

A. Patient information

1. Patient identifier 01120399 In confidence	2. Age at time of event: 26 yrs or Date of birth: [REDACTED]	3. Sex (X) female () male	4. Weight 52 lbs or kgs
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B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

() death (m/d/y)	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	() required intervention to prevent permanent impairment/damage
() other:	

3. Date of event (m/day/yr) 12/16/94

4. Date of this report (m/day/yr) 04/02/99

5. Describe event or problem

Notification via litigation of case summaries provided by MD/co-author of literature report (N Engl J Med 1997;337:1112-7). Info provided based on extracted data from med recs of pts hosp for acetaminophen ingestion b/t 1/1/92 & 4/30/95. According to extracted data, a 26 yo F w/hx regular ETOH use took 15 x 325 mg TYLENOL® x 3 wks (not more than 4 g/24 hrs) for toothache. Addl info rec'd 3/29/99: Med rec indicates pt took TYLENOL/TYLENOL #3 for wisdom tooth pain, & has been self-medicating w/approx 10-15 325 mg tablets daily x3 wks. Subacute ingestion of large doses acetaminophen (4.8 g=80 mg/kg/d x several wks). Last TYLENOL ingestion approx 8 d PTA. Pt experienced 3d PTA generalized fatigue (ASTHENIA), imbalance(DIZZINESS), NAUSEA & VOMITING, ANOREXIA, dark urine (URINE ABNORMAL). Two d PTA pt developed RUQ tenderness (ABDOMINAL PAIN), drowsiness(SOMNOLENCE). Pt admitted to hosp on 12/16/94. Pt rec'd full course MUCOMYST. Pt's Hep BSag=(+). Pt improved, LFT's decreased & PT normalized. Pt d/c'd on 12/19/94. Principal dx: hepatitis. Other morbid(See sec C10)

6. Relevant tests/laboratory data, including dates

12/16/94: H/H=11.7/35.4, NA=138, K=4.4, CL=102, CO2=28, Gluc=72, SCr=0.6, Urea=7, AST=2978, AP=266, T Bili= 5.5, ALB=3.6, AML=159, ALT=2672, globulin=3.7, A/G ratio= 1.0, urine HCG=(-), ETOH=(-), HBSAG=(+), a-HAV=(-), a-HIV1=(-), (See Sec 87)

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

s/p tubal ligation, no hx liver disease, hx occasional ETOH use (last intake 12 d PTA: less than 2 mixed drinks); (Sec B6 cont): APAP level less than 1, PT=13.6, PTT=38.1, echogram compl srvy abd imp: liver normal in size but demonstrates prominence & increase in echogenicity of the peripheral portal branches; 12/19/94 AST=1055, AP=178, (See sec C10)

C. Suspect medication(s)

1. Name (give labeled strength if known)

#1 Regular Strength TYLENOL Product

#2 TYLENOL #3

2. Dose, frequency & route used

#1 10-15 x 325 mg x 3 weeks

#2 unknown

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown-12/8/94; approx 3 wk

#2 unknown

4. Diagnosis for use (indication)

#1 toothache

#2 broken wisdom toothh 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 Unknown

#2 unknown

7. Exp. date (if known)

#1 Unknown

#2 unknown

8. Event reappeared after reintroduction

#1 () Yes () No (X) N/A

#2 () Yes () No (X) N/A

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

10. Concomitant medical products and therapy dates (exclude treatment of event) none; Sec B5 cont: conditions &/or complications listed as chronic Tylenol toxicity, hepatitis B infection; (Sec 87 cont) T Bili=3.1, ALB=3.1, ALT=1491, PT=12.8, PTT=40.6

G. All manufacturers

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

McNeil Consumer Healthcare
 Medical Affairs
 7050 Camp Hill Rd
 Ft. Washington, PA 19034

2. Phone number
215-273-7820

3. Report source (check all that apply)

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

4. Date received by manufacturer (ADVERSE EVENT REPORTING SYSTEM)

(A) NDA # 17-552
 IND #
 PLA #
 pre-1938 () Yes
 OTC product (X) Yes

5. Adverse event term(s)

ASTHENIA PAIN ABDOMINAL
 NAUSEA VOMIT ANOREXIA
 URINE ABNORMAL PAIN ABDOMINAL
 SOMNOLENCE

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

9. Mfr. report number
0905685A

E. Initial reporter

1. Name, address & phone #

[REDACTED] MD
 [REDACTED] Medical Ctr
 [REDACTED]

2. Health professional?
(X) Yes () No

3. Occupation
physician

4. Initial reporter also sent report to FDA
() Yes () No (X) Unk