



PROPULSID MDL II DEATH & INJURY CLAIMS

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WHAT THE RULES SAY AND DON'T SAY

- Death and cardiac arrest claims can be accompanied by a five-page memo plus up to 30 pages of exhibits, but
- “page,” “memo,” and “exhibit” are not defined.
- For other claims it’s a one-page memo with up to five pages of exhibits, but “page,” “memo,” and “exhibit” are again undefined.
- Expert medical reports aren’t allowed, but the rules are silent as to damages experts.

Who gets a claim memo?

- A memo in support of a claim goes to the Special Master, who provides a copies to the medical panel members.
- It does not go to the defense.
- The Special Master decides if documents submitted meet the medical records and claim form requirements.

What you must do vs. what you can do

- If a submission meets the minimum requirements, it goes to the medical panel, but should it be the panel’s job to find the strong points of a case?
- A submission doesn’t have to provide damages calculations, but should it be the special master’s job to guess at economic damages?



ECONOMIC LOSS

Medical expenses	838
Death/funeral expenses	9,557
Income, services, and benefit losses at present value:	
• Past and future lost Follansbee Steel wages to age 65	124,945
• Past and future lost Weirton Steel pension benefits	183,467
• Future lost Social Security benefits	157,881
• Value of past and future lost household services	108,997
Total	\$585,685



TELL YOUR CLIENT'S STORY

Claim 1 of 10 submitted by Hill Toriseva & Williams, Wheeling, West Virginia

In re: Propulsid Product
Liability Litigation,
MDL 1355, U.S.D.C., E.D. La.

Ally Phipps Propulsid Tier 1 claim brochure

Record ID No. 1943

Demographics

Claim type:
infant death.

Age at death:
three months.

Sex: female.

Venue: Arkansas.

Survivors:
mother and
father.

Contents

Sudden cardiac death	1
Autopsy	2
Proof of use	2
Circumstances support arrhythmia	2
Dr. Roden's insights	3
Family faces death	3
Medical history details	4
Economic loss	5
Supporting documents	5

Sudden cardiac death of a baby with congenital prolonged QT follows increase in Propulsid dose

Ally Phipps was a healthy baby born in July 1998 at 41 weeks, weighing 7½ pounds, with Apgar scores of 8 and 9 at one and 5 minutes.

Her physical examination was normal, and she was discharged the next day.

A month after birth, she was admitted to Baxter County (Arkansas) Regional Hospital with a diagnosis of right lung pneumonia. Cardiac rhythm strips from this hospitalization show QTc of .403 in lead II and .461 in lead V5. Some beats showed QTc up to .492.

Following an episode of respiratory distress, she was transferred to Arkansas Children's Hospital (ACH), where gastroesophageal reflux disease was diagnosed. After three days at ACH, she was discharged on prescriptions for Propulsid (1.2 ml four times a day) and Zantac.

Ally's Propulsid dose was increased to 1.5 cc four times a day in mid-October. On November 9, her father heard the sleep alarm go off. He responded immediately, but found her pulseless and not breathing.

The baby's father and grandfather started CPR and called 911. The ambulance run sheet shows that EMS squad

found CPR in progress on its arrival, but the child had no pulse or respirations. She was pale, with dilated, non-reactive pupils. The cardiac monitor showed asystole.

She was cyanotic and severely acidotic on arrival at the hospital emergency department. A code was called. According to the ER record, an agonal cardiac rhythm was obtained in about 15 minutes, and eventually sinus tachycardia was established. An EKG showed .478 QTc in Lead II and .626 in Lead V5.

She was taken by helicopter to Arkansas Children's Hospital and admitted to the pediatric ICU, where blood pressure and ventilator support were continued.

An EEG done the day after admission showed neurological devastation with no brain activity. The next day, her potassium began to rise, and her oxygenation became impaired. Her parents were advised of her hopeless prognosis, and they and agreed to remove ventilator support.

Ally was pronounced dead in her mother's arms at 5:25 pm on November 11, 1998.



Mom held her baby as the nurses disconnected life support equipment. Ally died in her mother's arms.



Mom and Ally

TELL YOUR CLIENT'S STORY

Claim 11 of 11 submitted by Hill Toriseva & Williams, Wheeling, West Virginia

In re: Propulsid Product
Liability Litigation,
MDL 1355, U.S.D.C., E.D. La.

Isaiah Wilson

Record No. 1940

Propulsid Tier 1 claim brochure

Demographics

Claim type:
infant death.

Age at death:
5 months.

Sex: male.

Venue: Florida.

Survivors:
mother and
father.

Contents

Sudden cardiac death	1
Autopsy	1
Propulsid use	2
Dr. Roden's insights	2
Circumstances	
Support arrhythmia	2
Life cut short	3
Losing a child	4
Economic loss	5
Support documents	5

Sudden cardiac death in an infant with diarrhea, probable hypokalemia

Isaiah was born August 12, 1998. His mother, Shalonda, and father, Ray, were young, first-time parents.

The baby was born at 25 weeks gestation, weighing 1.67 pounds, with Apgars of 6/6 at one and five minutes. He was kept at the hospital approximately ten weeks and weighed 5.1 pounds when discharged on November 2, 1998.

On November 9, he was started on Propulsid 1 mg/ml, .6cc four times daily for gastroesophageal reflux. He had bouts of projectile vomiting that sprayed his mother's clothing and hair.

He was ill the day and evening before he died, with vomiting, diarrhea, and sounding congested. His mother had planned to take him to the doctor by bus the next day. She did not have a car of her own.

Isaiah seemed perfectly normal at his 2:00 am feeding on January 30, 1998, but when his mom woke around 7:15 am, the room was strangely quiet. She looked at her baby. His lips and tongue were blue. He was not breathing. She tried to wake him, but he did not respond.

Shalonda screamed, woke Ray, and called 911. He went to a neighbor for help. The neighbor

and mom followed the CPR instructions the 911 operator gave them over the phone. A deputy sheriff, who responded to the 911 call, arrived and took over CPR.

The ambulance run sheet reveals that when the EMTs arrived Isaiah's pupils were fixed and dilated, and he was cyanotic.

Resuscitation attempts continued en route to the hospital, and attempts to revive him were continued for another 15 minutes in the emergency room before he was declared dead.

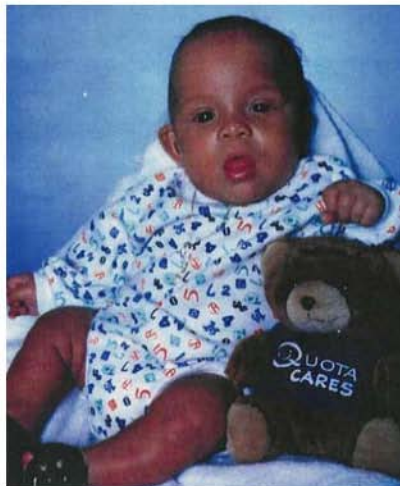
The cause of death given by the emergency room physician was cardiopulmonary arrest.

Autopsy

The medical examiner reports that Isaiah was well developed, well-nourished, and weighed 12 pounds when he died. The death was attributed to Sudden Infant Death Syndrome.

SIDS is not a cause of death, but rather the nomenclature used when an infant less than one year of age dies suddenly and unexpectedly, and the cause of death remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the baby's history.

There is no indication that drug-induced arrhythmia was considered as a possible cause of death



Raymond Isaiah Wilson

TELL YOUR CLIENT'S STORY

Claim 8 of 11 submitted by Hill Toriseva & Williams, Wheeling, West Virginia

In re: Propulsid Product
Liability Litigation,
MDL 1355, U.S.D.C., E.D. La.

Maxine Perry
Propulsid Tier 1 claim brochure

Record ID No. 1945

Demographics

Claim type:
adult death

Age at death: 44

Sex: female

Venue:

West Virginia

Survivors:
husband,
daughter, mother,
2 siblings

Contents

Sudden cardiac death	1
Autopsy	1
Circumstances support arrhythmia	2
Dr. Roden's insights	2
Propulsid use	2
Medical history	3
Family story	3
Economic loss	5
Supporting documents	5

Sudden cardiac death four days after Propulsid increased to double the maximum daily dose.

January 29	Propulsid first prescribed at 10 mg four times a day.
January 30	Dose increased to 20 mg four times a day. <i>Maximum daily dose</i>
February 4	Dose increased to 40 mg four times a day. <i>Double the maximum daily dose</i>
February 8	Cardiac arrest and death at age 44.

Maxine Perry was seen in the emergency department of a West Virginia hospital in November 1996 for atypical chest pain. Serial EKGs, cardiac enzymes, and a Cardiolite stress test were negative. However, telemetry revealed a QTc of .480. She was discharged on Maalox.

A January 1997 upper GI test revealed spontaneous reflux to the level of the upper esophagus. Dr. Cavender, Maxine's primary care physician, diagnosed reflux esophagitis.

Dr. Cavender prescribed Propulsid on January 29, 1997, providing samples and instructing Maxine to take 10 mg four times daily. The following day, Dr. Cavender told Maxine by phone to double her dose to 20 mg four times daily. Dr. Cavender documented this increase on the bottom of a radiology report in Maxine's chart.

Distraught at her unexpected death, Maxine's family requested an autopsy. A limited autopsy of the chest was performed, and found no evidence of a myocardial infarction, only some

four days later, in a second telephone conversation, Dr. Cavender again told Maxine to double the dose, and Maxine did as instructed by taking two 20 mg pills four times a day.

Four days into the redoubled dose, Maxine's husband, Tim Perry, had worked late, and Maxine was asleep when he arrived home at 11:00 pm. Maxine was still sleeping when he turned off the television to go to sleep himself around 1:30 am. He slept on the couch to avoid waking her.

The following morning he made coffee and then went to the bedroom to wake his wife. He found her unconscious in bed. She was in a sitting position with one arm hanging over the side of the bed and the other beneath her.

Tim called 911. The ambulance

revealed atherosclerosis and moderate hypertrophy of the left ventricle. The pathologist was of the opinion that the cause of death was arteriosclerotic heart disease.

run sheet reveals that it arrived 25 minutes after the call came in, and that on arrival Maxine had no vital signs. The cardiac monitor revealed asystole. Her skin was cold and mottled and rigor had already set in. Resuscitation was obviously futile and was not attempted.



Maxine Perry

TELL YOUR CLIENT'S STORY

Claim 5 of 11 submitted by Hill Toriseva & Williams, Wheeling, West Virginia

In re: Propulsid Product
Liability Litigation,
MDL 1355, U.S.D.C., E.D. La.

Kate Kersey

Record ID No. 1994

Propulsid Tier III claim summary

Demographics

Claim type: Tier III, adult
Torsade de Pointes with
cardioversion but without
cardiac arrest

Age at time of cardiac event:
85

Sex: female

Venue: West Virginia

Family: two adult sons and
an adult daughter

Supporting Documents

- 1/20/00 hospital pharmacy charge for Propulsid
2. Holter monitor report
3. Propulsid Rx
4. 1/25/00 Adm. H&P
5. 1/25/00 EKG
6. 1/26/00 OR report
7. 1/27/00 neuro consult
8. 1/31/00 OR report
9. 2/3/00 discharge summary
10. 3/22/00 cardiology consult
11. Death certificate
12. Medical expenses

Medical expenses
\$40,430

Hill Toriseva & Williams

of counsel for the
family of Kate Kersey

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Torsade requiring repeat cardioversion five days after beginning Propulsid Anoxic brain damage

In January 2000, Kate Kersey, 85, lived with her son, Tom.

Kate was admitted to Bluefield Regional Medical Center (BRMC) in West Virginia on January 14, 2000. Esophageal dysmotility was diagnosed.

On January 20, 2000, Propulsid three times a day before meals was ordered and provided by the hospital pharmacy. A cardiac work-up, including EKG and Holter Monitoring showed atrial flutter, but no significant ventricular arrhythmias.

Kate was discharged on January 22, 2000, and her Propulsid prescription was filled the same day at Goodykoontz Drug Store in Bluefield. She was taking digoxin and amiodarone, among other drugs, concomitantly with Propulsid.

On January 25, 2000, Tom took his mother to the office of her primary care physician, Dr. Elsarrag, because she felt dizzy and like she was going to pass out. Tom had checked her pulse and found it absent for about three seconds.

Dr. Elsarrag did an EKG in his office, and it showed what he interpreted as junctional bradycardia with ST segment changes. He called an ambulance to come to his office and take Kate to the hospital.

Upon arrival by ambulance at BRMC, she was put on telemetry. Dr. Elsarrag's admission History and Physical reports that Kate had two episodes of Torsade de Pointes, the second requiring cardioversion, and he concluded:



"Status post recurrent episodes of Torsade de Pointes secondary to Propulsid..."

Hospital discharge summary

"recurrent Torsade, probably secondary to Propulsid"

Kate's QT was 532 on her admission EKG, with a QTc of 500. A temporary pacemaker was inserted.

A January 27, 2000, consultation note from Dr. Razzaq, a neurologist, says, "The patient was on Propulsid. This was thought to be the cause of recurrent Torsade...She is disoriented completely...She obviously became hypovolemic, hypoxemic with the above cardiac event, causing some insult to the brain."

A surgery consult by Dr. Barker on January 31, 2000, states: "An 85 year old woman...presented with ventricular tachycardia...secondary to Torsade de

Pointe and bradycardia. The patient had her condition corrected by several days of temporary pacemaker and it was decided prudent to place a permanent pacemaker to avoid future problems."

The discharge summary states: **"Status post recurrent episodes of Torsade de Pointes secondary to Propulsid...therapy."**

In a subsequent admission to BRMC, her cardiologist wrote in a March 22, 2000, consultation report: "She is not taking Propulsid anymore and the episodes of Torsade have obviously resolved."

Kate Kersey died six months later from causes not claimed to related to the episodes of Torsade she experienced.



HYPERLINKED CD

- The claim memo can be put on CD.
- The supporting documents can be put on the same CD.
- The mention of a supporting document in the text of the memo can be hyperlinked to the document.
- Allows a reviewer to take your case home on a CD without a paper file.

Medical Records

- Can be submitted in paper or electronic form.
- Electronic is far less work in your office.
- No particular form of submission is required, but it's the lawyer's obligation to make documents user friendly.
- Highly recommended to submit medical records with an index, either hyperlinked to the records (if records are submitted electronically), or matched to tabbed, indexed, and separated records (if records are submitted on paper.)

Start Early

- Most of the medical records required are old at this point, and they are frequently not easy to get.
- The sooner you start, the better the chance of getting what you need.
- If something is unavailable, send a letter to the special master, saying you have made a good faith effort to obtain the record, but have not been able to because (whatever the reason), and ask for a waiver.

TIMING

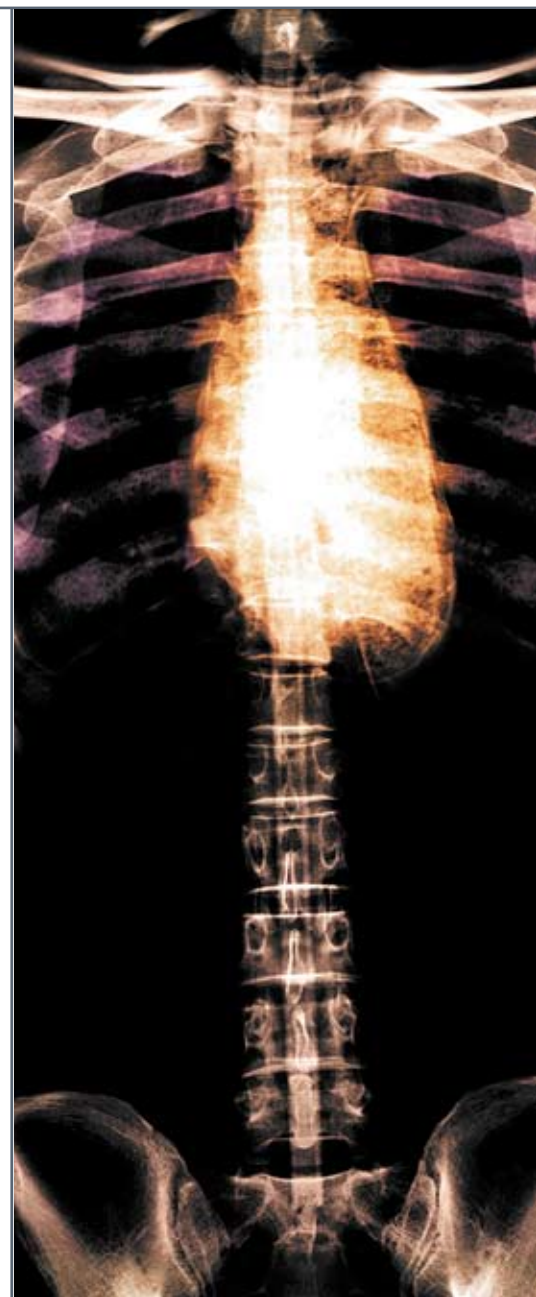
- Medical records are due 60 days after a claim form is submitted.
- Be cautious about submitting a claim for if you don't have most all of the medical records.
- Prudent course is to hold back on submitting a claim form until the records are as complete as they're going to get.

Deficiencies

- Special master's office will compare medical treatment indicated on the claim form with the medical records submitted.
- If there isn't a record to match with treatment listed in the claim form, a deficiency will be issued, unless a waiver is requested and extended.
- 60 days to remedy a deficiency or the claim will be held not compensable.

Janssen's submissions

- Janssen is allowed to submit the same documents in opposition to a claim that a claimant is allowed to submit in support of it.
- So, Janssen can submit a five-page memo plus exhibits on death and cardiac arrest claims and a one-page memo on other claims.
- Janssen is not required to serve its memo on the claimant's counsel, the same as claimant's counsel isn't required to serve Janssen.



ADMINISTRATIVE EXPENSES

- The expenses of the special master's office, including payment of the physician panel members, comes from the administrative fund, not from the fund for paying injury and death claims.
- The same is true for \$250 administrative claim payments.

Any money that is not used to pay claims or administrative expenses reverts to Janssen.

