FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr report #	2014344
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
DACTED	34 YEARS	[ ] female [X] male	lbs or 68 kgs

REDACTED

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[X] death 11/20/2000 (mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 11/20/2000

4. Date of this Rept 02/05/2002

5. Describe event or problem

A 34-year-old white male died on 20NOV00 while taking OxyContin (controlled-release oxycodone hydrochloride) for back pain. The immediate cause of death has been listed as central nervous system depression with an underlying cause of combined drug intoxication (oxycodone, benzodiazepines and diphenhydramine). The manner of death has been listed as accidental. Reportedly, this male had injured his back in 1996 and had been under a doctor's care since 1997 until his death. Was being treated for lumbar sprain, lower back pain and lumbosacral strain. At the time of death, was awaiting approval for surgery. His drug therapy was OxyContin, 80 mg, every eight hours. Found in his bedroom were a bottle of OxyContin 80 mg, filled 08NOV00 (100 issued, 50 remaining), amitriptyline 10 mg for [not the decedent's name, with 17 pink 'AP 10" pills (amitriptyline) and 12 white "DAN 5658" pills (cyclobenzaprine), a bottle of naproxen 500 mg pills, filled [03DEC99] for [no the decedent's name] (30 issued, 16 remaining), six Unisom (doxylamine succinate) sleepgel pills and eight Sominex (diphenhydramine hydrochloride) sleep-aid pills. Reportedly, "Up until one year before death, the decedent had also had a severe alcohol problem. He had been arrested for D.U.I. [driving under the influence] on multiple occasions. He had been sober for a year prior to his death. His family said he was also addicted to prescription drugs. There was a suspicion that the decedent would obtain these drugs illegally. According to his parents he had a history of abusing his OxyContin, so they would keep the pills and distribute them to him under their (CONTINUED)

6. Relevant tests/laboratory data, including dates

Relevant Tests and Laboratory Data: See text.

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

Back pain from a construction injury in 1966. Being treated for lumbar sprain, lower back pain and lumbosacral strain. History of being "a drinker of alcohol and a smoker," addicted to prescription drugs and abused OxyContin

C. SUSPECT MEDICATION(S)

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

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

2. Dose, frequency & route
#1 80 MG Q8H
#2 UNKNOWN

3. Therapy dates (if unk, give dur)
#1 UNKNOWN
#2 UNKNOWN

4. Diagnosis for use (indication)
#1 NON-MALIGNANT PAIN
#2 UNKNOWN

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [X] N/A
#2 [ ] yes [ ] no [X] N/A

6. Lot # (if known)
#1 UNKNOWN
#2 UNKNOWN

7. Exp. Date
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] N/A
#2 [ ] yes [ ] no [X] N/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.
1 STAMFORD FORUM
STAMFORD, CT 06901-3431

2. Phone number
(203) 588-8000

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

4. Date Rec'd by Mfr.
09/18/2001

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ] yes
OTC [ ] yes
product

6. If IND, protocol #

7. Type of report (check all that apply)
[ ] 15-day [ ] 15-day
[ ] 10-day [X] periodic
[X] init [ ] follow-up #

8. Adverse event term(s)
OVERDOSE ACCID
CNS DEPRESS

9. Mfr. report number
2014344

E. INITIAL REPORTER

1. Name, address & phone #

REDACTED

2. Health professional?
[X] yes [ ] no

3. Occupation
CORONER

4. Initial reporter also sent report to FDA
[ ] yes [ ] no [X] 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.

8003055976

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr report #	2014344
UF/Dist report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at event	3. Sex	4. Weight
	or DOB:	[ ] female [ ] male	lbs 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 02/05/2002

5. Describe event or problem

control." The autopsy revealed "No trauma, fibrinopurulent pericardial fluid with acute and chronic fibrinous pericarditis, cardiac right and left ventricular wall thicknesses at upper limits of normal, severe congestion of lungs, no evidence of aspiration of gastric contents or other foreign debris, polyps of sigmoid colon, mild chronic passive congestion of liver and spleen, mild periportal triaditis of liver, fatty metamorphosis of liver, IV drug-abuse type needle scars of right antecubital fossa. The toxicology report revealed that the serum was positive for diazepam 0.32 mcg/mL (therapeutic range 0.02 to 2.0), nordiazepam 1.08 mcg/mL (therapeutic range 0.02 to 1.8), diphenhydramine 1.60 mcg/mL (therapeutic range 0.01 to 0.1), ibuprofen 80.4 mcg/mL (therapeutic range 5 to 49), oxycodone 1.40 mcg/mL (toxic range 0.2 to 5.0). The urine was positive for pseudoephedrine, benzodiazepine metabolites, diphenhydramine, ibuprofen and oxycodone. This report was received on (8SEP0) in response to an inquiry from Purdue requesting copies of autopsy and toxicology reports from media reported deaths involving the use of oxycodone or OxyContin (controlled-release oxycodone hydrochloride) from the presiding Medical Examiner's Office, United States of America

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) (CONT)

#3 DIPHENHYDRAMINE
#4 IBUPROFEN

2. Dose, frequency & route
#3 UNKNOWN
#4 UNKNOWN

3. Therapy dates (if unk, give dur)
#3 UNKNOWN
#4 UNKNOWN

4. Diagnosis for use (indication)
#3 UNKNOWN
#4 UNKNOWN

5. Event abated after use stopped or dose reduced
#3 [ ]yes [ ]no DKIN/A
#4 [ ]yes [ ]no DKIN/A

6. Lot # (if known)
#3 UNKNOWN
#4 UNKNOWN

7. Exp. Date
#3
#4

8. Event reappeared after reintroduction
#3 [ ]yes [ ]no DKIN/A
#4 [ ]yes [ ]no DKIN/A

9. NDC # for prod problems only

10. Concomitant medical products and therapy dates

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

4. Date Rec'd by Mfr.

5. (A)NDA#
IND#
PLA#
pre-1938 [ ]yes
OTC [ ]yes
product

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]5-day [ ]15-day
[ ]10-day [ ]periodic
[ ]init [ ]follow-up #

8. Adverse event term(s)

9. Mfr. report number 2014344

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?
[ ] yes [ ] no

3. Occupation

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [ ]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.

8003055977

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Purdue Pharma L.P.

Page 3 of 3

FDA Approved 11/08/93

Mfr report # 2014344

UF/Dist report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier
2. Age at event: or DOB:
3. Sex: [ ] female [ ] male
4. Weight: lbs 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 02/05/2002
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)
   #5 PSEUDOEPHEDRINE
   #
2. Dose, frequency & route
   #5 UNKNOWN
   #
3. Therapy dates(if unk, give dur)
   #5 UNKNOWN
   #
4. Diagnosis for use (indication)
   #5 UNKNOWN
   #
5. Event abated after use stopped or dose reduced
   #5 [ ]yes [ ]no [X]N/A
   # [ ]yes [ ]no [ ]N/A
6. Lot # (if known)
   #5 UNKNOWN
   #
7. Exp. Date
   #5
   #
8. Event reappeared after reintroduction
   #5 [ ]yes [ ]no [X]N/A
   # [ ]yes [ ]no [ ]N/A
9. NDC # for prod problems only
10. Concomitant medical products and therapy dates

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)
   [ ] foreign
   [ ] study
   [ ] literature
   [ ] consumer
   [ ] health professional
   [ ] user facility
   [ ] company representative
   [ ] distributor
   [ ] other:
4. Date Rec'd by Mfr.
5. (A)NDA# ____ IND# ____ PLA# ____ pre-1938 [ ]yes OTC [ ]yes product
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)
9. Mfr. report number 2014344

E. INITIAL REPORTER

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

8003055978

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL, STATE OF CONNECTICUT

FDA Approved 11/05/93

MEDWATCH

Purdue Pharma L.P.

Mfr report # 2014468
UF/Dist report #
FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION

Patient identifier	2. Age at event	3. Sex	4. Weight
DACTED	51 YEARS or DOB:	[X] female [ ] male	lbs or 73 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

[X] Adverse Event and/or [ ] Product problem

Outcomes attrib. to event
[X] death 1/3/2001 (mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 1/3/2001

4. Date of this Rept 02/05/2002

5. Describe event or problem

A 51-year-old female died on 03JAN01 from effects of acute and chronic narcotic addiction while taking OxyContin (controlled release oxycodone hydrochloride) and methadone. This case was listed as an accidental death. The case was reported as follows: "51-year-old female (height 66", weight 73kg) with numerous medical problems including hospital stays for pain related problems, back surgery, depression, edema, ulcers, GI bleeding, and rheumatic fever as child. She was very angry at her physician for cutting back on her pain medications, was seeing a psychologist and was known for taking fistfuls of medications. The decedent was found unresponsive on couch. Medications included OxyContin, methadone, bupropion, gabapentin, flurazepam, hydrocodone, clonazepam, and diazepam." The toxicology report revealed that the heart blood was positive for OxyContin (oxycodone) 0.12mg/L and methadone 0.87mg/L. OxyContin was positive in femoral blood 0.35mg/L, the liver 0.11mg/kg, the urine 7.3mg/L, bile 0.19mg/L, vitreous 0.26mg/L, and gastric 5.9mg total. Three intact 20mg OxyContin tablets were found in the gastric contents. This case was received on 03OCT01 from a Coroner's Office in the United States of America.

6. Relevant tests/laboratory data, including dates

RELEVANT TESTS/LAB DATA: SEE NARRATIVE TEXT

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

HISTORY OF NUMEROUS MEDICAL PROBLEMS INCLUDING HOSPITAL STAYS FOR PAIN RELATED PROBLEMS, BACK SURGERY, DEPRESSION, EDEMA, ULCERS, GI BLEEDING, AND RHEUMATIC FEVER AS A CHILD, KNOWN TO TAKE FISTFULS OF MEDICATIONS, SEEING A PSYCHOLOGIST, 3 INTACT OXYCONTIN 20MG TABLETS FOUND IN GASTRIC CONTENTS

C. SUSPECT MEDICATION(S)

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

2. Dose, frequency & route
#1 60 MG QDH PO
#2 UNKNOWN

3. Therapy dates (if unk, give dur)
#1 UNKNOWN
#2 UNKNOWN

4. Diagnosis for use (indication)
#1 NON-MALIGNANT PAIN
#2 UNKNOWN

5. Event abated after use stopped or dose reduced
#1 [ ]yes [ ]no [X]N/A
#2 [ ]yes [ ]no [X]N/A

6. Lot # (if known)
#1 UNKNOWN
#2 UNKNOWN

7. Exp. Date
#1
#2

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

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)
[ ] foreign
[ ] study
[ ] literature
[ ] consumer
[X] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[X] other:
CORONER

4. Date Rec'd by Mfr.
10/03/2001

5. (A)NDA# 20-553
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 [X]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)
OVERDOSE ACCID

9. Mfr. report number
2014468

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?
[X] yes [ ] no

3. Occupation
CORONER

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [X]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.

8003056035

118,10

MEDWATCH

THE MEDICAL PRODUCTS REPORTING PROGRAM

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

Purdue Pharma L.P.
FDA Facsimile Approval 11-JUN-1999

Mfr report # USA-2002-0000605
UFDist report #
FDA Use Only

Patient information

ACTED REDACTED

Initials or patient identifier: Unknown
Date of birth: Date of birth
Age at time of event: 40 Years
3. Sex: [ ] female [ ] male
4. Weight: 132.0 lbs or 59.9 kgs

Adverse event or product problem

Adverse event and/or [ ] Product problem (e.g. defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

[ ] death
with date 11/25/1999 (mm/dd/yyyy)
[ ] life threatening
[ ] congenital anomaly
[ ] required intervention to prevent permanent impairment/damage
[x] hospitalization - initial or prolonged
[ ] other:

2. Date of event (mm/dd/yy): 12/02/1998
1. Date of this report (mm/dd/yy): 01/15/2002

5. Describe event or problem

Oxycodone toxicity[OVERDOSE ACCIDENTAL]
Emphysema [EMPHYSEMA]
pneumonia [PNEUMONIA]

Case Description:
A 41 year old White male died on 25NOV99 from oxycodone toxicity while taking oxycodone, hydrocodone, dihydrocodeine, lorazepam and nicotine. Chronic pulmonary emphysema was determined to be a contributing cause of death. The manner of death was accidental. Per the decedent's wife, the decedent had a history of prescription drug abuse and over medicating himself. During the early morning hours of 25NOV99 the decedent's wife noticed that the decedent was "staggering about." She thought that he may have over medicated himself and she told him to go to bed. Later that day at 0950 the decedent was found face down in bed. Paramedics responded to the emergency call and found the decedent dead upon arrival. The decedent was being treated for a "pinched nerve in his back" and was receiving physical therapy. A pharmacy continued in additional info section...

6. Relevant tests/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 Current Condition, (continued)
#2 --/--/1997, Current Condition, PAIN (continued)
#3 Historical Condition, (continued)
#4 Current Condition, SMOKER
continued in additional info section...

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

FDA - Form

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1. OxyContin Tablets 80 mg(OXYC (continued)
#2. OxyContin Tablets 40 mg(OXYC (continued)

2. Dose, frequency & route used
#1. 80 mg, tid, Oral
#2. 40 mg, tid, Oral

3. Therapy dates (if unknown, give duration) (mm/dd/yy or duration)
#1. 11/22/1999, duration UNK
#2. 07/17/1998 to 11/21/1999

4. Diagnosis for use (indication)
#1. UNK
#2. UNK

5. Event abated after use stopped or dose reduced
#1. [ ] yes [ ] no [x] doesn't apply
#2. [ ] yes [ ] no [x] doesn't apply

6. Lot # (if known)
#1. Unknown
#2. unknown

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

8. Event reappeared after reintroduction
#1. [ ] yes [ ] no [x] doesn't apply
#2. [ ] yes [ ] no [x] doesn't apply

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

10. Concomitant medical products and therapy dates (exclude treatment of event)
SOMA (CARISOPRODOL) Tablet --/--/1998 to ongoing
CLONIDINE (CLONIDINE) Patch 11/01/1999 to UNK

G. At Manufacturer

1. Contact office - name/address (& mfrg 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
[x] consumer
[x] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[x] other: Attorney, Med. Examiner

4. Date received by manufacturer (mm/dd/yy)
01/03/2002

5. (A)NDA # 20-553
IND #
PMA #
pre 1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)
[ ] 5-day [x] 15-day
[ ] 10-day [ ] periodic
[x] initial [ ] follow-up #

8. Adverse event term(s)
OVERDOSE ACCIDENTAL, EMPHYSEMA, PNEUMONIA

9. Mfr. report number
USA-2002-0000605

E. Initial reporter

1. Name & address
Name and address withheld.

phone # Withheld

2. Health professional?
[ ] yes [x] no

3. Occupation
UNK

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

8003057191

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

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

MEDWATCH # USA-2002-0000605
OTHER report #

FDA Use Only

C. Suspect medical device(s)

1. Name (give labeled strength & manufacturer, if known)
#3. Dihydrocodeine/Caffeine/Acet (continued)
#4. VICODIN (continued)

2. Dose, frequency & route used
#3. UNK mg, unk, Oral
#4. UNK unk, unk, UNK

3. Therapy dates (if unknown, give duration)
#3. duration 497 days
#4. --/--/1997 to --/--/1999

4. Diagnosis for use (indication)
#3. Unknown
#4. PAIN

5. Event abated after use stopped or dose reduced
#3. ☐ yes ☐ no ☒ doesn't apply
#4. ☐ yes ☐ no ☒ doesn't apply

6. Lot # (if known)
#3. Unknown
#4. unknown

7. Exp. date (if known)
#3. UNK
#4. UNK

8. Event reappeared after reintroduction
#3. ☐ yes ☐ no ☒ doesn't apply
#4. ☐ yes ☐ no ☒ doesn't apply

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

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

C. Suspect medical device(s)

1. Name (give labeled strength & manufacturer, if known)
#5. BROMAZEPAM(BROMAZEPAM)
#6. NICOTINE(NICOTINE) Unknown

2. Dose, frequency & route used
#5. UNK mg, unk, Oral
#6. UNK, (continued)

3. Therapy dates (if unknown, give duration)
#5. duration 497 days
#6. duration 497 days

4. Diagnosis for use (indication)
#5. Unknown
#6. Unknown

5. Event abated after use stopped or dose reduced
#5. ☐ yes ☐ no ☒ doesn't apply
#6. ☐ yes ☐ no ☒ doesn't apply

6. Lot # (if known)
#5. Unknown
#6. Unknown

7. Exp. date (if known)
#5. UNK
#6. UNK

8. Event reappeared after reintroduction
#5. ☐ yes ☐ no ☒ doesn't apply
#6. ☐ yes ☐ no ☒ doesn't apply

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

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

8003057192

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

Additional Information

B5. EVENT DESCRIPTION (cont.)

prescription bag containing some unidentified white tablets was found at the scene. Paramedics at the scene felt that the tablets appeared to be soma (carisoprodol). No other medications were found at the residence. An autopsy performed on 25NOV99 concluded that the decedent had died from oxycodone toxicity. Other findings included centrilobular emphysema with apical bullae emphysema and cerebral edema. Per the medical examiner, chronic pulmonary emphysema was a contributory cause of death. The results of the quantitative blood toxicology were positive for the presence of oxycodone at 4.60 mg/L and hydrocodone at 0.12 mg/L. Urine drug screen was positive for the presence of oxycodone, hydrocodone, dihydrocodeine, bromazepam and nicotine. This case was reported by a consumer's relative via an attorney in the United States of America.
***Additional information received on 08APR02 included copies of the decedent's prior medical records, physician progress notes and pharmacy records. These records reveal that the decedent was taking OxyContin (controlled-release oxycodone hydrochloride) and Vicodin ES (hydrocodone/acetaminophen) when he died. The records also reveal that the decedent had an ongoing problem with prescription drug abuse and a prior history of alcohol abuse. The decedent was also a known smoker and a chest x-ray taken on 09JAN99 revealed evidence of emphysema. Per the medical records, the patient had ongoing complaints of back pain secondary to injuries incurred from a motor cycle accident in 1997. On 04JAN97 while out-of-state, the decedent phoned his physician requesting pain medication because he "threw his back out again." A physician's progress note dated 27OCT97 noted that the decedent was complaining of back pain and was taking Vicodin. Physician notes dated JAN98 revealed that the decedent was on "Soma and Vicodin frequently." The results of a lumbosacral spinal x-ray taken on 26JAN00 showed a mild lumbosacral spine. The patient was advised to consult with an orthopedic specialist, but he refused. During this time the physician's records reveal that the patient continued to ask for prescription refills for Vicodin and Soma. On 04JUN98 the treating physician advised the patient that he would not refill any prescriptions for Vicodin or Soma until the patient was evaluated by an orthopedic specialist. An MRI (magnetic resonance imaging) of the lumbosacral spine performed on 29JUN98 revealed the presence of some degenerative changes of the facets resulting in some encroachment on the neural foramina. The canal was not compromised and there was no evidence of disc herniation. On 17JUL98 the patient started taking OxyContin 40 mg bid as prescribed by a pain specialist. On 04SEP98 the dose was increased to 40 mg qdh. On 18NOV98 the pain management specialist administered the first of several planned facet blocks for pain control. However, the patient "was a no show" for the subsequent appointments and did not receive any further treatment. It appears that the patient did not continue treatment with the pain specialist and received the last prescription for OxyContin from him on 27NOV98. A few days later, on 02DEC98 the patient developed pneumonia and was admitted to the hospital. On the same day (02DEC98) the patient's wife informed the physician that her husband was "getting addicted to Soma." The pneumonia resolved and the patient was discharged from the hospital on 06DEC98. On 23DEC98 the pain management physician informed the patient's regular physician that the patient refused further epidural (facet) injections and "instead he wants Soma and narcotics." On 15JAN99 the patient phoned a physician's office requesting "pain pills," stating that he had hurt his back earlier in the day. On 16JUN99 the patient began seeing a new primary physician. At this visit he complained of exacerbation of back pain and was continued on Vicodin and Soma. On 25JUN99 the patient requested a prescription for MS Contin (morphine sulfate controlled-release) 40 mg tid. He explained that the pain management specialist had prescribed the medication for him about 6 months ago, but now refuses to refill his prescription. The physician informed the patient on 16JUL99 that he would not prescribe OxyContin for low back pain. The physician recommended that the patient contact the pain management specialist and be re-evaluated. On 23OCT99 the patient stated that his pain medication was lost or stolen and he needed refills. On 25OCT99 the patient stated that his pain had increased and he now needed to take 2 tablets of Vicodin. The patient was referred back to the pain management physician and was given a prescription for Percocet (oxycodone/acetaminophen). On 04NOV99 the physician spoke with the pain specialist and noted in the patient's records, "Probable drug seeking behavior, plans epidural inject, Vicodin ES and Soma." During the period 05OCT99 - 08NOV99 the patient was assessed for "detox from pain medication." Per the therapist, the patient was having problems at work and his manager noticed inappropriate behavior. The patient agreed to seek help due to fear of losing his job. It was determined that the patient did not need to be in a detox, but "was in need for therapy regarding possible misuse of pain medication." Per the therapist, he did not show up for his appointments and was last seen on 08NOV99. On 01NOV99 the patient began treatment with the pain specialist and underwent a series of epidural injections. On 05NOV99 he was given a prescription for Vicodin ES, Soma and clonodine patches. On 08NOV99 and on 10NOV99 the patient received a prescription for OxyContin 40 mg qdh. On 22NOV99 the patient filled a prescription for 60 tablets of OxyContin 80 mg qdh. On 25NOV99 the patient died from oxycodone toxicity. Emphysema was considered a contributing cause of death.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1		Current Condition NONDEPENDENT ABUSE OF DRUGS	History of prescription drug abuse and self over-medication.
2	-/-/1997	Current Condition PAIN	Low back pain.
3		Historical Condition NONDEPENDENT ABUSE OF ALCOHOL	Entered into treatment program in 1982. Drinking escalated in 1993.
5	01/15/1999	Historical Condition EMPHYSEMA	Chest x-ray dated 15JAN99 - "Evidence of emphysema"

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6	12/02/1998 12/06/1998	Historical Condition PNEUMONIA, ORGANISM UNSPECIFIED	Hospitalized for pneumonia.

D1. Name (cont.)
Suspect Medication #1: OxyContin Tablets 80 mg(OXYCODONE HYDROCHLORIDE) CR Tablet
Suspect Medication #2: OxyContin Tablets 40 mg(OXYCODONE HYDROCHLORIDE) CR Tablet
Suspect Medication #3: Dihydrocodeine/Caffeine/Acetaminophen (similar to ANDA 88-584)(PARACETAMOL, CAFFEINE, DIHYDROCODEINE) Unknown
Suspect Medication #4: VICODIN(HYDROCODONE BITARTRATE, PARACETAMOL)

D2. Dose, frequency & route used (cont.)
Suspect Medication #6: UNK, UNK, Unknown

12145

Relsys International, Inc.
FDA Facsimile Approval: 11-JUN-1996

MEDWATCH
MEDICAL PRODUCTS REPORTING PROGRAM

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

MR report # 2012229
UNOM report #
FDA Use Only

A. Patient information

1. Patient identifier: REDACTED
2. Age of time of event: 33 Years
Date of birth: REDACTED
3. Sex: [x] female [ ] male
4. Weight: 135.0 lbs or 61.2 kgs

B. Adverse event or product problem

[x] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

Outcome attributed to adverse event (check all that apply)
[x] death 11/15/2000
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congenital anomaly
[ ] required intervention to prevent permanent impairment/damage
[x] other: Medically Significant

3. Date of event 11/15/2000
4. Date of this report 05/13/2002

5. Describe event or problem

Oxycodone and Tramadol Toxicity [OVERDOSE]
Drug Abuse [DRUG ABUSE]
Coronary Atherosclerosis [ATHEROSCLEROSIS]
Diabetes Mellitus [DIABETES MELLITUS]

Case Description:
An unidentified person reportedly died while taking OxyContin (controlled-release oxycodone hydrochloride). A Doctor of Dental Surgery (D.D.S.) informed a Purdue Sales Representative that a patient "passed away while on OxyContin plus other medications." The reporter only knew of the death and did not prescribe OxyContin for this patient. No other information was provided. This case was reported by a dental surgeon in the United States of America. Additional information is being sought. ***additional information received 15FEB02 in the form of a telephone call from the reporting dentist identifies this patient as a female who died on 15NOV00. Reportedly, the "Coroner report apparently

continued in additional info section...

6. Relevant tests/laboratory data, including dates
See Narrative History

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatorenal dysfunction, etc.)
#1 Current Condition, (continued)
#2 Current Condition, DIABETES MELLITUS
#3 Current Condition, ESSENTIAL HYPERTENSION
#4 Current Condition, CORONARY ATHEROSCLEROSIS
#5 Current Condition, RENAL FAILURE (continued)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1. OxyContin Tablets 20 mg(OXYC (continued)
#2. ULTRAM(TRAMADOL, (continued)

2. Dose, frequency & route used
#1. 20 mg, q8h, Oral
#2. 50 mg, prn, Oral

3. Therapy dates (if unknown, give duration)
#1. --/--/1999, duration UNK
#2. UNK

4. Diagnosis for use (indication)
#1. Chronic Pain
#2. UNKNOWN

5. Event abated after use stopped or dose reduced
#1. [ ] yes [ ] no [x] doesn't apply
#2. [ ] yes [ ] no [x] doesn't apply

6. Lot # (if known)
#1. UNKNOWN
#2. UNKNOWN

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

8. Event reappeared after reintroduction
#1. [ ] yes [ ] no [x] doesn't apply
#2. [ ] yes [ ] no [x] doesn't apply

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

10. Concomitant medical products and therapy dates (exclude treatment of event)
XANAX (ALPRAZOLAM) Tablet UNK to UNK
TRAZODONE (TRAZODONE) Unknown UNK to UNK
continued in additional info section...

D. Manufacturer

1. Contact office - name/address (& mfrlg 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
[x] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[x] other: Medical Examiner

4. Date received by manufacturer
04/29/2002

5. (A)NDA # 20-553
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)
[ ] 5-day [x] 15-day
[ ] 10-day [ ] periodic
[ ] initial [x] follow-up # 1

8. Adverse event term(s)
OVERDOSE, DRUG ABUSE, ATHEROSCLEROSIS, DIABETES MELLITUS

9. MR report number
2012229

E. Initial reporter

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

2. Health professional?
[x] yes [ ] no

3. Occupation
Dentist

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

FDA 3500A - Facsimile

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

15-May-2002 10:28:10

8003057439

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Additional Information

B5. EVENT DESCRIPTION (cont.)

listed resp. [respiratory] failure due to Oxycodone [not sure if OxyContin named specifically] and Ultram [tramadol]." On a subsequent telephone conversation on 20MAR02, the reporting dentist related that "this patient has a long history of abuse and has had two DUI's [driving under the influence]." Additional information is being requested.
***Follow-up information received on 29APR02 from the reporting dentist and from the presiding Medical Examiner's Office revealed that the decedent was a 33-year-old White female who died on 15NOV00 from an oxycodone and tramadol overdose while taking OxyContin and Ultram. The cause of death was ascribed to tramadol and oxycodone toxicity with coronary atherosclerosis and diabetes mellitus contributing to her demise. The manner of death was not provided. The cause of death was not associated with respiratory failure, as previously reported. The decedent had been taking OxyContin 20 mg q8h for chronic pain since 1999. Other prescription medications included Ultram 50 mg (tramadol) 2-4 tablets a day, Xanax (alprazolam) 0.5 mg, trazadone and Celexa (citalopram). Per the reporting dentist, the decedent had taken 55 tablets of OxyContin within 5 days of receiving a refill of her prescription. He also indicated that the decedent may have been abusing her medication. On 15NOV00 the decedent was found unresponsive at her residence. She was pronounced dead at the scene by the responding police officer. An autopsy performed on 16NOV00 revealed tramadol and oxycodone intoxication, pulmonary edema and coronary atherosclerosis as evidenced by 70% occlusion of the left anterior descending artery, 60% occlusion of the circumflex artery and 30% occlusion of the right coronary artery. Other findings included diabetes mellitus, mild diffuse nephrosclerosis and status post hysterectomy. Quantitative blood toxicology was positive for the presence of tramadol at 1900 ng/mL, O-desmethyl tramadol (tramadol metabolite) at 150 ng/mL (peak plasma levels following a single 100 mg oral dose: 25-75 ng) and oxycodone at 550 ng/mL. Reportedly, the decedent's past medical history was significant for diabetes mellitus, drug and alcohol abuse, kidney failure, atherosclerosis and hypertension.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1		Current Condition NONDEPENDENT ABUSE OF DRUGS	Long history of abuse and had had two DUI's [driving under the influence] on unspecified dates.
5		Current Condition RENAL FAILURE	Kidney Failure

C1. Name (cont.)
Suspect Medication #1: OxyContin Tablets 20 mg(OXYCODONE HYDROCHLORIDE) CR Tablet
Suspect Medication #2: ULTRAM(TRAMADOL HYDROCHLORIDE) Tablet

C10. CONCOMITANT MEDICAL PRODUCTS
CELEXA (CITALOPRAM HYDROBROMIDE) Unknown UNK to UNK

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12260

Relays International, Inc.
FDA Facsimile Approval 11-JUN-1998

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Mfr report # 2014470

FDA Use Only

Patient information

Patient identifier	2. Age at time of event	3. Sex	4. Weight
ED-F	66 Years or date of birth: REDACTED-PRIVACY	[x] female [ ] male	156.6 lbs or 71.0 kgs

Adverse event or product problem

[ ] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

Death 06/07/1999 (mm/dd/yy)

[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congenital anomaly
[ ] required intervention to prevent permanent impairment/damage
[ ] other:

3. Date of event (mm/dd/yy): 06/07/1999

4. Date of this report (mm/dd/yy): 05/28/2002

5. Describe event or problem

Heart Disorder [HEART DISORDER]
Breast Neoplasm Malignant Female [CARCINOMA]
Overdose Accidental [OVERDOSE ACCIDENTAL]

Case Description:
A 66-year-old female died on 07JUN99 from "Atherosclerotic coronary heart disease, metastatic breast carcinoma, [and] oxycodone effect" while taking OxyContin (controlled-release oxycodone hydrochloride), codeine, verapamil and doxepin. The case was reported as follows: "66-year-old female (64", 71 kg) with a history of breast cancer, heart disease, and dizzy spells. Found unresponsive outside her front door with trauma to the back of her head. Her purse and a bag of groceries were lying beside her. The following medications were prescribed: [OxyContin], acetaminophen with codeine, doxepin, and verapamil." Reportedly, OxyContin was prescribed at a dose of "20-mg 3 tabs Q 4 hours [and] 20-mg 2 tabs Q 8 hours." The toxicology report revealed that the heart blood was positive for oxycodone (0.18 mg/L), codeine (0.25 mg/L), 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 Historical Condition, (continued)
#2 Historical Condition, (continued)
#3 Historical Condition, (continued)

Suspect medication(s)

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

#1. OxyContin Tablets 20 mg(OXYC (continued)
#2. Hydrocodone Bitartrate (continued)

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) (mm/dd/yy or best estimate)
#1. 480 mg, daily, Oral	#1. UNK
#2. UNK, unk, UNK	#2. UNK

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1. UNKNOWN	#1. [ ] yes [ ] no [x] doesn't apply
#2. UNKNOWN	#2. [ ] yes [ ] no [x] 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 [x] doesn't apply
#2. [ ] yes [ ] no [x] 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

Manufacturer

1. Contact office - name/address (& mfrg 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
[x] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[x] other: MEDICAL EXAMINER

4. Date received by manufacturer (mm/dd/yy): 05/14/2002

5. (A)NDA # 20-553
IND # 59,175
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. IND, protocol #

7. Type of report (check all that apply)
[ ] 5-day [x] 15-day
[ ] 10-day [ ] periodic
[ ] initial [x] follow-up # 2

8. Adverse event term(s)

HEART DISORDER, CARCINOMA, OVERDOSE ACCIDENTAL

9. Mfr. report number: 2014470

Initial reporter

1. Name & address: Name and address withheld.

phone #Withheld

2. Health professional? [x] yes [ ] no

3. Occupation: Medical Examiner

4. Initial reporter also sent report to FDA: [ ] yes [ ] no [x] unk

FDA 3500A - Facsimile

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

8003057567

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Medication and Device Experience Report (continued)

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

Public Health Service - Food and Drug Administration

MR report # 2014470

UFURS report #

FDA Use Only

C. Suspect product(s)

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

2. Dose, frequency & route used
#3. UNK, unk, UNK
#4. UNK, unk, UNK

2. Therapy dates (if unknown, give duration)
#3. UNK
#4. UNK

4. Diagnosis for use (indication)
#3. UNKNOWN
#4. UNKNOWN

5. Event abated after use stopped or dose reduced
#3. ☐ yes ☐ no ☒ doesn't apply
#4. ☐ yes ☐ no ☒ doesn't apply

6. Lot # (if known)
#3. UNKNOWN
#4. UNKNOWN

7. Exp. date (if known)
#3. UNK
#4. UNK

8. Event reappeared after reintroduction
#3. ☐ yes ☐ no ☒ doesn't apply
#4. ☐ yes ☐ no ☒ doesn't apply

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

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

D. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#5. DOXEPIN(DOXEPIN)
#6.

2. Dose, frequency & route used
#5. UNK, unk, UNK
#6.

3. Therapy dates (if unknown, give duration)
#5. UNK
#6.

4. Diagnosis for use (indication)
#5. UNKNOWN
#6

5. Event abated after use stopped or dose reduced
#5. ☐ yes ☐ no ☒ doesn't apply
#6. ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#5. UNKNOWN
#6.

7. Exp. date (if known)
#5. UNK
#6.

8. Event reappeared after reintroduction
#5. ☐ yes ☐ no ☒ doesn't apply
#6. ☐ yes ☐ no ☐ doesn't apply

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

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

20-May-2002 W.30.14

8003057568

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Additional information

B5. EVENT DESCRIPTION (cont.)

verapamil (0.10 mg/L), doxepin (0.29 mg/L) and nordoxepin (1.4 mg/L). The femoral blood was positive for oxycodone (0.44 mg/L). The oxycodone level of the gastric contents was not quantitated but reportedly, the "Autopsy report states 10 intact 20-mg tablets." The manner of death was listed as accidental. This case was received on 03OCT02 from a Coroner's Office in the United States of America.
***Follow up information received on 07JUN02 from the presiding Coroner's Office revealed a 66-year-old Caucasian female died on 09JUN99 from atherosclerotic coronary artery disease with the significant conditions of metastatic infiltrating ductal carcinoma of the breast, oxycodone effect, and blunt force head trauma. The decedent was found unresponsive on the front tile patio of her residence by her son. There was a large amount of blood around the decedent. The police and paramedics were called and she was pronounced dead at the scene. The Coroner's Investigator's Report, based on an interview with a Police Department Detective and the Coroner's observations, described a right occipital skull injury as a gunshot wound behind the right ear. Gun shot residue was collected at the scene, and the GSR (gun shot residue) Data Sheet was completed as a homicide. A GSR Report was not provided. The autopsy revealed cardiomegaly, atherosclerotic coronary artery disease, 80% eccentric narrowing with calcification of the left anterior descending coronary artery, mitral valve leaflet calcification and degenerative change, aortic valve leaflet calcification and degenerative change, generalized severe atherosclerotic cardiovascular disease, bilateral pulmonary congestion edema and consolidation, focal pleural thickening of the right chest cavity, gall stones, metastatic breast carcinoma, bilateral benign nephrosclerosis, moderately differentiated infiltrating ductal carcinoma, status-post right mastectomy, and obesity. The multiple small yellow pills located in the stomach labeled "20" were identified as OxyContin and one large oval pill "x" identified as verapamil. She had a port-a-cath in the left upper chest. There was evidence of external blunt force injury. She sustained a laceration of the scalp, skull fracture, subarachnoid hemorrhage of the left parietal region, and fracture of the right thoracic ribs with intercostal hemorrhage. The Deputy Medical Examiner reported, "the injury to her head is the probable result of falling down due to her heart disease or in combination with effects of the drug OxyContin." The qualitative and quantitative blood toxicology report was positive for oxycodone 0.16 mcg/mL, free codeine 0.35 mcg/mL, doxepin 0.29 mcg/mL, nordoxepin <0.10 mcg/mL, verapamil <0.10 mcg/mL. The urine was positive for codeine and hydrocodone. There was no alcohol present. Additional information is being requested.
***Follow up information received on 14MAY02 from the forensic laboratory revealed the decedent did not have particles of gunshot residue on either the right or left hand adhesive lift samples.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1		Historical Condition MALIGNANT NEOPLASM OF FEMALE BREAST	STATUS POST RIGHT MASTECTOMY
2		Historical Condition OTHER ILL-DEFINED DESCRIP & COMPLICATIONS OF HEART DISEASE	HEART DISEASE
3		Historical Condition OTHER AND UNSPECIFIED PERIPHERAL VERTIGO	DIZZY SPELLS

C1. Name (cont.)
Suspect Medication #1: OxyContin Tablets 20 mg(OXYCODONE HYDROCHLORIDE) CR Tablet
Suspect Medication #2: Hydrocodone Bitartrate (similar to IND 59,175)(HYDROCODONE BITARTRATE) Unknown

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma, L.P.

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 4

Mfr report #	USA-2002-0001041
Dir/Dist report #	
	FDA Use Only

A. PATIENT INFORMATION

Patient identifier	2. Age at event	3. Sex	4. Weight
PRIVACY	55 Years or DOB: UNK	[X] female [ ] male	189.0 lbs or 85.7 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

[X] Adverse Event and/or [ ] Product problem

1. Outcomes attrib. to event
[X] death 03/24/2002(mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 03/24/2002

4. Date of this Rept 12/09/2002

5. Describe event or problem

A 55-year-old female patient died on 24MAR02 from an overdose of OxyContin (controlled-release oxycodone hydrochloride) 40 mg Tablets. Approximately 1 5 years ago, the patient began taking OxyContin 40 mg three times a day for pain associated with rheumatoid arthritis. On 24MAR02, the patient's husband woke up in the morning and found his wife still in bed with the bed covers partially covering her head. Reportedly, when he pulled back the covers, there was foam coming out of her mouth. The patient's left arm was cold and there was no pulse. Reportedly, a female friend staying at the home called 911. The police came, but no ambulance was sent to the home. Reportedly, in FEB02, the patient took "too many OxyContin" and had gone to the Emergency Room. The patient's husband related "my wife had no suicidal intention." An autopsy was performed. The Forensic Pathologist related "It is my opinion that the cause of death is oxycodone toxicity." The oxycodone level was 1.4 mcg/ml. This case was reported by the patient's husband. No further information was provided. ***Additional information received on 27JUN02 from the Medical Examiner's Office in the form of an autopsy report revealed that this 55-year-old white female had arteriosclerotic cardiovascular disease with a 30% occlusion of the right coronary artery. The manner of death was not reported. The qualitative and quantitative toxicology report revealed that the femoral blood was positive for oxycodone 1.4 mcg/mL.

6. Relevant tests/laboratory data, including dates

See Text

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

#1 Historical Condition, RHEUMATOID ARTHRITIS

C. SUSPECT MEDICATION(S)

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

#1 OxyContin Tablets 40 mg (OXYCODONE HYDROCHLORIDE)
#2 Hydrocodone Bitartrate (similar to IND 50,175) (HYDRO (CONT)

2. Dose, frequency & route

#1 40 mg, tid, Oral
#2 UNK mg, unk, Unknown

3. Therapy dates(if unk, give dur)

#1 UNKNOWN
#2 UNKNOWN

4. Diagnosis for use (indication)

#1 NON-MALIGNANT PAIN
#2 UNKNOWN

5. Event abated after use stopped or dose reduced

#1 [ ]yes [ ]no [X]N/A
#2 [ ]yes [ ]no [X]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 [X]N/A
#2 [ ]yes [ ]no [X]N/A

9. NDC # for prod problems only

10. Concomitant medical products and therapy dates

PAXIL
PREDNISONE

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
[X] consumer
[X] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[ ] other:

4. Date Rec'd by Mfr.
05/15/2002

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ]yes
OTC product [ ]yes

6. If IND, protocol #

7. Type of report (check all that apply)

[ ]15-day [ ]15-day
[ ]10-day [X]periodic
[X]init [ ]follow-up #

8. Adverse event term(s)

OVERDOSE

9. Mfr. report number
USA-2002-0001041

E. INITIAL REPORTER

1. Name, address & phone #

Name, address and phone withheld

2. Health professional?
[X] yes [ ] no

3. Occupation
Coroner

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [X]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.

8003060329

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma, L.P.

Mfr report # USA-2002-0001041
LP/Dist report #
FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 4

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
	or — DOB:	[ ] female [ ] male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] 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 UNKNOWN

4. Date of this Rept 12/09/2002

5. Describe event or problem

alprazolam 0.015 mcg/mL, caffeine, dextromethorphan 0.51 mcg/mL, and hydrocodone 0.008 mcg/ml. The blood from the heart was positive for mirtazapine 0.32 mcg/mL. The liver was positive for mirtazapine 1.5 mcg/g, dextromethorphan 3.3 mcg/g, and hydrocodone 0.026 mcg/g. The urine was positive for benzodiazepines and opiates.

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 ALPRAZOLAM (ALPRAZOLAM)
#4 CAFFEINE (CAFFEINE)

2. Dose, frequency & route
#3 UNK mg, unk, unknown
#4 UNK mg, unk, unknown

3. Therapy dates (if unk, give dur)
#3 UNKNOWN
#4 UNKNOWN

4. Diagnosis for use (indication)
#3 UNKNOWN
#4 UNKNOWN

5. Event abated after use stopped or dose reduced
#3 [ ]yes [ ]no [X]N/A
#4 [ ]yes [ ]no [X]N/A

6. Lot # (if known)
#3 UNKNOWN
#4 UNKNOWN

7. Exp. Date
#3 UNKNOWN
#4 UNKNOWN

8. Event reappeared after reintroduction
#3 [ ]yes [ ]no [X]N/A
#4 [ ]yes [ ]no [X]N/A

9. NDC # for prod problems only
- -

10. Concomitant medical products and therapy dates

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

4. Date Rec'd by Mfr.

5. (A)NDA#
IND#
PLA#
pre-1938 [ ]yes
OTC [ ]yes
product

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]15-day [ ]15 day
[ ]10-day [X]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)

9. Mfr. report number
USA-2002 0001041

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?
[ ] yes [ ] no

3. Occupation

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [ ]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.

8003060330

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma, L.P.

Mfr report #	USA-2002-0001041
Ur/Dist report #	
	FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
	or ——— DOB:	[ ] female [ ] male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[ ] death (mm/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] 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)
#5 DEXTROMETHORPHAN (DEXTROMETHORPHAN)
#6 MIRTAZAPINE (MIRTAZAPINE)

2. Dose, frequency & route
#5 UNK mg, unk, Unknown
#6 UNK mg, unk, Unknown

3. Therapy dates (if unk, give dur)
#5 UNKNOWN
#6 UNKNOWN

4. Diagnosis for use (indication)
#5 UNKNOWN
#6 UNKNOWN

5. Event abated after use stopped or dose reduced
#5 [ ]yes [ ]no DKN/A
#6 [ ]yes [ ]no DKN/A

6. Lot # (if known)
#5 UNKNOWN
#6 UNKNOWN

7. Exp. Date
#5 UNKNOWN
#6 UNKNOWN

8. Event reappeared after reintroduction
#5 [ ]yes [ ]no DKN/A
#6 [ ]yes [ ]no DKN/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.
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:

4. Date Rec'd by Mfr.

5. (A)NDA#
IND#
PLA#
pre-1938 OTC product [ ]yes [ ]yes

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]15-day [ ]15-day
[ ]10-day [X]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)

9. Mfr. report number
USA-2002-0001041

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?
[ ] yes [ ] no

3. Occupation

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [ ]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.

8003060331

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

3500A Continuation Page

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

#	Start/Stop	Cond. Type/Condition	Notes
1		Historical Condition RHEUMATOID ARTHRITIS	Rheumatoid Arthritis

C1. Suspect Medication Name (continued)

#2 Hydrocodone Bitartrate (similar to IND 59,175) (HYDROCODONE BITARTRATE)

8003060332

PRODUCED BY PURDUE TO THE OFFICE OF THE ATTORNEY GENERAL-STATE OF CONNECTICUT

DID 4900

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200146
UF/Dist report #	
	FDA Use Or

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
REDACTED	55 YEARS or DOB:	[X] female [ ] male	lbs or 57.3 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[X] death 2/21/2000 (mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 2//2000

4. Date of this Rept 03/24/2000

5. Describe event or problem

A 55-year-old female with a history of arthritis, depression and hypertension, died on 21FEB00 while receiving Oxycontin (controlled release oxycodone hydrochloride) tablets for arthritis, Elavil (amitriptylene hydrochloride) for depression and Toprol XL (metropolol succinate) for hypertension. On 15FEB00, the patient began taking Oxycontin (controlled release oxycodone hydrochloride) 10 mg tablets every 12 hours, Elavil 50 mg hs and Toprol XL 50 mg in the morning. On 16FEB00, the frequency of Oxycontin 10 mg tablets was increased to every 8 hours. On 18FEB00, the dose of Oxycontin was increased to 20 mg every 8 hours. On 20FEB00, the dose of Oxycontin was increased to 30 mg every 8 hours. The next day, on 21FEB00, the patient died. The reporting pharmacist thinks it [the death] is a drug interaction because drugs [the three suspect drugs Oxycontin, Elavil and Toprol XL] use the same CYP2D6 enzyme system." Additional information is being requested.

6. Relevant tests/laboratory data, including dates

Relevant tests and laboratory data: 15FEB00 Blood pressure at 1300: 169/93; at 1600: 173/83. QT prolongation. 16FEB00 Blood pressure 178/87; 156/86 17FEB00 Blood pressure 169/99; 157/90 18FEB00 Blood pressure 173/78; 161/98 19FEB00 Blood pressure 156/85; 187/71 20FEB00 Blood pressure 146/86; 148/74; 156/86 21FEB00 Blood pressure 134/75

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

Allergic to codeine, phenergan and penicillin. History of arthritis, depression, hypertension.

C. SUSPECT MEDICATION(S)

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

#1 OxyContin CR Tablets, 10 mg (oxycodone hydrochloride)
#2 ELAVIL (AMITRIPTYLLINE)

2. Dose, frequency & route
#1 30 MG Q8H PO
#2 150 MG HS PO

3. Therapy dates(if unk, give dur
#1 2/20/2000 - 2/20/2000 (STOP'D)
#2 2/15/2000 - 2/20/2000 (STOP'D)

4. Diagnosis for use (indication)
#1 PAIN DUE TO ARTHRITIS
#2 DEPRESSION

5. Event abated after use stopped or dose reduced
#1 [ ]yes [ ]no [X]N/A
#2 [ ]yes [ ]no [X]N/A

6. Lot # (if known)
#1 UNKNOWN
#2 UNKNOWN

7. Exp. Date
#1
#2

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

9. NDC # for prod problems only

10. Concomitant medical products and therapy dates
LORCET PLUS, VALIUM (DIAZEPAM), NEURONTIN (GABAPENTIN), AMBIEN (ZOLPIDEM TARTRATE), SYNTHROID (LEVOTHYROXINE), CELEBREX (CELECOXIB), REMERON (MIRTAZAPINE), PREMPRO (CONJ. ESTROGENS/MEDROXYPROGEST), CLONIDINE HCL, -- (CONTINUED)

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

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

4. Date Rec'd by Mfr. 03/21/2000

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ]yes
OTC [ ]yes
product

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]15-day [X]15-day
[ ]10-day [ ]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)
DRUG INTERACTION

9. Mfr. report number 200146

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?
[X] yes [ ] no

3. Occupation
PHARMACIST

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [X]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.

15-DAY ALERT REPORT

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report #	200146
UF/Dist report #	
	FDA Use Onl

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
	or DOB:	[ ] female [ ] male	lbs 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 03/24/2000

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 TOPROL XL (METOPROLOL SUCCINATE)
#

2. Dose, frequency & route
#3 50 MG QAM PO
#

3. Therapy dates(if unk, give dur)
#3 2/15/2000 - 2/20/2000 (STOP'D)
#

4. Diagnosis for use (indication)
#3 HYPERTENSION
#

5. Event abated after use stopped or dose reduced
#3 [ ]yes [ ]no [X]N/A
[ ]yes [ ]no [ ]N/A

6. Lot # (if known)
#3 UNKNOWN
#

7. Exp. Date
#3
#

8. Event reappeared after reintroduction
#3 [ ]yes [ ]no [X]N/A
[ ]yes [ ]no [ ]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.
100 Connecticut Ave.
Norwalk, CT 06850-3590

2. Phone number
(203) 854-7280

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#
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
[ ]init [ ]follow-up #

8. Adverse event term(s)

9. Mfr. report number
200146

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?
[ ] yes [ ] no

3. Occupation

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

MED INFO ASSOC
Facsimile
Form 3500A

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3500A Continuation Page

C10. CONCOMITANT MEDICAL PRODUCTS (continued)

FERROUS SULFATE, LASIX (FUROSEMIDE)

FDA REPORT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Purdue Pharma L.P.

Page 1 of 1

FDA Approved 11/08/93

S115

Mfr report #	200196
UF/Dist report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
u/1	or DOB:	[ ] female [X] male	lbs or 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:

3. Date of event	4. Date of this Rept 04/24/2000

Describe event or problem

male patient, with a history of AIDS, lymphoma, brain tumor, cancer spreading to the lungs and pancreas, toxoplasmosis to the brain, emphysema and other (unidentified) complications, died on an unspecified date of respiratory depression while taking Oxycontin (controlled-release oxycodone hydrochloride) 80 mg four times a day. This case was reported as follows: "Physician reports that he gave an AIDS patient 80 mg of Oxycontin four times a day and he went into respiratory depression and died. The patient was started on 40 mg of Oxycontin twice a day and did well. When the pain increased he was given 80 mg three times a day, then increased to 80 mg Oxycontin four times a day, and that is when there was a code blue." This case was reported via telephone by a physician. Several attempts to contact the reporter/physician for additional information have been unsuccessful.

6. Relevant tests/laboratory data, including dates

Relevant Tests and Laboratory Data: CD4 count of 12, viral load of 100,000.

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

AIDS, lymphoma, brain tumor, cancer spreading to the lungs and pancreas, toxoplasmosis to the brain, emphysema and other (unidentified) complications.

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	3. Therapy dates (if unk, give dur)
#1 40 MG BID PO #	#1 UNKNOWN (STOP'D) #

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

6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction
#1 UNKNOWN #	#1 #	#1 [ ]yes [ ]no [X]N/A # [ ]yes [ ]no [ ]N/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.
100 Connecticut Ave.
Norwalk, CT 06850-3590

2. Phone number (203) 854-7280

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

4. Date Rec'd by Mfr. 04/18/2000

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ]yes
OTC [ ]yes
product

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]5-day [X]15-day
[ ]10-day [ ]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)
HYPOVENTIL

9. Mfr. report number
200196

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

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

FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

Mfr report # 2010668

UF/Dist report #

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier REDACTED
2. Age at time of event: YEARS or DOB:
3. Sex: [X] female [ ] male
4. Weight: lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[X] death 5/9/1998 (mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 5/9/1998
4. Date of this Rept 05/24/2001

5. Describe event or problem

A 41 year old female with a history of chronic low back pain, died on May 9, 1998 while taking OxyContin (controlled-release oxycodone hydrochloride). This case was reported by a physician in the United States of America via Purdue's Individual Patient Assistance Program (IPAP). Additional information is being requested.
***Additional information received on 29MAR01 from the prescribing physician indicated that the patient presumably died on 09MAY98 from a cerebrovascular accident. The physician determined the event was possibly related to OxyContin therapy.

6. Relevant tests/laboratory data, including dates

Relevant Tests/Lab Data: Unknown

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

Chronic low back pain

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, 40 mg (oxycodone hydrochloride)

2. Dose, frequency & route
#1 80 MG TID PO
#2 MG PO

3. Therapy dates (if unk, give dur)
#1 4/22/1998 - 5/9/1998
#2 7/30/1997 - 5/9/1998

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 [X]N/A
#2 [ ]yes [ ]no [X]N/A

6. Lot # (if known)
#1
#2

7. Exp. Date
#1
#2

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

9. NDC # for prod problems only
- -

10. Concomitant medical products and therapy dates
CIPROFLOXACIN, CARDURA (DOXAZOSIN), DOCUSATE SODIUM, PHYTONADIONE, SPIRONOLACTONE, NAPROXEN

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)
[ ] foreign
[X] study
[ ] literature
[ ] consumer
[X] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[ ] other:

4. Date Rec'd by Mfr.
05/14/1998

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ]yes
OTC product [ ]yes

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]5-day [X]15-day
[ ]10-day [ ]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)
CEREBROVASC ACCID
REACT AGGRAV

9. Mfr. report number
2010668

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?
[X] yes [ ] no

3. Occupation
PHYSICIAN

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [X]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.

8003042545

Produced by Purdue to the Office of the Attorney General - State of Connecticut

15-DAY ALERT REPORT

MEDWATCH

Purdue Pharma L.P.

FDA Approved 11/08/93

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

Mfr report #	2013754
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
REDACTED	50 YEARS DOB:	[X] female [ ] male	lbs or 90.7 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[X] death 7/30/2001 (mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 7/30/2001

4. Date of this Rept 08/09/2001

5. Describe event or problem

A 50-year-old female patient became unresponsive and died on 30JUL01 while taking OxyContin (controlled-release oxycodone hydrochloride) for post-operative pain. The case was reported as follows: "49 yr [female] had foot surgery on [27JUL01] under general anesthesia. She experienced hypotension in recovery (systolic Bp [blood pressure] 70 mmHg) and was successfully treated with ephedrine. She received a prescription for OxyContin 20 mg 1-11 [1-2] tablets PO BID and 1 [tablet] PO q6h prn [for] breakthrough pain. This morning (30JUL01) she was unresponsive. Her husband called the EMS [Emergency Medical Service]. She awoke and refused to go to the hospital. After they left she became unresponsive again. Her husband convinced her to go to the hospital. He drove her there; in route she became unresponsive and was pronounced dead in the Emergency Dept. An autopsy will be performed." The case was reported on 30JUL0 by a physician [Doctor of Podiatric Medicine] in the United States of America. Additional information is being requested.

6. Relevant tests/laboratory data, including dates

Relevant Tests and Lab Data:
*(Unknown date): Negative Chest x-ray (unconfirmed).

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

History of back problems and stomach ulcers. No cardiac history. Negative chest-xray. Status-post foot surgery 27JUL01.

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 SEE TEXT PO
#

3. Therapy dates (if unk, give dur)
#1 7/27/2001
#

4. Diagnosis for use (indication)
#1 POST-OPERATIVE PAIN
#

5. Event abated after use stopped or dose reduced
#1 [ ]yes [ ]no [X]N/A
[ ]yes [ ]no [ ]N/A

6. Lot # (if known)
#1 UNKNOWN
#

7. Exp. Date
#1
#

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

9. NDC # for prod problems only

10. Concomitant medical products and therapy dates
ELAVIL (AMITRIPTYLLINE), PEPCID (FAMOTIDINE) (from 1991)

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)
[ ] foreign
[ ] study
[ ] literature
[ ] consumer
[X] health professional
[ ] user facility
[X] company representative
[ ] distributor
[ ] other:

4. Date Rec'd by Mfr.
07/30/2001

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ]yes
OTC product [ ]yes

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]15-day [X]15-day
[ ]10-day [ ]periodic
[X]Init [ ]follow-up #

8. Adverse event term(s)
DEATH

9. Mfr. report number
2013754

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?
[X] yes [ ] no

3. Occupation
PODIATRIST

4. Initial reporter also sent report to FDA
[ ]yes [ ]no [X]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.

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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Purdue Pharma L.P.

Page 1 of 3

11222

FDA Approved 11/08/93

Mfr report #	2014480
UF/Dist report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
REDACTED	49 YEARS or DOB: REDACTED	[X] female [ ] male	lbs or 52 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[X] death 8/22/2001 (mo/day/yy)
[ ] life-threatening
[ ] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm damage
[ ] other:

3. Date of event 8/22/2000

4. Date of this Rept 01/14/2002

5. Describe event or problem

A 50-year-old female died on 22AUG01 from "probable combined effects of coronary atherosclerosis and medication excess" while taking OxyContin (controlled-release oxycodone hydrochloride), butalbital, diphenhydramine, sertraline and tramadol. The case was reported as follows: "50-year-old female (61", 52 kg) with a history of lupus and constant pain was found unresponsive in bed. Prescription medications on the nightstand included (OxyContin), tramadol, butalbital, temazepam, diazepam, sertraline, and paroxetine." Reportedly, OxyContin was prescribed on 26JUN00 at a dose of "40-mg 2-3 tabs Q 8hrs" on 24JUL00 at a dose of "40-mg 2-3 tabs Q 8 hrs" on 21AUG00 "40-mg 2-3 tabs Q 8 hrs." The toxicology report revealed that the heart blood was positive for oxycodone (1.9 mg/L), butalbital (9.8 mg/L), diphenhydramine (0.28 mg/L), sertraline (0.47 mg/L), norsertraline (1.0 mg/L) and tramadol (0.08 mg/L). Oxycodone was present in the femoral blood (0.66 mg/L), the liver (1.9 mg/L), the urine (8.8 mg/L) and the bile (3.6 mg/L). Reportedly, 28 40-mg tablets were recovered from the duodenum. The manner of death was listed as accidental. This case was received on 03OCT01 from a Coroner's Office in the United States of America.
***Follow up information received on 07JAN02 from the presiding Coroner's Office revealed a Caucasian 50-year-old female died from the probable combined effects of coronary atherosclerosis and medication excess with the significant condition of myocardial fibrosis. The decedent also had a history of hypertension, digestive problems, and poor
(CONTINUED)

6. Relevant tests/laboratory data, including dates

Relevant Tests and Laboratory Data: See text.

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

History of lupus and constant pain, heavy smoker and drinker, hypertension, digestive problems, poor ciruculation, possible non-compliance with Ultram (tramadol).

C. SUSPECT MEDICATION(S)

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

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

2. Dose, frequency & route
#1 40 MG SEE TEXT PO
#2 UNKNOWN

3. Therapy dates(if unk, give dur)
#1 6/26/2000 - 8/22/2001
#2 UNKNOWN

4. Diagnosis for use (indication)
#1 UNKNOWN
#2 UNKNOWN

5. Event abated after use stopped or dose reduced
#1 [ ]yes [ ]no [X]N/A
#2 [ ]yes [ ]no [X]N/A

6. Lot # (if known)
#1 UNKNOWN
#2 UNKNOWN

7. Exp. Date
#1
#2

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

9. NDC # for prod problems only

10. Concomitant medical products and therapy dates
NORCO (HYDROCODONE/APAP), SKELAXIN, TEMAZEPAM, DIAZEPAM, VASOTEC (ENALAPRIL), MEDROXYPROGESTERONE ACET, NORVASC (AMLODIPINE), ESTRATEST (ESTRADIOL), IBUPROFEN

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)
[ ] foreign
[ ] study
[ ] literature
[ ] consumer
[X] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[X] other:
MEDICAL EXAMINER

4. Date Rec'd by Mfr. 01/07/2002

5. (A)NDA# 20-553
IND#
PLA#
pre-1938 [ ]yes
OTC [ ]yes
product

6. If IND, protocol #

7. Type of report (check all that apply)
[ ]5-day [X]15-day
[ ]10-day [ ]periodic
[ ]Init [X]follow-up # 1

8. Adverse event term(s)
CORONARY ART DIS
OVERDOSE ACCID
FIBRO MYOCARD

9. Mfr. report number 2014480

E. INITIAL REPORTER

1. Name, address & phone #
REDACTED

2. Health professional?
[X] yes [ ] no

3. Occupation
MEDICAL EXAMINER

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

MED INFO ASSOC

facsimile form 3500A

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FDA Approved 11/08/93

MEDWATCH

Purdue Pharma L.P.

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr report #	2014480
UF/Dist report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
	or DOB:	[ ] female [ ] male	lbs 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 01/14/2002

5. Describe event or problem

circulation. She was a heavy smoker and drinker. Her common law husband found her unresponsive in bed. The rescue squad was phoned and she was pronounced dead. The autopsy revealed coronary atherosclerosis, intake of oxycodone, butalbital, sertraline, diphenhydramine, and hepatomegaly. The qualitative and quantitative bile toxicology report was positive for oxycodone 3.6 mcg/mL, the femoral blood was positive for oxycodone 0.66 mcg/mL, the heart blood was positive for butalbital 9.8 mcg/mL, diphenhydramine 0.28 mcg/mL, norsertraline 1.0 mcg/mL, sertraline 0.47 mcg/mL, oxycodone 1.9 mcg/mL, and tramadol 0.08 mcg/mL. The liver was positive for oxycodone 1.9 mcg/g, the stomach content was positive for oxycodone 28 mg, and the urine was positive for oxycodone 8.8 mcg/mL (units differ from previous report). The "pill" from the duodenum was labeled "OC 40" = OxyContin and oxycodone was found present. No ethanol was detected in the blood. The manner of death was accidental.

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) (CONT)

#3 DIPHENHYDRAMINE HCL
#4 ZOLOFT (SERTRALINE HCL)

2. Dose, frequency & route
#3 UNKNOWN
#4 150 MG QD

3. Therapy dates (if unk, give dur)
#3 UNKNOWN
#4 UNKNOWN

4. Diagnosis for use (indication)
#3 UNKNOWN
#4 UNKNOWN

5. Event abated after use stopped or dose reduced
#3 [ ]yes [ ]no [X]N/A
#4 [ ]yes [ ]no [X]N/A

6. Lot # (if known)
#3 UNKNOWN
#4 UNKNOWN

7. Exp. Date
#3
#4

8. Event reappeared after reintroduction
#3 [ ]yes [ ]no [X]N/A
#4 [ ]yes [ ]no [X]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

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#
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
[ ]Init [ ]follow-up #

8. Adverse event term(s)

9. Mfr. report number 2014480

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?
[ ] yes [ ] no

3. Occupation

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

MED INFO ASSOC
Facsimile Form 3500A

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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Purdue Pharma L.P.

Mfr report #	2014480
UF/Dist report #	
FDA Use Only	

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
	or DOB:	[ ] female [ ] male	lbs 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 01/14/2002

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)
#5 ULTRAM (TRAMADOL)
#

2. Dose, frequency & route
#5 50 MG Q4-6H PO
#

3. Therapy dates(if unk, give dur)
#5 UNKNOWN
#

4. Diagnosis for use (indication)
#5 UNKNOWN
#

5. Event abated after use stopped or dose reduced
#5 [ ]yes [ ]no [X]N/A
[ ]yes [ ]no [ ]N/A

6. Lot # (if known)
#5 UNKNOWN
#

7. Exp. Date
#5
#

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

9. NDC # for prod problems only
- -

10. Concomitant medical products and therapy dates

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

4. Date Rec'd by Mfr.

5. (A)NDA#
IND#
PLA#
pre-1938 [ ]yes
OTC [ ]yes
product

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)

9. Mfr. report number
2014480

E. INITIAL REPORTER

1. Name, address & phone #

2. Health professional?
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3. Occupation

4. Initial reporter also sent report to FDA
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