

B

APPENDIX B

Non-fatal Adverse Events where OxyContin was Suspect (OxyContin prescribed q8h or more frequently)

No.	Age	Sex	Outcome	Adverse Event
1.	33	F	Hospitalization	Grand Mal Seizure
2.	42	F	Hospitalization	Nausea/Vomiting
3.	58	M	ND	Dysuria
4.	61	M	ND	Abdominal pain, somnolence
5.	50	F	ND	Withdrawal symptoms
6.	43	F	Intervention	Edema/urinary retention
7.	47	M	ND	Abdominal pain
8.	73	F	ND	Alopecia
9.	38	F	ND	Dizziness
10.	41	F	Hospitalization	Acute Pancreatitis
11.	59	F	Hospitalization	Myclonis/hypercapnia
12.	ND	F	Other: Med. Sig.	Prothrombin decreased
13.	42	F	Hospitalization	Drug dependence
14.	ND	F	Hospitalization	Hallucinations
15.	42	M	Hospitalization	Dizziness/muscle weakness
16.	40	F	Hospitalization	Drug dependence
17.	45	M	Other: Med. Sig.	Drug dependence/depression
18.	48	M	Other: Med. Sig.	Drug abuse/dyspepsia
19.	34	M	ND	Confusion/paranoia
20.	68	F	Hospitalization	Somnolence/sedation
21.	ND	M	Other: Med. Sig.	Drug dependence/somnolence
22.	53	F	Other: Med. Sig.	Drug dependence
23.	40	M	Other: Med. Sig.	Convulsions/paraesthesia
24.	41	F	Hospitalization	Drug dependence
25.	31	M	Other: Med. Sig.	Drug dependence
26.	50	M	ND	Hiccups
27.	32	F	ND	Nausea
28.	52	F	Hospitalization	Somnolence/asthenia
29.	43	F	ND	Volvulus/constipation
30.	45	F	ND	Abdominal pain/dizziness
31.	ND	F	Other: Med. Sig.	Abortion (involuntary)
32.	63	M	ND	Edema
33.	36	M	ND	Abdominal pain/nausea
34.	45	F	ND	Extreme constipation
35.	38	F	ND	Hypoglycemic Reac./confusion
36.	33	M	Other: Med. Sig.	Drug dependence

No.	Age	Sex	Outcome	Adverse Event
37.	46	M	ND	Nervousness/insomnia
38.	34	F	ND	Constipation
39.	48	F	ND	Urinary retention
40.	40	M	ND	Severe sweating
41.	ND	M	ND	Pruritus/urticaria
42.	38	M	Other: Med. Sig.	Drug dependence
43.	41	M	ND	Decreased libido
44.	45	M	ND	Dizziness/chest pain
45.	45	M	ND	Nausea/vomiting
46.	48	M	ND	Agitation/neurosis
47.	58	M	ND	CNS stimulation
48.	43	F	Other: Med. Sig.	Anaphylactoid reaction
49.	67	F	Hospitalization	Colitis/ileus/abd.pain
50.	46	F	ND	Withdrawal symptoms
51.	ND	M	Life-threatening	Drug interaction/coma
52.	42	F	Hospitalization	Obstructed intestine/nausea

ND = No Data

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INDEX

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3. FDA Talk Paper, July 25, 2001 (not included – FDA document).
4. OxyContin Package Insert.
5. “Understanding Addiction.”
6. FDA Consumer, September-October 2001 Issue. (not included – FDA Document).
7. “OxyContin: Its Use and Abuse” Friedman Testimony before House Energy/Commerce Investigative Subcommittee. (excerpt included – document available at <http://energycommerce.house.gov/107/hearings/08282001hearing.>)
8. Journal of Managed Care Pharmacy (May/June 2003.)
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10. “The Clinical Impact of Adverse Event Reporting,” Center for Drug Evaluation and Research. (FDA October, 1996) (not included – FDA Document)
11. MEDWATCH AERS Database (not included – available through AERS Database).*
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29. “Aggressive Pharmacological Treatment of Pain,” Pain Management in the Rheumatic Diseases (February 1999).
30. “Considerations for Acute Pain Management in Ambulatory Orthopedic Surgery,” Orthopedic Special Edition (2000).
31. “New Strategies In Opioid Therapy for Cancer Pain” The Journal of Oncology Management. (Jan/Feb 2000).
32. “Opioid Formulations: Tailoring to the Needs of Chronic Pain,” Reder Article.
33. 2003 OxyContin Budget Plan.

34. PPLP "Incentive Bonus Program."
35. PPLP OxyContin "Risk Management Program."
36. Internal PPLP Dosing Frequency Schedules.
37. PPLP Internal Document "Reviewing the Science of q12h." (Bates #003105).
38. PPLP Internal Document "Q12h vs. Q8h Warfare."
39. PPLP Internal Document "Q12H versus Q8H."
40. Form 3500A Adverse Event reporting forms supporting Appendix A.
41. Form 3500A Adverse Event reporting forms supporting Appendix B.
42. Submission of Documents and Communications from PPLP (Black notebook).

* The reports are not included at this time due to the voluminous number of Form 3500A Adverse Event reporting forms reviewed by this office as part of its analysis. Please contact Assistant Attorney General Michael E. Cole at (860) 808-5040 to arrange for delivery of these documents.