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LEGGE vs. LEES

The Death of Twin Three-Year Old Boys Following Tonsillectomies

Imagine you were a parent with twin three-year-old boys. Suppose that they were snoring and having difficulty breathing at night and were subsequently diagnosed with sleep apnea. You consulted a doctor/surgeon; routine tonsillectomies/adenoidectomies were scheduled and performed—on an outpatient basis—meaning they did not require an overnight hospital stay. You requested an overnight stay as you felt anxious at the thought of having such young children at home directly following surgery—routine or not. The insurance company refused to authorize an overnight stay; the surgeon was adamant that it was neither possible nor necessary; so you even offered to pay for the overnight stay yourself, but to no avail.

After surgery, the twins were observed for several hours and then sent home, despite your reservations. Fast forward a few more hours. You were given Tylenol w/Codeine to alleviate their pain and discomfort. You checked on them while they were sleeping—later that evening—and found one child to be unresponsive, limp and pale! You hysterically called in your spouse, called 911,



and an ambulance arrived. Frantic, you asked a neighbor to watch your other son, while you rushed back to the hospital with your child. Unbelievably, he was more or less dead on arrival. While you were there, the neighbor phoned 911 again—emergency service personnel returned to your home—your other child had gone into respiratory arrest! This second child was taken to a different hospital where they were able to perform resuscitation on him, but he eventually died a couple of days later from severe hypoxia due to respiratory arrest and depression.

To have twin, three-year-old boys both die, essentially within the space of a couple of hours, following what was supposedly a minor procedure, is the stuff of nightmares for parents. How could this possibly have happened?

The Case: Legge vs. Lees

This scenario, in fact, did happen, and it was a case that Gerry Leeseberg and his firm, Leeseberg & Valentine, were involved with. Here is what transpired, in his words, after the tragic deaths of the two, three-year-old twins.

The Original Theory: Intentional or Unintentional Overdose of Medication by the Mother

"The initial death certificates and findings of the Coroners were that the twins died from Tylenol toxicity. As a first step therefore, the Sheriff did an investigation. The bottle of Tylenol was seized, tested, and determined to contain the correct concentration of the medication made by the pharmacy, with the proper amount of Tylenol still left in the bottle. The twins hadn't been given an inappropriate, excessive, or accidental overdose.

As there were two hospitals involved, in two separate counties, there were two different autopsies performed by two different coroner's offices—no one had a cause of death for a while. In the interim, one of the coroners attended a seminar in Colorado, where he heard a speaker discuss a relatively new topic having to do with the genetic variations of individuals affecting the metabolization of drugs."

The Emerging Field of Genetic Variations: Genetic Mutations and Impaired Metabolizers

[As explained by Gerry] There are genetic variations among individuals that affect the metabolizing of drugs. This had proved to be a really big issue with regard to people who receive chemotherapy because they would metabolize the therapy differently. Some people would not get the benefit of chemotherapy; others would get a toxic reaction from chemotherapy; but the difference in reactions had been traced back to genetic variations in the ability to metabolize drugs. Subsequently, research revealed that this genetic variation is incredibly common, with many different categories of metabolizing ability that people fall into. Someone can be classified by their genetic makeup as either a "normal" metabolizer, a "rapid" metabolizer, or an "impaired" metabolizer. If you are an "impaired" metabolizer, it simply means that your body takes longer to metabolize a drug into its various components; whereas a "rapid" or "normal" metabolizer would metabolize drugs more quickly into their components, so the drug would affect the body more rapidly.

Conclusion:

So, after hearing the speech and as a result of the seminar, the Coroner sent samples of the boys' blood to be tested, where they were found to have a genetic mutation of an enzyme that is responsible for metabolizing drugs—including opiates, such as Tylenol w/Codeine. It was determined through the testing that the boys were "impaired" metabolizers. Furthermore, because they were twins, they both suffered from the same genetic mutation or variation in their ability to metabolize Tylenol and Codeine. That's what accounted for the elevated levels of the Tylenol in their blood stream. The conclusion was reached, therefore, that their deaths were the result of Tylenol toxicity—which was a product of their genetic mutation.

Gerry's Involvement:

Gerry continues: "So the family went to a law firm, and the law firm tried to put the case together, and were having a difficult time—in fact it was the law firm that I used to work for—and when they were running into a brick wall, they came to me and asked if I would take over the case, which I did, especially since it involved a child."

Defense Theory:

Gerry explains the Defense's case: "The defense claimed that since the boys were found to have elevated levels of Codeine on autopsy, the boys' genetic mutation had impaired their ability to metabolize Codeine into morphine. The defense trumpeted an article in a German medical journal regarding the deaths of twin, three-year-olds due to Codeine toxicity. In addition, the defense expert toxicologist/pharmacologist had written a case report on my clients' death for inclusion in a medical text book ascribing their deaths to this genetic mutation and impaired metabolization. Their premise being that when the boys were given Tylenol w/Codeine, because they were impaired metabolizers, they accumulated toxic levels of Tylenol w/Codeine in their blood system. And that superficially said to investigators and the

coroners, 'Aha, we have an explanation for their deaths'. Furthermore, it was the genetic mutation that caused the toxicity and therefore caused the death of the twins—it had nothing to do with the surgery. The fundamental problem with their theory was the fact that the boys were "impaired" metabolizers."

In summation:

"The defense alleged the children's deaths were due to Codeine toxicity, claiming it caused the children to suffer respiratory depression. The defense further claimed the underlying cause of the Codeine toxicity was their own genetic mutation resulting in impaired metabolization and accumulation of Codeine, which was an unknown anomaly and, therefore, not the result of any medical malpractice."

The Plaintiff's Case:

"We alleged that because the twins were "impaired" metabolizers, it slowed the rate by which the Codeine was metabolized into morphine. Morphine increases the likelihood of respiratory depression ten-fold. Therefore, slowed metabolization would actually create a protection against respiratory depression and rule out the genetic anomaly as the cause of the respiratory depression.

The accumulation of Codeine means it has not metabolized into morphine; and while that might result in elevated levels of Codeine which could be considered "toxic", there is no scientific evidence that the "toxic" levels of Codeine the twins suffered from would cause respiratory depression sufficient to cause death."

"An overdose of Codeine can result in elevated blood levels that are classified as Codeine toxicity. The symptoms of Codeine toxicity can include respiratory depression. There are varying levels of Codeine toxicity, and respiratory depression sufficient to result in death *can* occur with an acute and severe overdose. (One can commit suicide by taking an overdose of Codeine. There is an established "LD", or lethal dose, for Codeine between 800mg and 1.2gms.)

However, the children received the *prescribed* dosages, over many hours, and an "overdose" (intentional or accidental) by their mother was ruled out. Simply put, the children never received what would be considered a LD. The defense then was forced to contend that the boys' respiratory depression was from appropriate doses of Codeine because they were genetically anomalous (abnormal) metabolizers. As I mentioned before, that theory could fly *if* the children were "super" metabolizers rather than "impaired" metabolizers. The literature discussing children dying from Codeine toxicity pertains only to children who are "super" metabolizers—not "impaired" metabolizers. (Codeine toxicity is a misnomer in the literature because it is really excessively fast morphine production that causes the death; but the medication being taken is Codeine, not morphine, which is why the literature describes it that way.)"

Conclusion:

"The boys suffered from a well-known complication following airway surgeries—respiratory depression due to swelling and physiological collapse of the soft tissues shortly after surgery. Had they been kept overnight—as the mother wanted but the insurance company refused to authorize—Pulse Oximetry Monitoring would have detected the respiratory depression (regardless of its cause) and allowed nursing personnel to resuscitate the boys. After the surgery, the mother had asked the surgeon if it would not be possible to have the children admitted overnight, and the surgeon told her no—there was no justification for doing that. In essence, 'I am not going to be paid for that, so I am not going to agree to that'. It was not his decision to make—it was the patient's decision to make—in this case, the mother of the patients. He made reference that the insurance company would not pay for that. She responded, 'I don't care; I am willing to pay for the overnight stay'. And he said, 'No, that is not necessary'."

The Aftermath:

"This was one of the most fascinating, difficult, complex, and tragic cases I have ever worked on. After the verdict, I actually worked with the defense expert to modify his manuscript to accurately describe what happened to these boys, in order to help educate the medical profession. At the same time, we basically forced the defense experts to acknowledge that their opinions as to the pediatric otolaryngology "standard of care" was in reality dictated by the insurance industry's refusal to authorize payment for in-patient surgeries on children three years and over, despite the fact that the risk of airway collapse was only reduced a miniscule amount before and after a child's third birthday. However, insurance companies remain impervious to this problem. They simply refuse to reimburse for in-patient charges, placing the onus on surgeons to advise patients of the risk, and forcing patients' families to cover the costs out-of-pocket, and exposing surgeons to risk, if procedure is done as an outpatient and patient dies. Just another example of how the insurance industry, and not malpractice attorneys, is the real threat to physicians."

With Regard to the Family:

"The family felt vindicated by the verdict in their favor, which rejected the faulty defense claim that there was something "defective" about the boys because of the genetic mutation for metabolizing Codeine. The family became strong advocates for warning other parents about the unknown risk of this "simple, common childhood surgery", and the need to advocate for doing the procedures as in-patient surgery."