pelvic pain; multiple sclerosis; migraine headaches; mitral valve prolapse; irritable bowel syndrome; degenerative disc disease of the lumbar spine			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride) #			
2. Dose, frequency & route #1 10 MG 2-3/DAY PO #		3. Therapy dates (if unk, give dur) #1 5/20/2000 - 6/12/2000 (STOP'D) #	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN #	7. Exp. Date #1 #	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
9. NDC # for prod problems only - -			
10. Concomitant medical products and therapy dates INDERAL (PROPRANOLOL) (CONTIN)			
6. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
4. Date Rec'd by Mfr. 06/14/2000		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 200350		8. Adverse event term(s) CONSTIP	
E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation PHYSICIAN	
		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

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Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200406
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 38 YEARS or DOB:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 58.5 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged			
3. Date of event 9/12/1999			
4. Date of this Rept 02/08/2001			
5. Describe event or problem A 38-year-old female patient, with no history of diabetes and a history of tuberculosis, experienced reactive hypoglycemia, confusion, nausea and vomiting on 12SEP99 while taking OxyContin (controlled-release oxycodone hydrochloride) 80 mg three times a day for intercostal neuritis. Reportedly, the patient, an Intensive Care Unit Nurse, had not eaten for about 18 hours prior to her episode of confusion, nausea and vomiting which occurred at least 8 hours following a routine dose of OxyContin on 12SEP99. A subsequent glucose tolerance test was compatible with reactive hypoglycemia. OxyContin was discontinued and the patient recovered. This case was reported by a physician in the United States of America. ***Additional information received 12DEC00 from the reporting physician relates that OxyContin was prescribed for intercostal neuralgia (not intercostal neuritis as originally reported) following thoracotomy in 00OCT98. The reporting physician relates that on the evening of 11SEP99, at 9 p.m., the patient took two tablets of Esigic (bitalbital/caffeine/apap) and one OxyContin, 80 mg and on 12SEP99, eight hours after taking one OxyContin 80 mg tablet and one 25 mg Phenergan (promethazine), the patient experienced an episode of confusion and at approximately 10:30 a.m. an episode of loss of consciousness. Prior to the episode of unconsciousness, the patient reported that during the morning of 12SEP99, she felt mentally sluggish and tired, with difficulty organizing her thoughts. Reportedly, the patient recalls having had a more rapid and strong heart beat the morning of 12SEP99, and has no clear (CONTINUED)			
6. Relevant tests/laboratory data, including dates Relevant Tests and Laboratory Data: Glucose Tolerance Test: Compatible with reactive hypoglycemia.			
7. Other relevant history, including preexist. med. conditions Patient is not a diabetic. History of tuberculosis (diagnosed in October, 1998), tension headaches and rare migraines. Tension headaches controlled with Esigic (bitalbital/caffeine/apap) 1-2 tablets every 6 hours at most 1-2 days each week. Patient has been on this regimen for 15 years. About twice yearly, her headaches evolve into a severe bilateral migraine, associated with nausea and vomiting, and photophobia. Occasionally, the pain is localized behind her left eye. These headaches last up to two days, and are not relieved by any intervention.			

C. SUSPECT MEDICATION(S)		
1. Name (give labeled strength & mfr/Labeler, if known) (CONT)		
#1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride) #2 OxyIR Capsules (oxycodone hydrochloride)		
2. Dose, frequency & route		3. Therapy dates (if unk, give dur)
#1 80 MG TID PO #2 MG UNKNOWN PO		#1 4/30/1999 - 9/12/1999 (STOP'D) #2 UNKNOWN
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced
#1 INTERCOSTAL NEURALGIA #2 BREAKTHROUGH PAIN		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction
#1 UNKNOWN #2 UNKNOWN	#1 #2	
9. NDC # for prod problems only		
#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A		
10. Concomitant medical products and therapy dates ESGIC (BUTALBITAL/CAFFEINE/APAP), PHENERGAN (PROMETHAZINE), RIFAMPIN/ISONIAZID (CONTIN), RIFAMPIN (CRIFMAPICIN) (CONTIN), ISONIAZID (ISONIAZID) (CONTIN)		
G. ALL MANUFACTURERS		
1. Contact office - name/address		2. Phone number (203) 588-8000
Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
4. Date Rec'd by Mfr. 07/06/2000	5. (A)NDA# 20-553	
6. If IND, protocol #	IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product	8. Adverse event term(s) HYPOGLYCEM REACT CONFUS NAUSEA VOMIT SYNCOPE (CONTINUED)
9. Mfr. report number 200406		
E. INITIAL REPORTER		
1. Name, address & phone # REDACTED		
2. Realth professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHYSICIAN	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

MED INFO ASSOC
Facsimile Form 3500A

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MEDWATCH

Purdue Pharma L.P.

Mfr report #	200406
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 3

A. PATIENT INFORMATION			
1. Patient identifier	2. Age at event	3. Sex [] female [] male	4. Weight [lb or kgs]

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. [] Adverse Event and/or [] Product problem	
2. Outcomes attrib. to event [] death (mo/day/yy) [] life-threatening [] hospitalization - initial or prolonged	[] disability [] congen anomaly [] required intervention to prevent perm damage [] other:

3. Date of event	4. Date of this Rept 02/08/2001
------------------	---------------------------------

5. Describe event or problem
recollection of the events that transpired from when she was relieved of her nursing duties and when she was awakened, having been found asleep on the floor. The reporting physician relates that there were no contusions and the patient had not been incontinent. The patient was found with candy bars partially eaten. No clinical evaluation was performed following her episode of unconsciousness, other than a urine toxicology screen, which revealed the presence of prescribed medications. Reportedly, the patient had a complete recovery and the reporting physician relates that the reported events were probably related to the drug therapy.

6. Relevant tests/laboratory data, including dates
--

7. Other relevant history, including preexist. med. conditions
--

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known)	#3 PHENERGAN (PROMETHAZINE)

2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
#3 25 MG UNKNOWN PO	#3 UNKNOWN

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#3 UNKNOWN	#3 [] yes [] no [X] N/A [] yes [] no [] N/A

6. Lot # (if known)	7. Exp. Date
#3 UNKNOWN	#3

8. Event reappeared after reintroduction	9. NDC # for prod problems only
#3 [] yes [] no [X] N/A [] yes [] no [] N/A	#3

10. Concomitant medical products and therapy dates
--

G. ALL MANUFACTURERS	
1. Contact office - name/address	2. Phone number (203) 588-8000
Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	3. Report Source (check all that apply)
	[] foreign [] study [] literature [] consumer [] health professional [] user facility [] company representative [] distributor [] other:

4. Date Rec'd by Mfr.	5. (A)NDA#
	IND#
6. If IND, protocol #	PLA#

7. Type of report (check all that apply)	pre-1938 [] yes OTC [] yes product [] yes
[] 15-day [] 115-day [] 110-day [] periodic [] Init [] follow-up #	

8. Adverse event term(s)
9. Mfr. report number 200406

E. INITIAL REPORTER			
1. Name, address & phone #			

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
[] yes [] no		[] yes [] no [] Junk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

G8. ADVERSE EVENT TERMS (continued)

ASTHENIA
SONNOLENCE
TACHYCARDIA

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200446
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient Identifier REDACTED	2. Age at event YEARS	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input checked="" type="checkbox"/> other: MEDICALLY SIGNIFICAN
3. Date of event 2//2000	4. Date of this Rept 02/08/2001

5. Describe event or problem

Case 5 of 5 reports: Physician reports that a 33-year-old male patient is abusing OxyContin (controlled-release oxycodone hydrochloride). Additional information is being requested.

***Additional information received 01SEP00 from the reporting physician relates that on an unspecified date in November, 1999, the patient started OxyContin 20 mg three times a day for back pain. Reportedly, starting in FEB00, the patient developed addictive symptoms and according to the reporting physician the patient had "upper respiratory Sxs [symptoms]" and had possibly been "snorting" the drug. OxyContin was discontinued in MAR00. The outcome is unknown since the patient was "lost to follow-up." The reporting physician determined that the event was definitely due to OxyContin.

6. Relevant tests/laboratory data, including dates
Relevant Tests and Laboratory Data: UNKNOWN

7. Other relevant history, including preexist. med. conditions
Back pain; insomnia

C. SUSPECT MEDICATION(S)		
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride)		
2. Dose, frequency & route #1 20 MG TID PO	3. Therapy dates (if unk, give dur) #1 11/1999 - 3/2000 (STOP'D)	
4. Diagnosis for use (indication) #1 PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
9. NDC # for prod problems only -		
10. Concomitant medical products and therapy dates AMBIEN (ZOLPIDEM TARTRATE)		

D. ALL MANUFACTURERS		
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 07/18/2000		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	5. (A)NDA# 20-553	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	IND# PLA# pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	8. Adverse event term(s) DRUG DEPEND
9. Mfr. report number 200446		

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHYSICIAN	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> Unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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MEDWATCH

Purdue Pharma L.P.

Mfr report #	200608
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient Identifier RJ	2. Age at event 46 YEARS or DOB: 12/3/1953	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or 109 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged			
<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:			
3. Date of event 6/1/2000	4. Date of this Rept 02/08/2001		
5. Describe event or problem A 46-year-old Caucasian male experienced nervousness/jitteriness, excessive sweating, not sleeping on 01JUN00 while receiving OxyContin (controlled-release oxycodone hydrochloride) 60 mg every eight hours for an unspecified period of time for pain due to failed back surgery. Therapy with OxyContin continues. This case was reported by the patient's wife, who is a registered nurse in the United States of America, via a company representative. No further information was provided.			
6. Relevant tests/laboratory data, including dates Relevant Tests and Laboratory Data: UNKNOWN			
7. Other relevant history, including preexist. med. conditions UNKNOWN			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride)			
2. Dose, frequency & route #1 60 MG Q8H PO		3. Therapy dates (if unk, give dur) #1 UNKNOWN (CONTIN)	
4. Diagnosis for use (indication) #1 PAIN DUE TO FAILED BACK SURGERY		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> IN/A	
6. Lot # (if known) #1 UNKNOWN		7. Exp. Date #1	
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> IN/A		9. NDC # for prod problems only #1	
10. Concomitant medical products and therapy dates TRAZODONE HYDROCHLORIDE (CONTIN), EFFEXOR (VENLAFAXINE) (CONTIN), CELEBREX (CELECOXIB) (CONTIN)			
G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
4. Date Rec'd by Mfr. 09/21/2000		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 200608		8. Adverse event term(s) NERVOUSNESS SWEAT INSOMNIA	
E. INITIAL REPORTER			
1. Name, address & phone # PATIENT'S WIFE IS R.N. USA Phone: (610) 431-5420			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation NURSE	
		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200626
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier JF	2. Age at event 34 YEARS or DOB: 1/8/1966	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. DQ Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death (no/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event	9/29/2000	4. Date of this Rept	02/08/2001
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5. Describe event or problem

A 34-year-old female patient experienced constipation on 29SEP00 while taking OxyContin (controlled-release oxycodone hydrochloride) 80 mg every eight hours for chronic pain. The patient began taking OxyContin on 01JUN00 and on 29SEP00 complained of constipation. The reporting pharmacist related that the patient self-treated the constipation with lactulose and therapy with OxyContin was not interrupted. This case was reported by a pharmacist in the United States of America. No further information was provided.

***Additional information received on 25OCT00 from the reporting pharmacist revealed that on 15JUN00, the patient began taking OxyContin 160 mg (2 x 80 mg tablets) three times a day (not 80 mg every 8 hours as previously reported). On an unspecified date, the patient "was constipated for about 5 days, when she finally had a BM (bowel movement) she noticed 3 tab-5 tabs floating on surface of water. She then scooped them out and crushed the tablets. She said they were still full of white powder." Reportedly, the patient took Constulose (lactulose) and the symptom abated. The reporting pharmacist assessed causality of the event as probably related to OxyContin.

6. Relevant tests/Laboratory data, including dates

Relevant Tests and Laboratory Data: UNKNOWN

7. Other relevant history, including preexist. med. conditions

UNKNOWN

C. SUSPECT MEDICATION(S)		
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)		
2. Dose, frequency & route #1 160 MG TID PO	3. Therapy dates (if unk, give dur) #1 6/15/2000 (CONTIN)	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> DQ/N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A	
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> DQ/N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A
9. NDC # for prod problems only		
10. Concomitant medical products and therapy dates IMITREX (SUMATRIPTAN) (from 6/15/2000 (CONTIN)), PHENERGAN (PROMETHAZINE) (CONTIN)		

G. ALL MANUFACTURERS		
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 09/29/2000		5. (A)NDA# 20-553
6. If IND, protocol #		IND# PLA#
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 30-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		8. Adverse event term(s) CONSTIP
9. Mfr. report number 200626		

E. INITIAL REPORTER			
1. Name, address & phone # JIM KILLINBACK, R.PH. MEIJER PHARMACY 1920 PIKESTONE ROAD BENTON HARBOR, MI 49020; USA Phone: (616) 934-6733			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHARMACIST	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

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MEDWATCH

Purdue Pharma L.P.

Mfr report #	200642
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier MS	2. Age at event 48 YEARS or DOB:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 60.8 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:	
3. Date of event 10/6/2000	4. Date of this Rept 02/08/2001		
5. Describe event or problem A 48-year-old female patient experienced urinary retention on 29SEP00, two days after the dose of OxyContin (controlled-release oxycodone hydrochloride) was increased from an unspecified dose) to 80 mg every 12 hours for back pain. Therapy with OxyContin was not discontinued. This case was reported by a physician in the United States of America. No further information was provided. ***Additional information received 14NOV00 from the reporting physician relates that the patient experienced inability to urinate on 06OCT00 (and not on 29SEP00 as originally reported), and the event lasted for two weeks until 20OCT00. On 06OCT00 the dose of OxyContin was reduced to 60 mg every 6 hours; however, the symptoms persisted to a minor degree with dose reduction and the patient insisted upon stopping OxyContin. The reporting physician related that the patient had a complete recovery upon discontinuation of OxyContin and that the adverse event was probably due to the drug therapy. No further information was provided.			
6. Relevant tests/laboratory data, including dates Relevant Tests and Laboratory Data: UNKNOWN			
7. Other relevant history, including preexist. med. conditions UNKNOWN			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/Labeler, if known) #1 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride) #			
2. Dose, frequency & route #1 80 MG Q12H PO #		3. Therapy dates (if unk, give dur) #1 9/27/2000 (STOP'D) #	
4. Diagnosis for use (indication) #1 BACK PAIN #		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN #		7. Exp. Date #1 #	
9. NDC # for prod problems only -			
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
10. Concomitant medical products and therapy dates PREMARIN (CONJUGATED ESTROGENS), PROZAC (FLUOXETINE)			
G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
4. Date Rec'd by Mfr. 10/05/2000		5. (A) NDA# 20-553	
6. If IND, protocol #		IND# PLA#	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 200642		8. Adverse event term(s) URIN RETENT	

E. INITIAL REPORTER			
1. Name, address & phone # DAVID GAST, M.D. 850 NORTH OTSEGO AVENUE GAYLORD, MI 49735, USA Phone: (517) 732-8986			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHYSICIAN	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

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MEDWATCH

Purdue Pharma L.P.

Mfr report # 200656

UF/Dist report #

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FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

1. Patient identifier AM	2. Age at event 40 YEARS or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:
3. Date of event 10//2000	4. Date of this Rept 02/08/2001

5. Describe event or problem

An unidentified patient experienced sweating on an unspecified date, while taking OxyContin (controlled-release oxycodone hydrochloride) and OxyIR (immediate-release oxycodone hydrochloride) for an unspecified indication. Additional information is being requested. This case was reported by a physician via a company sales representative.

***Additional information received on 13OCT00 from the reporting physician revealed that the patient is a 40-year-old male who began taking OxyContin and OxyIR one year ago. Reportedly, the patient was taking one OxyContin 20 mg tablet three times a day, one OxyContin 40 mg tablet twice a day and one OxyIR 5mg capsule every 2 hours as needed for postoperative back pain. In OCT00, the patient experienced severe sweating. OxyContin and OxyIR were discontinued and the symptom abated. On an unspecified date, OxyContin was restarted at a dose of 80 mg twice a day and OxyIR at a dose of 5 mg every 2 hours. The symptom has not recurred. Treatment with OxyContin and OxyIR continues. No further information was provided.

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/LAB DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions

Back surgery

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) (CONT)	
#1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride) #2 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)	
2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
#1 20 MG TID PO #2 40 MG BID PO	#1 1999 - 10/2000 (STOP'D) #2 1999 - 10/2000 (STOP'D)
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 NON-MALIGNANT PAIN #2 NON-MALIGNANT PAIN	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
6. Lot # (if known)	7. Exp. Date
#1 UNKNOWN #2 UNKNOWN	#1 #2
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> N/A	
9. NDC # for prod problems only	
10. Concomitant medical products and therapy dates PROZAC (FLUOXETINE)	

G. ALL MANUFACTURERS

1. Contact office - name/address	2. Phone number
Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	(203) 588-8000
4. Date Rec'd by Mfr.	5. (A)NDA#
10/04/2000	20-553
6. If IND, protocol #	IND#
	PLA#
7. Type of report (check all that apply)	8. Adverse event term(s)
<input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	SWEAT
9. Mfr. report number	
200656	

E. INITIAL REPORTER

1. Name, address & phone #			
ROBERT C STEINMAN, MD LANCASTER NEUROSCIENCE ASSOC. PO BOX 10247 LANCASTER, PA 17605; USA Phone: 717 569 5331			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	PHYSICIAN	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC
Facsimile
Form 3500A

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MEDWATCH

Purdue Pharma L.P.

Mfr report # 200656

UF/Dist report #

FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 2

A. PATIENT INFORMATION			
1. Patient identifier	2. Age at event or _____ DOB: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____	
3. Date of event	4. Date of this Rept 02/08/2001		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexist. med. conditions			

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known) #3 OxyIR Capsules (oxycodone hydrochloride) #	
2. Dose, frequency & route #3 5 MG Q2H PO #	3. Therapy dates (if unk, give dur) #3 1999 - 10/2000 (STOP'D) #
4. Diagnosis for use (indication) #3 NON-MALIGNANT PAIN #	5. Event abated after use stopped or dose reduced #3 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
6. Lot # (if known) #3 UNKNOWN #	7. Exp. Date #3 #
8. Event reappeared after reintroduction #3 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
9. NDC # for prod problems only #	
10. Concomitant medical products and therapy dates	

G. ALL MANUFACTURERS	
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	2. Phone number (203) 588-8000
4. Date Rec'd by Mfr.	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health <input type="checkbox"/> professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
5. (A)NDA# IND# PLA#	6. If IND, protocol #
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input type="checkbox"/> follow-up #	8. Adverse event term(s)
9. Mfr. report number 200656	

E. INITIAL REPORTER		
1. Name, address & phone #		
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200697
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier EG	2. Age at event or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event //2000	4. Date of this Rept 02/08/2001
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5. Describe event or problem

A male patient developed urticaria and a rash while taking OxyContin (controlled-release oxycodone hydrochloride) 40 mg twice daily for an unspecified indication. Reportedly, several months ago, the patient began taking OxyContin 40 mg twice daily. On an unspecified date, he developed urticaria and a rash and experienced insomnia. Reportedly, the patient is currently taking OxyContin 80 mg three times daily and "the adverse events are not getting better if he stays on the same dose." No further information was provided.

***Additional information received on 23OCT00 from Roche Pharmaceuticals related that the patient developed a rash which was "oozing and itching" and had severe insomnia. Reportedly, the rash was treated with antibiotics.

6. Relevant tests/laboratory data, including dates
RELEVANT TESTS/LAB DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions
Hepatitis C; diabetes

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known)	
#1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)	
#2 OxyContin CR Tablets, 80 mg (oxycodone hydrochloride)	

2. Dose, frequency & route	3. Therapy dates (if unk, give dur)
#1 40 MG BID PO #2 80 MG TID PO	#1 UNKNOWN (STOP'D) #2 UNKNOWN

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 UNKNOWN #2 UNKNOWN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no DX/N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no DX/N/A

6. Lot # (if known)	7. Exp. Date
#1 UNKNOWN #2 UNKNOWN	#1 #2

9. NDC # for prod problems only	8. Event reappeared after reintroduction
-	#1 <input type="checkbox"/> yes <input type="checkbox"/> no DX/N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no DX/N/A

10. Concomitant medical products and therapy dates
UNKNOWN

G. ALL MANUFACTURERS

1. Contact office - name/address	2. Phone number (203) 588-8000
Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	3. Report Source (check all that apply)
	<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer health <input checked="" type="checkbox"/> professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:

4. Date Rec'd by Mfr. 10/23/2000	5. (A)NDA# 20-553
6. If IND, protocol #	IND# PLA#

7. Type of report (check all that apply)	8. Adverse event term(s)
<input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #	URTICARIA RASH PRURITUS INSOMNIA

9. Mfr. report number 200697	pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product
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E. INITIAL REPORTER

1. Name, address & phone #		
PATIENT IS A PHARMACIST ; USA		

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	PHARMACIST	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200793
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

1. Patient identifier REDACTED	2. Age at event 38 YEARS or DOB: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or 67.1 kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem	
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input checked="" type="checkbox"/> other: MEDICALLY SIGNIFICAN
3. Date of event	4. Date of this Rept 02/08/2001

5. Describe event or problem
A 38-year-old male patient, with a history of drug abuse, became addicted to OxyContin (controlled-release oxycodone hydrochloride) on an unspecified date, while being treated for back pain. Reportedly, the patient has been on OxyContin 40 mg four times a day for back pain for quite a while and complains that he cannot sleep at night. This case was reported by a licensed practical nurse of a mental and drug rehabilitation hospital in the United States of America. No further information was provided.

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)	
2. Dose, frequency & route #1 40 MG q6h PO	3. Therapy dates (if unk, give dur.) #1 (CONTIN)
4. Diagnosis for use (indication) #1 BACK PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	9. NDC # for prod problems only -
10. Concomitant medical products and therapy dates NEURONTIN (GABAPENTIN) (CONTIN), TEGRETOL (CARBAMAZEPINE) (CONTIN), KLONOPIN (CLONAZEPAM) (CONTIN)	

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 11/14/2000		5. (A)NDA# 20-553
6. If IND, protocol #		IND# PLA#
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up # _____		8. Adverse event term(s) DRUG DEPEND INSOMNIA
9. Mfr. report number 200793		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:

6. Relevant tests/laboratory data, including dates
Relevant Tests and Laboratory Data: UNKNOWN

7. Other relevant history, including preexist. med. conditions
History of drug abuse.

E. INITIAL REPORTER

1. Name, address & phone # REDACTED			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation LIC PRACTICAL NURSE	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 350DA

Mfr report #	200794
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 41 YEARS or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event	7//2000	4. Date of this Rept	02/08/2001
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5. Describe event or problem

A 41-YEAR-OLD MALE PATIENT EXPERIENCED "A DECREASE IN SEXUAL DRIVE" IN JUL00, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 80 MG TABLETS FOR CHRONIC BACK PAIN. IN JUN00, THE PATIENT BEGAN TAKING OXYCONTIN 80 MG FOUR TIMES A DAY WITH GOOD PAIN RELIEF. IN JUL00, THE PATIENT EXPERIENCED A DECREASE IN SEXUAL DRIVE. THE PHYSICIAN WAS CONSULTED. REPORTEDLY, THE PATIENT WAS ADVISED TO CONTINUE OXYCONTIN TREATMENT. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions

UNKNOWN

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, .80 mg (oxycodone hydrochloride) #			
2. Dose, frequency & route #1 80 MG QID PO		3. Therapy dates (if unk, give dur) #1 6/2000 - 11/9/2000 (CONTIN) #	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN #		7. Exp. Date #1 UNKNOWN #	
9. NDC # for prod problems only - -		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
10. Concomitant medical products and therapy dates UNKNOWN			

D. ALL MANUFACTURERS		
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 11/09/2000		5. (A)NDA# 20-553
6. If IND, protocol #		IND# PLA#
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up #		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes
9. Mfr. report number 200794		8. Adverse event term(s) LIBIDO DEC

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200820
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 45 YEARS or DOB: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____	
3. Date of event 10//2000		4. Date of this Rept 02/08/2001	
5. Describe event or problem A 45-YEAR-OLD MALE PATIENT EXPERIENCED DIZZINESS, FATIGUE, WEAKNESS, INTERMITTENT CHEST PAINS AND LOW BLOOD PRESSURE IN OCT00, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 10 MG TABLETS FOR NEUROPATHIC PAIN. IN EARLY OCT00, THE PATIENT BEGAN TAKING OXYCONTIN 10 MG FOUR TIMES A DAY. REPORTEDLY, AFTER THE FIRST DOSE, THE PATIENT EXPERIENCED DIZZINESS, FATIGUE, WEAKNESS AND INTERMITTENT CHEST PAINS. THE SYMPTOMS PERSISTED AND TWO WEEKS LATER, THE PATIENT FOUND THAT HIS BLOOD PRESSURE HAD DROPPED FROM 138/74 TO 101/48. THE PHYSICIAN WAS CONSULTED. THE DOSE OF OXYCONTIN WAS DECREASED TO THREE TABLETS A DAY. THE PATIENT STATED "IMMEDIATELY MY BLOOD PRESSURE WENT BACK UP TO NORMAL (130/68) AND THE DIZZINESS, FATIGUE AND WEAKNESS STOPPED." REPORTEDLY, THE CHEST PAINS HAVE INCREASED TO "ALMOST DAILY." THE PATIENT WILL CONSULT THE PHYSICIAN. NO FURTHER INFORMATION WAS PROVIDED.			
6. Relevant tests/laboratory data, including dates RELEVANT TESTS/DATA: BLOOD PRESSURE HAD DROPPED FROM 138/74 TO 101/48.			
7. Other relevant history, including preexist. med. conditions DIABETES, HYPERTENSION			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride) #			
2. Dose, frequency & route #1 10 MG QID PO		3. Therapy dates (if unk, give dur) #1 10/2000 - 11/17/2000 (REDUCD) #	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN #		7. Exp. Date #1 UNKNOWN #	
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
9. NDC # for prod problems only - - -			
10. Concomitant medical products and therapy dates INSULIN (CONTIN), LASIX (FUROSEMIDE) (CONTIN), VASOTEC (ENALAPRIL) (CONTIN), PROCARDIA (NIFEDIPINE) (CONTIN), PRIOSECC (OMEPRAZOLE) (CONTIN), ASPIRIN (ACETYSALICYLIC ACID) (CONTIN), (CONTINUED)			

G. ALL MANUFACTURERS			
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000	
4. Date Rec'd by Mfr. 11/17/2000		5. (A)NDA# 20-553	
6. If IND, protocol #		IND# _____ PLA# _____	
7. Type of report (check all that apply) <input type="checkbox"/> 35-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up # _____		pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes	
9. Mfr. report number 200820		8. Adverse event term(s) DIZZINESS ASTHENIA PAIN CHEST HYPOTENS	

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

C10. CONCOMITANT MEDICAL PRODUCTS (continued)

NEURONTIN (GABAPENTIN) (CONTIN), LOPRESSOR (METOPROLOL)
(CONTIN), LIPITOR (ATORVASTATIN) (CONTIN)

MEDWATCH

Purdue Pharma L.P.

Mfr report # 200859

UF/Dist report #

FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

1. Patient identifier REDACTED	2. Age at event 45 YEARS or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:

3. Date of event	4. Date of this Rept 02/08/2001
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5. Describe event or problem

A 45-year-old male patient experienced vomiting on an unspecified date, while taking OxyContin (controlled-release oxycodone hydrochloride) 20 mg twice daily for pain associated with fibromyalgia. Reportedly, the patient had previously been taking OxyContin 10 mg twice daily without any problems. On an unspecified date, the dose was increased to 20 mg every 8 hours and the patient experienced vomiting after taking the first dose. Therapy with OxyContin continues. The clinical outcome is unknown. No further information was provided. This case was reported by a physician via a company sales representative.

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/LAB DATA: Unknown

7. Other relevant history, including preexist. med. conditions

Fibromyalgia

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride) #
--

2. Dose, frequency & route #1 20 MG Q8H PO #	3. Therapy dates (if unk, give dur) #1 UNKNOWN (CONTIN) #
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4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A
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6. Lot # (if known) #1 UNKNOWN #	7. Exp. Date #1 #	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A
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9. NDC # for prod problems only - -	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> IN/A
--	---

10. Concomitant medical products and therapy dates
UNKNOWN

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM - STAMFORD, CT 06901-3431	2. Phone number (203) 588-8000	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
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4. Date Rec'd by Mfr. 11/30/2000	5. (A)NDA# 20-553
6. If IND, protocol #	IND# PLA#

7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> init <input type="checkbox"/> follow-up #	8. Adverse event term(s) VOMIT
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9. Mfr. report number 200859	pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes
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E. INITIAL REPORTER

1. Name, address & phone # REDACTED

2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHYSICIAN	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200906
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 48 YEARS or DOB: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____

3. Date of event	6//2000	4. Date of this Rept	02/08/2001
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5. Describe event or problem

A 48-YEAR-OLD MALE PATIENT EXPERIENCED PANIC ATTACKS AND CLAUSTROPHOBIA IN JUN00, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 40 MG TABLETS FOR BACK PAIN. IN MAR00, THE PATIENT BEGAN TAKING OXYCONTIN 40 MG, 3 TO 4 TIMES A DAY WITH GOOD PAIN RELIEF. APPROXIMATELY THREE MONTHS LATER, IN JUN00, THE PATIENT EXPERIENCED PANIC ATTACKS AND CLAUSTROPHOBIA 45 MINUTES AFTER TAKING A DOSE OF OXYCONTIN. REPORTEDLY, THE SYMPTOMS ARE CONTINUOUS. THE PATIENT RELATED THAT THE SYMPTOMS BECAME WORSE IN AUG00, AFTER THE UNEXPECTED DEATH OF HIS WIFE. THE PATIENT CONSULTED THE PHYSICIAN AND XANAX (ALPRAZOLAM) WAS PRESCRIBED TO TREAT THE SYMPTOMS. REPORTEDLY, THE TREATMENT IS EFFECTIVE. THERAPY WITH OXYCONTIN CONTINUES AND THE SYMPTOMS PERSIST. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/DATA: UNKNOWN

7. Other relevant history, including preexist. med. conditions

UNKNOWN

C. SUSPECT MEDICATION(S)		
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)		
2. Dose, frequency & route #1 40 MG SEE TEXT PO	3. Therapy dates (if unk, give dur) #1 3/2000 - 12/11/2000 (CONTIN)	
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	
6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1 UNKNOWN	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
9. NDC # for prod problems only - -		
10. Concomitant medical products and therapy dates SENOKOT S (SEMNOIDES/DCCUSATE) (CONTIN)		

G. ALL MANUFACTURERS		
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 12/11/2000		5. (A)NDA# 20-553
6. If IND, protocol #		IND# _____ PLA# _____
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> init <input type="checkbox"/> follow-up		8. Adverse event term(s) AGITATION NEUROSIS
9. Mfr. report number 200906		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:

E. INITIAL REPORTER			
1. Name, address & phone # REDACTED			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

KEDWATCH

Purdue Pharma L.P.

Mfr report #	200931
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier REDACTED	2. Age at event 58 YEARS or DOB: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM	
1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> (mo/day/yy) life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____

3. Date of event	4. Date of this Rept 02/08/2001
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5. Describe event or problem

A 58-YEAR-OLD MALE PATIENT EXPERIENCED STIMULATION, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 40 MG TABLETS FOR NECK AND BACK PAIN. IN 1998, THE PATIENT BEGAN TAKING OXYCONTIN 320 MG DAILY (40 MG 8 TIMES A DAY). ON AN UNSPECIFIED DATE, THE PATIENT EXPERIENCED STIMULATION WITH THE USE OF OXYCONTIN. THE PATIENT STATED "THIS IS AN UNCONTROLLABLE STIMULATE WHICH I CANNOT CONTROL OR IGNORE WHILE UNDER THE INFLUENCE OF THE MEDICINE. AFTER I TAKE MORE THAN 80 MILLIGRAMS OF OXYCONTIN, I CANNOT SIT STILL. I HAVE TO DO SOMETHING AND NORMALLY THAT SOMETHING IS SOME FORM OF WORK. I EITHER DO GARDENING, OR SOME OTHER FORM OF PHYSICAL LABOR, WHICH I AM NOT SUPPOSED TO BE DOING." THE PATIENT FURTHER STATED "BECAUSE OF THIS SIDE EFFECT, I FIND THAT I AM DOING THINGS THAT I SHOULDN'T BE DOING AND IN SOME INSTANCES I FIND MYSELF CAUSING MORE HARM TO THE BODY THAN IF I HAD NOT TAKEN THE MEDICINE IN THE FIRST PLACE." REPORTEDLY, THE PHYSICIAN WAS CONSULTED BUT NO TREATMENT WAS PRESCRIBED. THERAPY WITH OXYCONTIN CONTINUES AND THE SYMPTOM PERSISTS. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/laboratory data, including dates RELEVANT TESTS/DATA: UNKNOWN
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7. Other relevant history, including preexist. med. conditions UNKNOWN

C. SUSPECT MEDICATION(S)	
1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)	

2. Dose, frequency & route #1 40 MG SEE TEXT PO	3. Therapy dates (if unk, give dur) #1 1998 - 12/11/2000 (CONTIN)
--	--

4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
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6. Lot # (if known) #1 UNKNOWN	7. Exp. Date #1 UNKNOWN	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
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9. NDC # for prod problems only -	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
--------------------------------------	---

10. Concomitant medical products and therapy dates
MEVACOR (LOVASTATIN) (CONTIN)
CELEXA (CITALOPRAM HYDROBROMIDE) (CONTIN)

D. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STANFORD FORUM STAMFORD, CT 06901-3431	2. Phone number (203) 588-8000	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
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4. Date Rec'd by Mfr. 12/11/2000	5. (A)NDA# 20-553
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6. If IND, protocol #	IND# _____ PLA# _____
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7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> init <input type="checkbox"/> follow-up	8. Adverse event term(s) CNS STIMULAT
---	--

9. Mfr. report number 200931

E. INITIAL REPORTER

1. Name, address & phone # REDACTED

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

15-DAY ALERT REPORT

8150

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200867
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)					
1. Patient identifier REDACTED	2. Age at event 43 YEARS	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or 95.4 kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)					
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route #1 160 MG Q8H PO		3. Therapy dates (if unk, give dur) #1 9/2/1999 - 11/12/2000 (STOP'D)			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input checked="" type="checkbox"/> other: MED. SIGNIFICANT		6. Lot # (if known) #1 UNKNOWN			
3. Date of event 11/12/2000		4. Date of this Rept 03/01/2001		7. Exp. Date #1		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A # <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
5. Describe event or problem A 43-year-old female patient experienced an anaphylactoid reaction in NOV00 while taking an unspecified dose of OxyContin (controlled-release oxycodone hydrochloride) for an unspecified indication. Reportedly, in NOV00, the patient experienced throat constriction, hives and itching after taking an unspecified dose of OxyContin. OxyContin was discontinued and the patient was treated with an unspecified dose of Benadryl (diphenhydramine). On an unspecified date, the symptoms abated and the patient was switched to MS Contin. No further information was provided. ***Follow-up information received 16FEB01 from the reporting physician related that OxyContin 40 mg tablets were prescribed for failed back syndrome at a dose of four 40 mg tablets every eight hours. Reportedly, the patient started therapy with OxyContin on 02SEP99 and discontinued on 12NOV00. Reportedly, on 12NOV00, the patient experienced a "feeling of being choked associated with urticaria." The patient was treated with Benadryl (diphenhydramine) 50 mg three times a day. The event lasted 24 hours and the patient recovered. The reporting physician related that the event was probably related to OxyContin.				9. NDC # for prod problems only -				10. Concomitant medical products and therapy dates ESTRATEST (ESTRADIOL) (from 1999 (CONTIN)), EFFEXOR (VENLAFAXINE) (from 1999 (CONTIN))	
6. Relevant tests/laboratory data, including dates RELEVANT TESTS/LAB DATA: Unknown				G. ALL MANUFACTURERS					
7. Other relevant history, including preexist. med. conditions Failed back syndrome; depression.				1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431		2. Phone number (203) 588-8000			
				4. Date Rec'd by Mfr. 02/16/2001		5. (A)NDA# 20-553			
				6. If IND, protocol #		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:			
				7. Type of report (check all that apply) <input checked="" type="checkbox"/> 15-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input checked="" type="checkbox"/> follow-up # 1		8. Adverse event term(s) ANAPHYL LARYNGISMUS URTICARIA PRURITUS			
				9. Mfr. report number 200867		E. INITIAL REPORTER			
				1. Name, address & phone # REDACTED					
				2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation PHYSICIAN			
				4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk					

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

8003040228

15-DAY ALERT REPORT

#8184

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	2011149
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION				C. SUSPECT MEDICATION(S)					
1. Patient identifier REDACTED	2. Age at event 67 YEARS or DOB:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride)					
B. ADVERSE EVENT OR PRODUCT PROBLEM				2. Dose, frequency & route #1 20 MG TID PO		3. Therapy dates (if unk, give dur) #1 UNKNOWN			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem				4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other:		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> N/A			
3. Date of event		4. Date of this Rept 03/05/2001		6. Lot # (if known) #1 UNKNOWN		7. Exp. Date #1			
5. Describe event or problem A 67-year-old female patient developed colitis, ileus and abdominal pain on an unspecified date, while taking Oxygesic (controlled-release oxycodone hydrochloride) 20 mg three times daily for rheumatoid arthritis. The case was reported as follows: "A 67-year-old female patient was treated with OXYGESIC (oxycodone hydrochloride controlled release tablets) in a daily dose of 60 mg (3 x 20 mg) because of pain associated with chronic polyarthritis. She repeatedly experienced abdominal pain which was thought to be caused by a cystitis. Later on she developed a subileus which led to hospital admission where she was diagnosed as having unspecified colitis. Under the suspicion of a causal relationship to OXYGESIC the drug was stopped and patient recovered. After discharged patient restarted OXYGESIC on her own wish without recurrence of the symptoms." This case was reported by a healthcare professional in Germany via Mundipharma GmbH (Manufacturer Control No. E2FI 00565).				9. NDC # for prod problems only - -				10. Concomitant medical products and therapy dates METHOTREXATE	
G. ALL MANUFACTURERS									
1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431				2. Phone number (203) 588-8000		3. Report Source (check all that apply) <input checked="" type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:			
4. Date Rec'd by Mfr. 02/20/2001		5. (A)NDA# 20-553		6. If IND, protocol #		7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> init <input type="checkbox"/> follow-up #			
6. Relevant tests/laboratory data, including dates RELEVANT TESTS/LAB DATA:				8. Adverse event term(s) COLITIS ILEUS PAIN ABDO		9. Mfr. report number 2011149			
7. Other relevant history, including preexist. med. conditions Chronic polyarthritis				E. INITIAL REPORTER					
				1. Name, address & phone # REDACTED					
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation UNKNOWN		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> unk					

MED INFO ASSOC
Facsimile
Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

8003040239

MEDWATCH

PURDUE PHARMA L.P.

Mfr report # 2011526

UF/Dist report #

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier REDACTED	2. Age at event 46 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____
3. Date of event 2//2001	4. Date of this Rept 04/09/2001

5. Describe event or problem

A 46-YEAR-OLD FEMALE PATIENT EXPERIENCED WITHDRAWAL SYMPTOMS IN FEB01, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 160 MG TABLETS AND OXYIR (IMMEDIATE-RELEASE OXYCODONE HYDROCHLORIDE) 5 MG CAPSULES FOR PAIN ASSOCIATED WITH AMYOTROPHIC LATERAL SCLEROSIS (ALS). APPROXIMATELY FIVE YEARS AGO, THE PATIENT BEGAN TAKING OXYCONTIN. ON AN UNSPECIFIED DATE, THE PATIENT BEGAN TAKING OXYCONTIN 40 MG FOUR TIMES A DAY. APPROXIMATELY 1.5 WEEKS LATER, THE DOSE WAS INCREASED TO 80 MG FOUR TIMES A DAY AND OXYIR 5 MG, UP TO 20 CAPSULES A DAY, WAS PRESCRIBED FOR BREAKTHROUGH PAIN. APPROXIMATELY FOUR YEARS AGO, THE DOSE OF OXYCONTIN WAS INCREASED TO 160 MG FOUR TIMES A DAY AND OXYIR WAS INCREASED TO UP TO 30 CAPSULES A DAY. ON AN UNSPECIFIED DATE, THE OXYCONTIN WAS INCREASED TO 200 MG FOUR TIMES A DAY (1 X 160 MG TABLET AND 1 X 40 MG TABLET). REPORTEDLY, THAT DOSE MADE THE PATIENT SLEEPY. IN FEB01, THE PATIENT WAS TRANSFERRED TO A NEW PHYSICIAN. THE DOSE OF OXYCONTIN WAS REDUCED TO 160 MG FOUR TIMES A DAY. THE DOSE OF OXYIR WAS REDUCED TO UP TO 18 CAPSULES A DAY. THAT SAME MONTH, THE PATIENT EXPERIENCED WITHDRAWAL SYMPTOMS (DESCRIBED AS ABDOMINAL CRAMPS, DIARRHEA, LOSS OF APPETITE, WEIGHT LOSS, BACK PAIN, INSOMNIA AND UNABLE TO WALK). THE PHYSICIAN WAS CONSULTED. REPORTEDLY, THE PATIENT WAS TOLD "FACE IT, YOU'RE ADDICTED TO OXYCONTIN." OXYCONTIN TREATMENT CONTINUES AND THE SYMPTOMS PERSIST. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/laboratory data, including dates RELEVANT TESTS/DATA: UNKNOWN
7. Other relevant history, including preexist. med. conditions AMYOTROPHIC LATERAL SCLEROSIS (ALS)

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known) #1 OxyContin CR Tablets, 160 mg (oxycodone hydrochloride) #2 OxyIR Capsules (oxycodone hydrochloride)	
2. Dose, frequency & route #1 160 MG QID PO #2 100 MG UNKNOWN PO	3. Therapy dates (if unk, give dur) #1 2/2001 - 3/13/2001 (CONTIN) #2 2/2001 - 3/13/2001 (CONTIN)
4. Diagnosis for use (indication) #1 NON-MALIGNANT PAIN #2 NON-MALIGNANT	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
6. Lot # (if known) #1 UNKNOWN #2 UNKNOWN	7. Exp. Date #1 #2
9. NDC # for prod problems only - -	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
10. Concomitant medical products and therapy dates ZANAFLEX (TIZANIDINE HYDROCHLORIDE) (CONTIN), DILAUDID (HYDROMORPHONE) (CONTIN)	

G. ALL MANUFACTURERS

1. Contact office - name/address PURDUE PHARMA L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	2. Phone number (203) 588-8000
4. Date Rec'd by Mfr. 03/13/2001	5. (A)NDA# 20-553
6. If IND, protocol #	IND# _____ PLA# _____
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 115-day <input type="checkbox"/> 110-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Init <input type="checkbox"/> follow-up # _____	8. Adverse event term(s) WITHDRAW SYND PAIN ABDO DIARRHEA ANOREXIA WEIGHT DEC (CONTINUED)
9. Mfr. report number 2011526	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:

E. INITIAL REPORTER

1. Name, address & phone # REDACTED			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

G8. ADVERSE EVENT TERMS (continued)

PAIN BACK
INSOMNIA
GAIT ABNORM
SOMNOLENCE

MEDWATCH

15-DAY ALERT REPORT

Purdue Pharma L.P.

FDA Approved 11/08/93

Mfr report # 2012485

UF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION

1. Patient identifier REDACTED	2. Age at event YEARS or DOB: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lbs or kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. DO Adverse Event and/or <input checked="" type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged	and/or <input type="checkbox"/> Product problem <input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input checked="" type="checkbox"/> required intervention to prevent perm damage <input checked="" type="checkbox"/> other: MED. SIGNIFICANT
---	---

3. Date of event 5/3/2001	4. Date of this Rept 07/26/2001
---------------------------	---------------------------------

5. Describe event or problem

An unidentified patient who was being treated with Bacillin (penicillin G), became comatose (considered medically significant) after OxyContin (controlled-release oxycodone hydrochloride) was added to his treatment regimen. The treating physician reported that the patient was hospitalized (Unknown reason) and was receiving Bacillin (penicillin G). OxyContin 40 mg was administered to the patient. The dose of Bacillin was increased. The patient became comatose. Narcan (naloxone hydrochloride) was administered and the patient reponded. The physician is unsure if the event was caused by OxyContin, Bacillin, or the combined effect of both drugs. This case was reported by a physician in the United States of America. Additional information is being requested.

***Additional information received on 15JUN01 from the reporting physician related that the patient was male, who was on baclofen (not Bacillin as previously reported) and OxyContin went into a coma after receiving a blood transfusion. Narcan (naloxone) was given and the patient recovered. The physician stated that since this patient has been on OxyContin without any incidence in the past, he suspects the event may have been a reaction to the baclofen. The physician also stated that the event was not a reaction to the blood transfusion.

***Follow-up information received from the treating physician on 19JUL01 revealed the following: On 03APR01 the patient was started on OxyContin 40 mg q8h [every eight hours] and his dose of baclofen was increased from 10 mg to 20 mg TID [three times a day]. The medications were

(CONTINUED)

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/DATA: Unknown

7. Other relevant history, including preexist. med. conditions

Allergic to penicillin and Rocephin, hypertension, diabetes mellitus, gastroesophageal reflux disease, neurogenic bladder.

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)

#1 OxyContin CR Tablets, 40 mg (oxycodone hydrochloride)
#2 BACLOFEN (LIORESAL)

2. Dose, frequency & route #1 40 MG Q8H PO #2 20 MG TID PO	3. Therapy dates (if unk, give dur) #1 4/3/2001 - 5/3/2001 (STOP'D) #2 4/3/2001 - 5/3/2001 (STOP'D)
--	---

4. Diagnosis for use (indication) #1 CHRONIC PAIN #2 SPASMS	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
---	---

6. Lot # (if known) #1 UNKNOWN #2 UNKNOWN	7. Exp. Date #1 #2	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> N/A
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9. NDC # for prod problems only

-

10. Concomitant medical products and therapy dates
PAXIL (PAROXETINE), LANSOPRAZOLE, DETROL LA (TOLTERODINE TARTRATE), ACTOS (PIOGITAZONE)

G. ALL MANUFACTURERS

1. Contact office - name/address Purdue Pharma L.P. 1 STAMFORD FORUM STAMFORD, CT 06901-3431	2. Phone number (203) 588-8000
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4. Date Rec'd by Mfr. 07/19/2001	5. (A)NDA# 20-553	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	IND# PLA#	

7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input checked="" type="checkbox"/> follow-up # 1	8. Adverse event term(s) DRUG INTERACTION COMA DELIRIUM HYPOTERS APNEA (CONTINUED)
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E. INITIAL REPORTER

1. Name, address & phone #

REDACTED

2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PHYSICIAN	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

8003045079

3500A Continuation Page

B5. DESCRIBE EVENT OR PROBLEM (continued)

continued while the patient was hospitalized [unspecified reason/dates]. On 03MAY01, while in the hospital, the patient experienced acute delirium, hypotension and apnea. The symptoms were treated with Narcan (naloxone hydrochloride) 2 mg administered intravenously. Following the administration of Narcan the patient "awoke" but had evidence of withdrawal. The withdrawal symptoms improved following administration of intravenous morphine. OxyContin and Baclofen were discontinued on 03MAY01 and the patient made a complete recovery. The treating physician indicated that the events were life-threatening, resulted in prolonged hospitalization and were medically significant. The physician assessed causality of the events as probably related to drug therapy and stated: "Baclofen was increased to 20 mg TID on [03APR01]. This may have potentiated apnea, but would not be expected to respond to Narcan." Concomitant medications included lisinopril, Paxil (paroxetine), lansoprazole, Actos (pioglitazone) and Detrol LA (tolterodine tartrate).

B6. ADVERSE EVENT TERMS (continued)

WITHDRAW SYND

8003045080

#10756

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	2014990
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

1. Patient identifier REDACTED	2. Age at event 42 YEARS or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> Adverse Event and/or	<input type="checkbox"/> Product problem
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm damage <input type="checkbox"/> other: _____

3. Date of event	6/7/2001	4. Date of this Rept	12/07/2001
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5. Describe event or problem

A 42-YEAR-OLD FEMALE PATIENT EXPERIENCED A BOWEL OBSTRUCTION LEADING TO HOSPITALIZATION ON AN UNSPECIFIED DATE, WHILE TAKING OXYCONTIN (CONTROLLED-RELEASE OXYCODONE HYDROCHLORIDE) 20 MG TABLETS FOR POST-OPERATIVE PAIN. AT THE END OF JUNE, THE PATIENT BEGAN TAKING OXYCONTIN 20 MG EVERY 8 HOURS FOLLOWING ABDOMINAL SURGERY. AFTER TAKING OXYCONTIN FOR APPROXIMATELY 3 OR 4 DAYS, THE PATIENT DEVELOPED A BOWEL OBSTRUCTION AND SHE WAS HOSPITALIZED FOR 12 DAYS. OXYCONTIN WAS DISCONTINUED DURING THE HOSPITAL STAY. A FEW MONTHS LATER, THE PATIENT TOOK OXYCONTIN 20 MG EVERY 8 HOURS AGAIN FOR BURSTITIS IN THE SHOULDER. AFTER TWO DOSES, THE PATIENT EXPERIENCED NAUSEA, VOMITING AND HEADACHES. OXYCONTIN WAS DISCONTINUED. THE SYMPTOMS ABATED. NO FURTHER INFORMATION WAS PROVIDED.

6. Relevant tests/laboratory data, including dates	RELEVANT TESTS/DATA: UNKNOWN
--	------------------------------

7. Other relevant history, including preexist. med. conditions	ABDOMINAL SURGERY; BURSTITIS IN THE SHOULDER
--	--

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)	#1 OxyContin CR Tablets, 20 mg (oxycodone hydrochloride)
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2. Dose, frequency & route	#1 20 MG Q8H PO	3. Therapy dates (if unk, give dur)	#1 6/2001 (STOP'D)
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4. Diagnosis for use (indication)	#1 NON-MALIGNANT PAIN	5. Event abated after use stopped or dose reduced	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
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6. Lot # (if known)	#1 UNKNOWN	7. Exp. Date	#1 UNKNOWN	8. Event reappeared after reintroduction	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
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9. NDC # for prod problems only	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A
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10. Concomitant medical products and therapy dates	UNKNOWN
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G. ALL MANUFACTURERS

1. Contact office - name/address	Purdue Pharma L.P. 1 STANFORD FORUM STANFORD, CT 06901-3431	2. Phone number (203) 586-8000	3. Report source (check all that apply)
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4. Date Rec'd by Mfr.	11/29/2001	5. (A)NDA#	20-553
6. If IND, protocol #	IND# _____ PLAN# _____	7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product <input type="checkbox"/> yes

8. Adverse event term(s)	OBSTRUCT INTTEST NAUSEA VOMIT HEADACHE
9. Mfr. report number	2014990

E. INITIAL REPORTER

1. Name, address & phone #	REDACTED
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2. Health professional?	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation		4. Initial reporter also sent report to FDA	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A

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