



Mfr report # A0141275A
UF/Dist report #
FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Patient information

1. Patient identifier
2. Age at time of event: 43Y
3. Sex: [X] male
4. Weight (lb): 174.9
Date of birth: 08Mar1956

B. Adverse event or product problem

1. [X] Adverse event and/or [] Product problem
2. Outcomes attributed to adverse event: [X] death 21Feb2000
3. Date of event: 18Feb2000
4. Date of this report: 16Aug2001

5. Describe event or problem
A lawyer reported that a 43 year old Asian American male physician (internist) with a history of hepatitis A received inhaled zanamivir (Relenza) for flu-like symptoms. The lawyer reported that the patient received zanamivir therapy a few days preceding hospitalization for acute illness. Medical records later received from the lawyer provided additional case details related to the patient's hospital course and autopsy findings. The patient was noted to have ingested no new foods, had not traveled and had not had contact with sick persons. Approximately four days prior to admission, the patient developed fevers as high as 103 degrees Fahrenheit (spiking every three hours), explosive and watery diarrhea and a flu-like prodrome (including myalgias, arthralgias, and fever with chills). The day prior, he had right upper quadrant pain with coffee-ground emesis. On triage in the emergency room, he was noted to have a "several day" history of abdominal pain, coffee-ground emesis (two to three episodes continued on next page

6. Relevant tests/laboratory data, including dates
Feb2000:
Esophagogastroduodenoscopy (EGD): normal.
18Feb2000:
EGD: hiatal hernia, gastritis with shallow ulcerations.
Initial chest X-ray normal with 11pm chest x-ray displaying pulmonary edema.
Acetaminophen: 8 (5-20 ug/ml)
White blood cells of 4900 with 90 polys and continued on next page

7. Other relevant history, including preexisting medical conditions (eg. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
No history of alcohol or tobacco use.
History of aspirin and Motrin (ibuprofen) allergy (results in hives).
Seasonal allergies.
No history of rheumatological diseases.
Purified protein derivative negative. DSS

AUG 21 2001

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Relenza Rotadisk (Zanamivir)
#2 Paracetamol (formulation unknown) (Acetaminophen)
2. Dose / frequency / route used
#1 UNK / Inhaled
#2 Eight times per day / Oral
3. Therapy dates
#1 Feb00 - Unknown
#2 Days
4. Diagnosis for use (indication)
#1 Influenza-like illness
#2 Hypoalgesia
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) #1 None #2 None
7. Exp. date (if known) #1 #2
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)
Cetirizine hydrochloride UNK

G. All manufacturers

1. Contact office - name/address
GlaxoSmithKline
Global Clinical Safety
PO Box 13398
Research Triangle Park
NC 27709
2. Phone number
1-888-825-5249
ext. 37070
3. Report source
[] foreign
[] study
[] literature
[] consumer
[X] health professional
[] user facility
[] company representative
[] distributor
[] other:
4. Date received by manufacturer
02Aug2001
5. (A)NDA # 21-036
IND #
ELA #
pre-1938 [] yes
OTC product [] yes
6. If IND, protocol #
7. Type of report
[] 5-day [X] 15-day
[] 10-day [] periodic
[] Initial [X] follow-up # 2
8. Adverse event term(s)
Eosinophilic myocarditis
Allergy to drug
Adult resp. distress synd.
Acute illness
Deterioration: condition
continued on next page
9. Mfr. report number
A0141275A

E. Initial Reporter

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



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3781214-0-00-02

SmithKline

Approved by the FDA on 3Nov93

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| MDR report # | A0141275A |
| UFDist report # | |
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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

(Page 2 of 8)

5. Describe event or problem (cont'd)

on the day of admission) fever and chills. For that time, he had taken one gram of acetaminophen every 3 to 4 hours for analgesia. In the emergency room, he received treatment for continued flu-like symptoms with fever with meperidine (Demerol), famotidine (Pepcid), ampicillin/sulbactam (Unasyn), prochlorperazine (Compazine), vancomycin and ceftazidime. Furthermore, he received a liter bolus of fluids followed by two liters while in the ER. On physical examination, the patient was noted to be acutely ill. He had a few rhonchi on the left and right side, but had no wheezing, retractions or cyanosis. His abdomen was tender on palpation of the left upper quadrant with guarding and no rebound. The physician was unable to palpate the liver or spleen below the costal margin. Bowel sounds were decreased, but present. He had no bruises, petechiae or ecchymosis. The patient denied any blood in stools or dark tarry stools. An esophagogastroduodenoscopy (EGD) with biopsy gastritis noted in the fundus with very shallow ulcerations. At that time, the patient reported a week history of left upper quadrant pain with nausea and vomiting. Pylorus biopsy results found mild chronic gastritis with a negative helicobacter stain. While in the ER, he was noted to have a urinary tract infection. However, urine cultures yielded no growth after forty-eight hours. A chest X-ray was performed due to shortness of breath and showed mild changes of congestive failure with normal heart size suggesting non-cardiac edema. Also, a small right pleural effusion was present and bilateral calcified hilar lymph nodes and small calcified granulomas of the central lung fields. The patient was admitted to the medical floor on telemetry and initially appeared to be stable. Over the night, his condition deteriorated. His temperature rose to as high as 104.9 degrees Fahrenheit requiring cooling blankets and he complained of generalized body pain. He was subsequently transferred to the intensive care unit. A positive D-dimer test was found and the patient appeared to have disseminated intravascular coagulation (DIC). Approximately seven hours later, a repeat X-ray (performed due to cough) showed diffuse severe changes of pulmonary edema and bilateral infiltrates with normal heart size. A prominent assiduous vein was found. The changes suggested ARDS and possible biventricular changes. On four liters of oxygen, the patient had a blood pH of 7.45 with partial pressure of carbon dioxide of 26 and oxygen of 61. Three units of fresh frozen plasma were to be infused en route to another hospital. He was transferred to another medical center with the following discharge diagnoses: disseminated intravascular coagulation, probable septicemia, mild upper gastrointestinal bleed secondary to gastritis, protracted nausea and vomiting for one week and status-post appendectomy (remote). He was transferred on normal saline with potassium, vancomycin Unasyn, meperidine, prochlorperazine and famotidine.

The patient was admitted to the hospital with unabating hyperthermia, nausea, vomiting, diarrhea and respiratory distress with new patchy infiltrates on chest X-ray. On admission, his vital signs included temperature of 103.6 degrees Fahrenheit, pulse rate 136, blood pressure 120/68, respirations 28 per minute, and an oxygen saturation of 96% on two liters of oxygen. Lungs had diffuse crackles. He had mild, diffuse tenderness around his belly with some mottling and hyperemia of the abdominal wall. Extremity exam revealed negative capillary refill with mottling. No skin rashes, muscular/joint swelling or pain or urinary tract infection symptoms were noted, but right upper quadrant abdominal pain and chronic dry cough were present. Initially, sepsis was suspected. Treatment included ciprofloxacin, azithromycin and piperacillin/tazobactam (Zosyn). Further treatment included omeprazole (Prilosec) and hemodynamic support (for dropping platelet count). While hospitalized, he received albuterol (per nebulizer and metered dose inhaler) and ipatropium (Atrovent) (per metered dose inhaler) for shortness of breath and wheezing. Chest X-rays were consistent with early adult respiratory distress syndrome (ARDS) with patchy bilateral infiltrates. He had diffuse airway disease which was increased in the bases, but clearing toward the apices. Arterial blood gases showed an oxygen saturation rate of 90% on two liters of oxygen. Abdominal X-ray series noted air filled loops of the small and large bowel which were nondistended and consistent with ileus. Upon evaluation by a pulmonologist, the patient had had a productive cough with white mucoid sputum and had shortness of breath since admission. The pulmonologist also noted one episode of confusion earlier on the day of admission, but at the time of evaluation the patient had no focal central nervous system symptoms (but oriented to place, person and partially to time) with headache, dry mouth, dysuria, and mild respiratory distress (respiratory rate of 28 with 96% oxygenation on 2 liters). A viral

continued on next page

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3781214-0-00-03

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New report # A0141275A

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(Page 3 of 8)

B5. Describe event or problem (cont'd)

syndrome was suspected with possible infection from unknown source. His condition progressed rapidly to ARDS with an inability to oxygenate and hypovolemic shock with hypotension. With volume resuscitation (crystalloids), the patient had difficulty oxygenating and was intubated. In the intensive care unit, suspected diagnoses included ARDS secondary to infection, septic syndrome of unknown etiology (viral, legionella, and pneumococcal suspected), gastrointestinal infection (enteropathogen, clostridium difficile), intravascular volume depletion secondary to leaky capillary syndrome due to systemic inflammatory response to infection, and depressed cardiac index secondary to volume depletion and sepsis. His white blood cell count remained at 4,700. Echocardiogram noted hypokinesis of the left ventricle, small right ventricle, but no decrease in left ventricular end systolic volume index. Later that day, the patient's X-ray showed full blown ARDS. He was unable to oxygenate on 100% oxygen, with paralysis and nitric oxide therapy oxygenation (ECMO) with right venoarterial ECMO which was tolerated well, but had no improvement in symptomatology (hospital day two). Clostridium difficile assay was negative. He developed lactic acidosis (lactate as high as 6) which was initially thought to be due to washout of his lower extremities. The patient's condition continued to decline clinically requiring bicarbonate for acidosis and fluid boluses to maintain adequate flow. He developed cardiorespiratory collapse and his renal function deteriorated to acute renal failure which subsequently required dialysis. Vasopressors (dopamine, dobutamine) and sedation (morphine, midazolam (Versed), vecuronium (Norcuron)) were required. Other medications included the following: calcium gluconate, magnesium sulfate, potassium chloride, potassium phosphate and lorazepam. The following morning, a flexible sigmoidoscopy was normal. EGD noted non-bleeding superficial small gastric ulcers of the gastric body and antrum thought to be indicative of viral syndrome, ischemia and naso-gastric tube trauma. Broad spectrum antibiotics (vancomycin and clindamycin) were initiated with ganciclovir and acyclovir therapy. Also while hospitalized, he received treatment with rifampin and multiple blood transfusions (packed cells and platelets). Due to a distended abdomen, a diagnostic peritoneal lavage was performed and within normal limits. A transthoracic echocardiogram noted no evidence of pericardial tamponade, but a small amount of fluid (anterior effusion). The heart was grossly akinetic. A bilateral tube thoracostomy was performed with 500cc of serosanguineous fluid drained bilaterally. He was diagnosed with ARDS secondary to infection and septic syndrome with multisystem organ failure. His extremities were edematous, mottled and cold with no Doppler signal. He had increasing anasarca and swelling of the lower extremities. Clinical examination by the orthopedic, surgery and vascular team was consistent with compartment syndrome (of all four extremities). The patient underwent bilateral lower extremity fasciotomies in thighs and calves (pressures as high as 100mmHg). Clinical findings were consistent with rigor mortis (ankles were fixed). He had bilateral irreversible muscle ischemia below the knees. Amputation was not performed after consulting with the family. He continued to decompensate with escalating fluid requirements. Subsequently, the patient was no longer volume responsive and flows could not be achieved to five liters. Approximately one hour and forty minutes prior to death, an electrocardiogram noted sinus tachycardia with left axis deviation, nonspecific lateral T-wave abnormalities, inferior infarct and anterior infarct. The patient's condition was deemed irreversible. The family agreed to withdraw care and the patient expired. Autopsy findings noted the cause of death to be acute eosinophilic myocarditis. Other anatomic diagnoses reported were mild diffuse alveolar damage, cerebral edema, massive generalized edema, multiple gastric erosions and recent centrilobular necrosis with macrodroplet fatty change and cholestasis. Autopsy found acute eosinophilic myocarditis with destruction of the ventricular myocardium. Rickettsial serologies were negative and no virus was cultured. Drug related hypersensitivity myocarditis seemed likely which was possibly due to acetaminophen or antiviral medication. Liver changes were possibly due to acetaminophen toxicity. The autopsy reported that "the patient was known to have taken acetaminophen on a regular basis over the course of his illness, together with an antiviral medication".

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3781214-0-00-04

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(Page 4 of 8)

B6. Relevant tests/laboratory data (cont'd)

5 lymphs.

Urinalysis: specific gravity 1.030 (1.003-1.030), pH 6.0 (5.0-8.0), protein greater than 300, nitrates positive, 4 white blood cells, glucose-negative, ketones 15, negative blood, bilirubin small, urobili 0.2, trace leukocytes, trace bacteria. Culture was pending.

Strep A screen: negative

D-dimer titer positive at 1:4 (negative 1:8)

Hepatitis B surface antigen: negative, hepatitis A virus antibody: positive, anti HBc: positive, Hepatitis B surface antibody: 108 miu/ml (>10miu/ml equals immunity), anti-HCV: negative

Blood cultures: no growth at 24 hours, 7 days. Urine: no growth after 48 hours.

While in ER, heart rate ranged from 126 to 152, with respiration rate ranged from 27 to 40, his temperature rose to 104.3.

Chest X-ray: No evidence of pneumothorax, post median sternotomy. Bibasilar atelectasis noted.

19Feb2001: Chest X-ray consistent with early adult respiratory distress syndrome (increase in pulmonary alveolar edema).

While hospitalized: white blood cell count 4,700. First echocardiogram found hypokinesia of the left ventricle. Second noted fluid and gross akinesia.

Flexible sigmoidoscopy normal; EGD noted small gastric ulcers.

Peritoneal lavage: normal.

20Feb2000:

Positive airway pressure: 26/15

Pulmonary capillary wedge pressure: 15

Cardiac output: 18.8

Cardiac index: 9.5

22Feb2000

Autopsy: Microscopic description:

Liver shows marked centrilobular necrosis with hepatocellular fatty change and mild bile tasis. The sinusoids show mild to moderate congestion in some areas.

Lungs show slight congestion and areas with changes consistent with mild diffuse alveolar damage. There was no definite polymorphonuclear leukocyte infiltrate observed. Within the lower lobes, there is a mild to moderate pulmonary edema also noted with congestion.

All sections of the heart showed acute eosinophilic myocarditis throughout. In multiple areas, the heart musculature showed marked destruction with cardiac myocyte necrosis.

Numerous lymphocytes and eosinophils were seen throughout. Occasionally, a large significant infiltrate was observed surrounding the vasculature. Neuro examination of cerebral cortex, cerebellum and spinal cord found no histopathologic abnormality, but a small acute infarct in the tegmentum of the pons was noted.

Blood cultures: no growth

Lung cultures: light growth of sphingomonas paucimobilis. Gram stain showed no organisms, rare polymorphonuclear white blood cells and few red blood cells.

B6. Relevant tests/laboratory data (cont'd)

| Test Date | Name | Result | Low | High |
|-----------|----------------------------|--------------|------|------|
| 18Feb2000 | Temperature | 99Fahrenheit | | |
| 18Feb2000 | Heart rate/ pulse | 120 | | |
| 18Feb2000 | Respiratory rate | 30 | | |
| 18Feb2000 | Blood pressure - Diastolic | 70 | | |
| 18Feb2000 | Partial Pressure of Oxygen | 54mmHg | | 86 |
| 18Feb2000 | Partial pressure of CO2 | 26mmHg | | 35 |
| 18Feb2000 | pH, Serum | 7.44 | 7.37 | 7.43 |
| 18Feb2000 | Blood Pressure - Systolic | 103 | | |
| 18Feb2000 | Bilirubin, total | 1.7mg/dl | 0.1 | 1.2 |
| 18Feb2000 | CO2 | 18mmol/l | 24 | 32 |
| 18Feb2000 | Chloride, serum | 97mmol/l | 95 | 108 |
| 18Feb2000 | Potassium | 3.8mmol/l | 3.6 | 5.2 |

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46. Relevant tests/laboratory data (cont'd)

| | | | | |
|-----------|--------------------------------|--------------|------|------|
| 18Feb2000 | Creatinine, Serum | 1.1mg/dl | 0.2 | 1.0 |
| 18Feb2000 | Urea Nitrogen, Blood | 14mg/dl | 8 | 23 |
| 18Feb2000 | Glucose, Blood (random) | 114mg/dl | 70 | 110 |
| 18Feb2000 | Sodium, Serum | 126mmol/l | 135 | 142 |
| 18Feb2000 | Alanine Transaminase, Serum | 195u/l | 10 | 44 |
| 18Feb2000 | Aspartate Transaminase, Serum | 169u/l | 10 | 34 |
| 18Feb2000 | Monocytes, Blood | 0.1thou/mm3 | 0.2 | 1.0 |
| 18Feb2000 | Lymphocytes, Blood | 4.4% | 24 | 40 |
| 18Feb2000 | Lymphocytes, Blood | 0.2thou/mm3 | 1.0 | 4.6 |
| 18Feb2000 | Neutrophils, Blood | 91% | 40.8 | 65 |
| 18Feb2000 | Neutrophils, Blood | 91% | 40.8 | 65 |
| 18Feb2000 | Neutrophils, Blood | 5.0thou/mm3 | .8 | 9.0 |
| 18Feb2000 | White Blood Cell Count | 5.4thou/mm3 | 4.5 | 11.0 |
| 18Feb2000 | Bilirubin, direct | 0.9mg/dl | 0.0 | 0.3 |
| 18Feb2000 | Alkaline Phosphatase, Serum | 100u/l | 42 | 122 |
| 18Feb2000 | CO2 | 22.7mmol/l | 24 | 32 |
| 18Feb2000 | Chloride, serum | 94mmol/l | 95 | 103 |
| 18Feb2000 | Potassium | 3.6mmol/l | 3.6 | 5.2 |
| 18Feb2000 | Urea Nitrogen, Blood | 12.8mg/dl | 8 | 23 |
| 18Feb2000 | Glucose, Blood (random) | 133mg/dl | 70 | 110 |
| 18Feb2000 | Platelet Count, Blood | 152thou/mm3 | 150 | 500 |
| 18Feb2000 | Red cell distribution width | 12.1% | 11.0 | 14.5 |
| 18Feb2000 | Mean Corpuscular Hb Conc. | 34.0g/dl | 32.0 | 35.0 |
| 18Feb2000 | Mean Corpuscular Haemoglobin | 30.2pg | 25.0 | 32.0 |
| 18Feb2000 | Haematocrit (Packed Cell Vol) | 47.5% | 38 | 49 |
| 18Feb2000 | Haemoglobin | 15.7g/dl | 12.8 | 16.5 |
| 18Feb2000 | Red Blood Cell Count | 5.34mill/mm3 | 4.6 | 6.2 |
| 18Feb2000 | Basophil | 0.6% | 0.0 | 2.0 |
| 18Feb2000 | Basophil | 0.0thou/mm3 | 0.0 | 0.2 |
| 18Feb2000 | Eosinophils, Blood | 0.0% | 0.0 | 5.0 |
| 18Feb2000 | Eosinophils, Blood | 0.0thou/mm3 | 0.0 | 0.5 |
| 18Feb2000 | Monocytes, Blood | 3.1% | 1.0 | 8.0 |
| 18Feb2000 | Monocytes, Blood | 0.2thou/mm3 | 0.2 | 1.0 |
| 18Feb2000 | Partial pressure of CO2 | 26mmHg | 35 | 45 |
| 18Feb2000 | Partial Pressure of Oxygen | 61mmHg | 86 | 100 |
| 18Feb2000 | Bicarbonate | 18.3mEq/l | 23 | 27 |
| 18Feb2000 | Bicarbonate | 18.0mEq/l | 23 | 27 |
| 18Feb2000 | Fibrinogen | 750mg | 175 | 375 |
| 18Feb2000 | Partial Prothrombin Time | 44.0secs | 25.0 | 30.0 |
| 18Feb2000 | Prothrombin Time | 12.1 | 1.5 | 13.5 |
| 18Feb2000 | Albumin, Serum | 3.1g/dl | 3.2 | 4.5 |
| 18Feb2000 | International normalised ratio | 1.11 | | |
| 18Feb2000 | pH, Serum | 7.45 | | |
| 18Feb2000 | Protein, Serum, Total | 5.8g/dl | 7.37 | 7.43 |
| 18Feb2000 | Calcium, Serum | 7.4mg/dl | 6.0 | 8.6 |
| 18Feb2000 | Platelet Count, Blood | 132thou/mm3 | 8.7 | 10.5 |
| 18Feb2000 | Red cell distribution width | 11.5% | 150 | 500 |
| 18Feb2000 | Mean Corpuscular Hb Conc. | 33.1g.dl | 11.0 | 14.5 |
| 18Feb2000 | Mean Corpuscular Hb Conc. | 33.1g.dl | 32.0 | 35.0 |
| 18Feb2000 | Mean Corpuscular Haemoglobin | 29.5pg | 32.0 | 35.0 |
| 18Feb2000 | Mean Corpuscular Volume | 89fl | 25.0 | 32.0 |
| 18Feb2000 | Lymphocytes, Blood | 5.7% | 82 | 98 |
| 18Feb2000 | Lymphocytes, Blood | 0.3thou/mm3 | 24 | 40 |
| 18Feb2000 | Neutrophils, Blood | 90.6% | 1.0 | 4.6 |
| 18Feb2000 | Neutrophils, Blood | 4.4thou/mm3 | 40.8 | 65 |
| 18Feb2000 | Amylase, Serum | 47.9u/l | 2.8 | 9.0 |
| 18Feb2000 | Albumin, Serum | 3.6g/dl | 25 | 100 |
| 18Feb2000 | Protein, Serum, Total | 6.6g/dl | 3.2 | 4.5 |
| 18Feb2000 | Calcium, Serum | 7.8mg/dl | 6.0 | 8.6 |
| | | | 8.7 | 10.5 |

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3781214-0-00-06

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(Page 6 of 8)

56. Relevant tests/laboratory data (cont'd)

| | | | | |
|-----------|--------------------------------|-----------------|------|------|
| 18Feb2000 | Mean Corpuscular Volume | 88.9fl | 82 | 98 |
| 18Feb2000 | Haemoglobin | 16.0g/dl | 12.8 | 16.5 |
| 18Feb2000 | Red Blood Cell Count | 5.29mill/mm3 | 4.6 | 6.2 |
| 18Feb2000 | Basophil | 1.9% | 0.0 | 2.0 |
| 18Feb2000 | Basophil | 0.1thou/mm3 | 0.0 | 0.2 |
| 18Feb2000 | Eosinophils, Blood | 0.0thou/mm3 | 0.0 | 0.5 |
| 18Feb2000 | Eosinophils, Blood | 0.1% | 0.0 | 0.2 |
| 18Feb2000 | Monocytes, Blood | 2.5% | 1.0 | 8.0 |
| 18Feb2000 | International normalised ratio | 1.05 | | |
| 18Feb2000 | Partial Prothrombin Time | 40secs | 25.0 | 30.0 |
| 18Feb2000 | Prothrombin Time | 11.9 | 11.5 | 13.5 |
| 18Feb2000 | Platelet Count, Blood | 132000 | | |
| 18Feb2000 | Haematocrit (Packed Cell Vol) | 47% | 38 | 49 |
| 18Feb2000 | White Blood Cell Count | 4.9thou/mm3 | 4.5 | 11.0 |
| 18Feb2000 | Aspartate Transaminase, Serum | 214u/l | 10 | 34 |
| 18Feb2000 | Alkaline Phosphatase, Serum | 94u/l | 42 | 122 |
| 19Feb2000 | Temperature | 103.4Fahrenheit | | |
| 19Feb2000 | Heart rate/ pulse | 136 | | |
| 19Feb2000 | Blood Pressure - Systolic | 120 | | |
| 19Feb2000 | Blood pressure - Diastolic | 68 | | |
| 19Feb2000 | Respiration rate | 28 | | |
| 19Feb2000 | Oxygen Saturation | 96% 2 liters O2 | | |
| 19Feb2000 | White Blood Cell Count | 4.7 | | |
| 19Feb2000 | Red cell distribution width | 12.6 | | |
| 19Feb2000 | Glucose, Blood (random) | 111 | | |
| 19Feb2000 | Creatinine, Serum | 1.1 | | |
| 19Feb2000 | Urea Nitrogen, Blood | 14 | | |
| 19Feb2000 | Bicarbonate | 17 | | |
| 19Feb2000 | Chloride, serum | 107 | | |
| 19Feb2000 | Potassium | 3.4 | | |
| 19Feb2000 | Sodium, Serum | 128 | | |
| 19Feb2000 | Lactate | 2.2 | | |
| 19Feb2000 | Aspartate Transaminase, Serum | 190 | | |
| 19Feb2000 | Anion gap | 4 | | |
| 19Feb2000 | Fibrin degradation products | 0.25-0.5 | | |
| 19Feb2000 | Fibrinogen | 468 | | |
| 19Feb2000 | Oxygen Saturation | 90% on 2L | | |
| 19Feb2000 | Partial pressure of CO2 | 54 | | |
| 19Feb2000 | Partial Pressure of Oxygen | 24 | | |
| 19Feb2000 | pH, Serum | 7.44 | | |
| 19Feb2000 | Sodium, urine | 15 | | |
| 19Feb2000 | Mean Corpuscular Volume | 82 | | |
| 19Feb2000 | Partial Prothrombin Time | 33 | | |
| 19Feb2000 | International normalised ratio | 1.27 | | |
| 19Feb2000 | Phosphate, serum | 1.5 | | |
| 19Feb2000 | Magnesium, serum | 1.6 | | |
| 19Feb2000 | Bilirubin, total | 1.3 | | |
| 19Feb2000 | Albumin, Serum | 1.9 | | |
| 19Feb2000 | Amylase, Serum | 73 | | |
| 19Feb2000 | Lipase, Serum | 68 | | |
| 19Feb2000 | Alanine Transaminase, Serum | 155 | | |
| 19Feb2000 | Conjugated bilirubin | 0.9 | | |
| 19Feb2000 | Eosinophils, Blood | 0 | | |
| 19Feb2000 | Haematocrit (Packed Cell Vol) | 36.8 | | |
| 19Feb2000 | Band neutrophils (blood) | 28 | | |
| 19Feb2000 | Lymphocytes, Blood | 7 | | |
| 19Feb2000 | Monocytes, Blood | 3 | | |
| 19Feb2000 | Segmented neutrophils | 88 | | |
| 20Feb2000 | Blood Pressure - Systolic | 95 | | |

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3781214-0-00-07

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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

(Page 7 of 8)

B6. Relevant tests/laboratory data (cont'd)

| | | |
|-----------|--------------------------------|-------------|
| 20Feb2000 | Creatinine, Serum | 2.9 |
| 20Feb2000 | Platelet Count, Blood | 41 |
| 20Feb2000 | White Blood Cell Count | 9.2 |
| 20Feb2000 | Haematocrit(Packed Cell Vol) | 38.2 |
| 20Feb2000 | Haemoglobin | 13.5 |
| 20Feb2000 | Lactate | 5.6 |
| 20Feb2000 | Magnesium, serum | 2.0 |
| 20Feb2000 | Phosphate, serum | 3.8 |
| 20Feb2000 | Calcium, Serum | 3.9 |
| 20Feb2000 | Glucose, Blood (random) | 126 |
| 20Feb2000 | Oxygen Saturation | 100% |
| 20Feb2000 | Partial Pressure of Oxygen | 352 |
| 20Feb2000 | Partial pressure of CO2 | 36 |
| 20Feb2000 | pH, Serum | 7.35 |
| 20Feb2000 | Fibrin degradation products | 0.25-0.5 |
| 20Feb2000 | Fibrinogen | 335 |
| 20Feb2000 | Partial Prothrombin Time | 44 |
| 20Feb2000 | International normalised ratio | 1.27 |
| 20Feb2000 | Prothrombin Time | 13.9 |
| 20Feb2000 | Blood pressure - Diastolic | 64 |
| 20Feb2000 | Blood Pressure - Systolic | 73 |
| 20Feb2000 | Heart rate/ pulse | 146 |
| 20Feb2000 | Temperature | 37.4Celsius |
| 20Feb2000 | Urea Nitrogen, Blood | 22 |
| 20Feb2000 | Blood pressure - Diastolic | 68 |
| 20Feb2000 | Potassium | 4.7 |
| 20Feb2000 | Chloride, serum | 108 |
| 20Feb2000 | Bicarbonate | 20 |
| 20Feb2000 | Sodium, Serum | 135 |
| 19Feb2001 | Glucose, Blood (random) | 134 |
| 19Feb2001 | CO2 | 16 |
| 19Feb2001 | Haematocrit(Packed Cell Vol) | 40.6 |
| 19Feb2001 | Platelet Count, Blood | 120 |
| 19Feb2001 | White Blood Cell Count | 5.1 |
| 19Feb2001 | Albumin, Serum | 1.9 |
| 19Feb2001 | Phosphorus | 2.2 |
| 19Feb2001 | ionized calcium | 3.6 |
| 19Feb2001 | Magnesium, serum | 1.6 |
| 19Feb2001 | Urea Nitrogen, Blood | 13 |
| 19Feb2001 | Sodium, Serum | 129 |
| 19Feb2001 | Potassium | 4.1 |
| 19Feb2001 | Chloride, serum | 107 |
| 19Feb2001 | Creatinine, Serum | 1.1 |
| 19Feb2001 | Lactate | 6 |

B7. Other relevant history (cont'd)

| | | | |
|--------------|---------|---------|------------|
| Condition | Started | Ended | Continuing |
| Appendectomy | 1975 | Unknown | Unknown |
| Hepatitis A | Unknown | Unknown | Unknown |
| Allergy | Unknown | Unknown | Unknown |

B8. Adverse event term(s) (cont'd)

- Sepsis
- Fever
- Nausea
- Vomiting
- Diarrhea
- Respiratory distress
- Tachycardia

DSS

continued on next page

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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.

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oSmithKline

Approved by the FDA on 3Nov93

MR report #

A0141275A

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(Page 8 of 8)

G8. Adverse event term(s) (cont'd)

Acute renal failure
 Renal impairment
 Lactic acidosis
 Cardiac hypokinesia
 Possible viral syndrome
 Abdominal tenderness
 Infiltrates
 Decreased oxygen saturation
 Gastric ulcer
 Abdominal distention
 Pericardial effusion
 Possible infection
 Edema of extremities
 Compartmental syndrome
 Alveolar damage
 Cerebral edema
 Generalized edema
 Hepatic necrosis
 Fatty liver
 Cholestasis
 Acute infarct:spinal cord
 Ischemia of limb(s)
 Sinus tachycardia
 Abnormal T wave
 Inferior infarction
 Anterior myocardial infar
 Hypovolemic shock
 Hypotension
 Skin mottling
 Slow capillary refill
 Shortness of breath
 Sneeze
 Paralytic ileus
 Cardiorespiratory arrest
 Cough
 Productive cough
 Headache
 Xerostomia
 Dysuria
 Abdominal pain
 Coffee-ground vomit
 Chills
 Hiatus hernia
 DIC
 Gastritis
 Pleural effusion
 Pulmonary granuloma
 Pain in body
 Upper G.I. hemorrhage
 Poss. urinary tract infec
 Abnormal lab.test values

DSS

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