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STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY

PROCEEDINGS AGAINST

KENNETH J. ENGEL, R.Ph.	FINAL DECISION AND ORDER
RESPONDENT.	LS9908051PHM

The State of Wisconsin, Pharmacy Examining Board, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, makes the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Board of Nursing.

The Division of Enforcement and Administrative Law Judge are hereby directed to file their affidavits of costs with the Department General Counsel within 15 days of this decision. The Department General Counsel shall mail a copy thereof to respondent or his or her representative.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated this 14th day of June, 2000.

John P. Bohlman, R.Ph.

A Member of the Board

STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF

DISCIPLINARY PROCEEDINGS AGAINST

KENNETH J. ENGEL, R.Ph. LS9908051PHM

RESPONDENT

PROPOSED DECISION

The parties to this proceeding for the purposes of sec. 227.53, Stats., are:

Kenneth J. Engel, R.Ph.
225 21st Street
Rice Lake, WI 54868

Department of Regulation & Licensing
Division of Enforcement
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

State of Wisconsin Pharmacy Examining Board
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

A Class II hearing was held in the above-captioned matter on February 1, 2000, at 1400 East Washington Avenue, Madison, Wisconsin. Respondent Kenneth J. Engel appeared personally and by Attorney Thomas J. Graham. The Division of Enforcement appeared by Attorney Arthur Thexton.

Based upon the entire record in this case, the administrative law judge recommends that the Pharmacy Examining Board adopt as its final decision in the matter the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Kenneth J. Engel, R.Ph. (Mr. Engel), 225 21st Street, Rice Lake, Wisconsin is licensed to practice as a pharmacist in the State of Wisconsin by license #9751, granted on June 6, 1980.

2. At all times relevant to the matters set forth herein, Mr. Engel was the Director of Pharmacy at the Lakeview Medical center, 1100 North Main Street, Rice Lake, Wisconsin, a seventy-five bed hospital.

3. On July 31, 1996, Kellen Czyscon, born on July 6, 1996, was admitted to Lakeview Medical Center for a surgical procedure called a pyloromyotomy to correct a problem with the patient's gastrointestinal tract. At the time of admission, the patient weighed 9 pounds, 15 ounces, or 4.5 kilograms, and was in his 25th or 26th day.

4. Following the successful surgical procedure, the anesthesiologist, Dr. John Brendel, wrote into the patient's Post Anesthesia Care Orders the following order: "Morphine .3 mg IV every 10 minutes as needed for pain up to 2 mg." Morphine was not administered pursuant to that order.

5. Gwen D. Martin, M.D. who assumed the patient's post-surgical care, placed the following order in the patient's chart for treatment of pain: "MSO_4 .5-1 mg IV qH@hr with .2 mg IV q 1 hr PRN." (morphine sulfate, 0.5 to 1 milligram IV each hour with 0.2 milligram IV per hour as needed). The physician's order was presented to Mr. Engel by Carol Nickell, the nurse on the unit, for preparation of the morphine infusion. Mr. Engel's recollection is that Ms. Nickell described the patient as one month old and weighing 5 kilograms or nine pounds, and at the time in question he thought of the patient as an infant rather than a neonate.

6. A neonate is variously defined as a child from birth to the age of four weeks or from birth to the age of one month. An infant is generally defined as a child from one month to one year old. Whether a patient should be treated as a neonate or an infant in terms of medication dosage may vary depending upon factors other than age, including whether the baby was born prematurely, whether there were complications associated with the birth, and the weight and size of the child.

7. Mr. Engel prepared the infusion as ordered by Dr. Martin, and did not consult with the ordering physician, any pharmacy colleague, or any reference materials prior to filling the physician's order. While recognizing that the order constituted an aggressive dose of morphine, Mr. Engel also recognized that it was consistent with past orders for similar patients in similar circumstances by this anesthesiologist and this treating physician in this hospital.

8. Routine post-operative monitoring of surgical patients at Lakeview Medical center at the time of these events would have called for monitoring of the patient's blood pressure, pulse, temperature and sedation every 15 minutes, gradually diminishing to every half hour and then to every hour.

9. The surgical procedure occurred at 12:30 p.m., and the patient was transferred to the floor at about 3:25 p.m. Starting at about 5:00 p.m., morphine was administered at the rate of 0.5 milligrams per hour. At approximately 10:15 p.m., Dr. Martin checked with the attending nurse, and was notified that the patient was sleeping with respiration rate of 28. Dr. Martin thereupon reduced the morphine rate to 0.2 milligrams per hour.

10. At approximately 1:55 a.m. on August 1, 1996, the patient was discovered by nursing staff to have no respirations or heartbeat. Attempts to resuscitate the patient were unsuccessful, and the patient was declared dead at 3:04 a.m. An autopsy was performed and the cause of death was listed as morphine toxicity.

11. Various references recommend various dosages for IV administration of morphine to pediatric patients.

- A monograph published by Minneapolis Children's Medical Center, entitled *Pediatric Pain Management and the Treatment and Prevention of Iatrogenic Narcotic Withdrawal*, which was introduced as Exhibit 19, lists the pediatric dose for continuous infusion as "0.01 to 0.02 mg/kg/hour adjusted to balance pain control and respiratory depression." Based upon the patient's weight, the specified dosage would be 0.045 mg/hour to 0.09 mg/hour
- The *American Hospital Formulary Service*, an excerpt of which was admitted as Exhibit 20, states, "For postoperative analgesia, children have received maintenance dosages by IV infusion at a rate of 0.01-0.04 mg/kg per hour; however, because elimination of the drug may be slower in neonates and they may be more susceptible to CNS effects of the drug, some clinicians suggest that the rate of IV infusion generally not exceed 0.015-0.02 mg/kg per hour in this age group."
- An excerpt from *United States Pharmacopeia Drug Information* introduced as Exhibit 22, lists as the "Usual pediatric dose," "Intravenous, 50 to 100 mcg (0.05 to 0.1 mg) per kg of body weight, administered very slowly." It specifies nothing in terms of a continuous infusion rate per hour.
- The Pediatric Dosage Handbook, introduced as Exhibit 23, specifies the dosage for neonates as between 0.01 to 0.02 mg/kg/hour; and for infants and children as from 0.01 to 0.04 mg/kg/hour for post-operative pain. Based upon the patient's weight, the specified dosage would be 0.045 mg/hour to 0.09 mg/hour if considered a neonate, and 0.045 mg/hour to 0.18 mg/hr if considered an infant.
- The Harriet Lane Handbook, introduced as Exhibit 25, specifies the dosage for neonates as 0.01 to 0.02 mg/kg/hour, and for infants and children as 0.025 to 2.6 mg/kg/hour. Based upon the patient's weight, the specified dosage would be 0.045 mg/hour to 0.09 mg/hour if considered a neonate, and 0.11 mg/hour to 4.5 mg/hr if considered an infant.

12. The dosage of morphine ordered for the patient constituted aggressive treatment of pain, but was not an unacceptably large dosage and, in preparing the infusion consistent with Dr. Martin's medication order, Mr. Engel's practice as a pharmacist did not evidence a lack of knowledge or ability to apply professional principles or skills, and respondent did not engage in the practice of pharmacy which constituted a danger to the health, safety or welfare of patient or public, and did not dispense a drug that he should have known would harm the patient.

CONCLUSIONS OF LAW

1. The Pharmacy Examining Board has jurisdiction in this matter pursuant to sec. 450.10(1)(b), Stats.

2. Respondent, in preparing the patient's morphine IV infusion consistent with Dr. Martin's medication order did not engage in conduct which evidenced a lack of knowledge or ability to apply professional principles or skills, within the meaning of sec. 450.10(1)(a)6., Stats.; did not engage in a pharmacy practice which constituted a danger to the health, welfare, or safety of patient or public or practice in a manner which substantially departed from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient within the meaning of sec. Phar 10.03(2) Code; and did not dispense a drug which respondent should have known would harm the patient for whom the medication was prescribed, within the meaning of sec. Phar 10.03(3), Code.

ORDER

NOW, THEREFORE, IT IS ORDERED that this matter be, and hereby is, dismissed.

OPINION

Res Ipsa Loquitur is Latin legalese which translates literally as "the thing speaks for itself." The concept expressed is that an accident or event resulting in harm was one that ordinarily would not have occurred in the absence of negligence. That would seem to be the case here, for there is no suggestion that the infant patient's death resulted from anything other than morphine poisoning. This does not mean that the *res ipsa loquitur* rule of evidence is applicable to this case so as to find respondent to be negligent, however, because the doctrine requires application of a three part test. First a layman must be able determine as a matter of common knowledge, or an expert must testify, that the result which occurred does not ordinarily occur in the absence of negligence. Second, it must be shown that the agent or instrumentality causing the harm was within the exclusive control of the defendant. Third, the evidence offered must be sufficient to remove the causation question from the realm of conjecture, but not so substantial that it provides a full and complete explanation of the event.

The second element of this three-pronged test is absent in this case, for it is clear that Kenneth Engel was not in exclusive control of the instrumentality, in this case morphine, that caused the harm. Indeed, the prosecution apparently concludes that there is plenty of blame to pass around; at least one of the other principals in the patient's care has already been disciplined. The ALJ takes notice that on January 20, 1999, Gwen D. Martin, M.D., the physician who wrote the analgesic medication order for the patient, was reprimanded by the Medical Examining Board after she stipulated that her conduct in the matter constituted negligence.

But if Mr. Engel may not be said to have been negligent as a matter of law, may it not nonetheless be concluded that inasmuch as the medication dosage ordered turned out to be a lethal one, should he not, as a minimally competent pharmacist, have known or at least suspected that fact and have taken whatever precautions were necessary either to confirm that the medication order was medically appropriate under all the circumstances or, if not appropriate, to ensure that the medical order was not carried out as written. The prosecution's position is that he should have known that the ordered dosage was too high, and should have checked references and/or consulted with a colleague about that dosage level. The core question is thus this one: Should a minimally competent pharmacist have known that the dosage of IV morphine ordered for a baby of this patient's age and weight was inappropriate and a possible danger to his health and safety.

In arguing that respondent should have known that the dosage was too high, complainant elicited expert testimony for essentially two propositions. First, because the baby was 25 days of age and weighed 4½ kilograms, he should have been considered to be a neonate, and the morphine dosage should have been consistent with recommended dosage for neonates. Second, given that the patient was a neonate, the dosage ordered was five to ten times the recommended dosage. Complainant's expert, Paul Rosowski, R.Ph., testified in part as follows:

> Q. In your opinion, was it within the standard of care -- well, let me ask a different question than that. In your opinion, was it a substantial departure from the standard of care for Kenneth Engel to dispense the order which he received on January 31st for Kellen Czyscon as written by Dr. Martin?
>
> A. Yes, it was.
>
> Q. Okay. And why?
>
> A. Because I believe the -- the dose was excessive of what would be considered allowable in this case.
>
> Q. And can you describe why you believe this as fully as you can.
>
> A. Well, the dose, to the best of my knowledge -- what reads on the sheet is 0.5 to 1 milligram as a continuous infusion. When going back and checking the resources that are given for pediatric dosing, I find the dosing range to be starting initially at 0.01 milligram per kilogram per hour, which could then range up not to exceed a rate of 0.015 milligram to 0.02 milligrams per kilogram per hour. In so doing, when you make that calculation, you come up with a total dose of 0.09 milligrams to 0.045 milligrams as -- per hour as a continuous infusion. The dose as written is 0.5 milligrams to 1 milligram as a continuous infusion. To me, that would imply have anywhere from a five to tenfold overdose or excessive dose of medication for a neonate.
>
> Q. In your professional opinion, was this patient a neonate?
>
> A. Yes, this patient was a neonate.
>
> Q. And why do you believe that this patient was a neonate and not an infant as Mr. Engel said?
>
> A. The patient was 25 days old. Fitting the textbook definition, a neonate is defined as anywhere from zero to one month, which I would consider approximately 30 days. In pediatrics or in neonates, I would

always err in the conservative side, knowing especially what's written in the references that morphine can cause excess central nervous system sedation and problems, and I would err on the -- on the most conservative side when I would -- you know, looking at the therapy, until the patient would perhaps, you know, be able to tolerate that, but --

* * * *

Q. Could you look at Exhibit 19, please. . . . Does Exhibit 19 support the opinions which you have just rendered?

A. Well, what I see on this Exhibit 19 doesn't -- following Page 5 -- it's numbered after that -- but it would be Page 6, Page 7, headed with "Analgesics, drug, morphine sulfate," where we have listed on the left-hand column, "Dose," and then going over to the right-hand column, we have, "Continuous infusion." And it says, "0.01 to 0.02 milligrams per kilogram per hour, adjusted to balance pain control and respiratory depression."

* * * *

Q. What's Exhibit 20?

A. It's American Hospital Formulary Service, 1996.

* * * *

Q. All right. Does the hospital formulary provide any assistance to the pharmacist in Mr. Engel's position being asked to prepare continuous infusion morphine for a child whom he believes to be certainly no older than a month and certainly no more than 5 kilograms?

* * * *

A. There is one postoperative analgesia. It does say, "0.01 to 0.04 milligrams per kilogram per hour; however, because the elimination of the drug may be slow in neonates and maybe more susceptible to CMS effects of the drug. Some clinicians suggest a rate -- IV infusion rate not to exceed 0.015 to 0.02 milligrams per kilogram per hour in this age group."

Q. Are those the rates that you talked about earlier as being proper?

A. Yes, they are. (Tr. pp. 53-61)

There are two problems with Mr. Rosowski's expert testimony. First, his testimony relied almost entirely on the various guidelines and handbooks introduced as Exhibits 19 through 25, rather than on any experience he may have had as a hospital pharmacist in the treatment of pediatric patients. This is understandable inasmuch as his experience in that regard is limited. He was employed as Director of Pharmacy Services at St. Joseph's Memorial Hospital and Home, Hillsboro, Wisconsin, from September, 1993 to October, 1994; and Director of Pharmacy Services at memorial Hospital of Iowa County and Memorial Hospital of Lafayette County from November, 1994 to July, 1996. His experience with pediatric surgical patients during those periods of employment was minimal, if any. He was unable to recall any cases of pediatric surgery being performed at any of those hospitals, and he testified that if any pediatric surgery was performed, it would have been "very, very infrequently." (Tr., pp. 85 & 87)

The second problem with Mr. Rosowski's testimony was that his opinion relating to the dosage ordered and prepared for the patient was premised on his conclusion that the patient was a neonate. There was considerable testimony and argument addressing the issue whether the patient was a neonate or an infant, and whether the classification was particularly relevant given that the patient's age was close to the dividing line between a neonate and an infant. Whether or not the patient should in fact be considered to be a neonate based upon his actual age at the time in question, the fact remains that at the time respondent mixed the morphine bag, he had concluded, based upon what Nurse Nickell had told him, that he was dealing with a month-old five kilogram infant. Mr. Rosowski's testimony was thus based on a false premise: that Engel knew or should have known that the patient was a neonate, and the patient should have been dosed accordingly. If the sources upon which Mr. Rosowski relied were consulted based upon what respondent reasonably believed at the time the morphine was prepared, that is, that the patient was an infant, then those same sources would lead to the conclusion that the dosage, as ordered, was much less than five to ten times the recommended dosage as testified by Mr. Rosowski.

The first of the three references which differentiated between neonates and infants in terms of recommended dosage was the *American Hospital Formulary Service* (Exhibit 20), which recommends maintenance dosages by IV infusion at a rate of 0.01-0.04 mg/kg per hour; but suggests that some clinicians recommend a dosage of 0.015-0.02 mg/kg per hour for neonates. This translates to a dosage of 0.05 to 0.2 mg per hour for a five kilogram infant, compared to the ordered dosage of 0.5 to 1.0 kg per hour.

The *Pediatric Dosage Handbook* (Exhibit 23), specifies the dosage for neonates as between 0.01 to 0.02

mg/kg/hour; and for infants and children as from 0.01 to 0.04 mg/kg/hour for post-operative pain. This also translates to a dosage of 0.05 to 0.2 mg per hour for a five kilogram infant.

The *Harriet Lane Handbook* (Exhibit 25), specifies the dosage for neonates as 0.01 to 0.02 mg/kg/hour, and for infants and children as 0.025 to 2.6 mg/kg/hour. This translates to a dosage of 0.125 to 13 mg per hour for a five kilogram infant.

Of the three sources cited above, only the *Harriet Lane Handbook*, recommends dosages for infants well within the range ordered for the patient in this case, even when calculated utilizing the child's actual weight of 4.5 kilograms. Mr. Rosowski testified that this was an authoritative source for pediatric dosing, and could have been relied upon had it been consulted. It was not, however, and, in light of the lower dosages recommended by the other reference works, and the significantly lower doses recommended for neonates, the question remains whether in the total circumstances of this case, Mr. Engel acted reasonably.

Mr. Engel's experience has been in the field of hospital pharmacy since 1981. As Director of Pharmacy at Lakeview Medical Center in Rice Lake (Lakeview), respondent supervises three pharmacists and three technicians. There is a pain management committee and a pain clinic at Lakeview, headed by Dr. Brendel, the anesthesiologist in this matter, and respondent was aware of both his and Dr. Martin's pain management practices through his participation in the hospital's Pharmacy and Therapeutics Committee. Respondent testified that their treatment of pain was "consistent with the medical practice at the time, which was aggressive" (Tr., p. 141).

> Q. (by Mr. Graham) You indicated that when you -- earlier, that when you talked to Carol Nickell, when she first came up to you, she reported to you that Kellen Czyscon was a one-month-old child, correct?
>
> A. (by Mr. Engel) Yes.
>
> Q. You have seen the exhibit from the Pediatric Dosi -- Dosage Handbook, Exhibit Number 23 -- excuse me -- 24, which refers to the definitions of neonate and infant?
>
> A. Yes, I have seen that.
>
> Q. And when Carol Nickell indicated to you that Kellen Czyscon was a one-month-old child, what did you interpret that to be? What did you classify in your own mind at that time? How did you classify Kellen . . . . in terms of a neonate versus an infant or --
>
> A. Infant or a peds. is what -- how I would have classified it.
>
> Q. From your experience -- you've heard Mr. Rosowski testify this morning about Kellen being a 25- or 26-day-old child. From your experience, simply looking at the Pediatric Dosage Handbook, he would qualify or fall within the category of a neonate?
>
> * * * *
>
> A. Yeah, yes.
>
> Q. Beyond that, are there factors that you have to take into consideration in identifying where a patient falls within that classification of either neonate or infant?
>
> A. Yes.
>
> Q. And you've -- can you indicate what factors you would take into consideration?
>
> A. Yeah. It's -- it's just not feasible to me to say that if someone is 27 days old, they're a neonate and 28 days old, they're an infant. There's -- every patient varies in their -- in -- in how they grow and -- and you just can't treat every patient like that or you'd be under-treating or over-treating a lot of patients, so you have to take into account how old that patient is, you have to take into account the weight, were they premature, were they not premature, and also you have to take into account your experience at the hospital where you work and how you've treated those patients in the past.
>
> Q. How did you view the dosage as set forth by Dr. Martin, in terms of he morphine?
>
> A. I -- I seen it as aggressive but acceptable.
>
> Q. When you say acceptable, why do you say that?
>
> A. Because morphine therapy -- at that time, there was a lot of work being done throughout not only our hospital but throughout the entire country that was reaching not under-treating patients but treat morphine aggressively with -- with monitoring. That was becoming the norm, and that's definitely what

was becoming the norm in our hospital.

Q. In terms of how you would dose a particular medication, what's the first thing you go to look at as a pharmacist?

A. As far as -- as -- the first thing I -- the reference I look at first when I -- is that what you're asking?

Q. Yeah. Let's take a look at Exhibit Number 33. What is that, please?

A. That's a -- that's a package insert for morphine sulfate.

Q. And what -- what's the package insert, is that something that comes with the morphine sulfate?

A. It comes with the morphine sulfate, and Joint Commission requires that one of these be on the shelf with each drug.

Q. Did you have one at the pharmacy at that time?

A. We keep a package insert with all the medications in our pharmacy.

Q. Does the pharmacy -- does the package insert, Exhibit Number 33, speak to the dosage for neonates or infants, in terms of an I -- continuous IV?

A. Not accord -- not in exact -- it has that age group but it doesn't say anything about continuous IV.

Q. What does -- what do you do once it talks -- doesn't talk about continuous IV? Where do you go?

A. Well, if it's -- if it's not on -- on the insert it's an off-label use of the product, and -- and for morphine, it's an off-label use.

Q. When you talk about off-label use, that means that it's not set forth in that product insert and now you have to go elsewhere?

A. Correct. The FDA hasn't been -- there was no studies done by the companies with pediatric or neonates to get it approved for continuous infusion, so -- so it's not part of the labeling.

Q. What -- what do you go to or what -- what do you turn to then to determine whether the order as written is appropriate?

A. You -- you look at either literature, textbooks, the norms of what's going on in the medical community and your experience with the product.

Q. When you talk about norms that are going on with the medical community -- well first, before we get to that, you're familiar with the Harriet Lane book --

A. Yes.

Q. -- is that correct? And you had a chance before this hearing to take a look at the dosing for an infant, a 30-day-old person; is that correct?

A. Yes.

Q. And you had -- you'd been here present when Mr. Rosowski indicated that it was .025 to 2.6 milligrams per kilogram per hour?

A. Uh-huh, yes.

Q. Was the dosage for Kellen Czyscon within that dosing range?

A. Yes.

Q. Well within that?

A. As a matter of fact, well within that. (Tr., 151-155)

Respondent's expert witness was David M. Watson, R.Ph. Following receiving his doctoral degree in pharmacy in 1979, Dr. Larson became employed by Abbot Northwestern Hospital, Minneapolis, as a clinical pharmacist. While there, he worked part time at the Children's Hospital, which was affiliated with Abbot Northwestern. Beginning in 1981, Dr. Larson practiced as a clinical pharmacist at Minneapolis Children's Medical Center, assuming the position

of Assistant Clinical Director in 1985, and Director of Pharmacy in 1988, in which position he served until 1996. Minneapolis Children's Medical center was a 165 bed pediatric hospital, employing 50 pharmacists and technicians, with neonatal and pediatric intensive care units, and with specialties in nephrology and hematology oncology.

In the Fall of 1996, Dr. Watson received a call from the Hospital Director at Lakeview Medical Center, who explained that there had been a death of a pediatric patient at Lakeview. The Director asked Dr. Watson to perform a review of the circumstances of the event for the hospital's internal use. Dr. Watson agreed, and ultimately issued a written summary of his assessment, which was admitted at hearing as Exhibit 35. In answering the question whether there was a specific knowledge or performance deficit on Mr. Engel's part, Dr. Watson wrote in part;

> No; . . . Had this patient been a couple weeks younger, not full term, or had other risk factors (cardiac or respiratory), the ordered dose should have been viewed as not only aggressive, but potentially hazardous. It is my understanding that this was not the case for this patient. Therefore, patient harm would not have been expected at the time of processing the Order.

Answering the question whether the standard of care for a pharmacist had been met, Dr. Watson wrote in part, "Yes. When you strictly limit the assessment to the traditional pharmacy components, I believe the pharmacist acted within professional expectations having the information available at the time of dispensing the morphine."

After having conducted an even more extensive review of the hospital records in preparation for his testimony for the hearing in this matter, Dr. Watson testified that his opinion had not changed. When asked whether he still felt that the dosage, from his experience at Children's Hospital was an acceptable dosage for someone of Kellen Czyscon's age and weight, Dr. Watson responded that he did. What follows is an excerpt of some of his testimony in that regard.

> Q. (by Mr. Graham) Was that dosage, from your experience at Children's Hospital, an acceptable dosage for someone of Kellen Czyscon's age and weight?
>
> A. Yes. I -- I'd have to say we -- we use a lot I'd have to say we -- we use a lot more with weight than we do with age, but -- but looking at approximately .1 milligram per kilo was something that we had routinely done at Children's.
>
> Q. You've had a -- have you had a chance since your discussions with Mr. Johnson, Mr. Engel, and your writing Exhibit Number 35 to review other materials?
>
> A. Yes.
>
> Q. What types of things have you reviewed?
>
> A. I reviewed depositions of myself, Mr. Rosowski, and forgetting the nurse's name, but the nurse.
>
> Q. Carol Nickell?
>
> A. Carol Nickell, par -- excuse me. I had reviewed the chart or copy of the chart, I should say.
>
> * * * *
>
> Q. Okay. When you saw the hospital chart, did your impressions from your letter change?
>
> A. Not substantially, no.
>
> Q. Did they change in any way?
>
> A. As -- again, at the time that I saw the chart was about three years after I had done this review, and so trying to think back three years, the retrospective vision, I had the opinion that there -- that there wasn't a whole lot of monitoring that was -- that was done, and when I looked at the chart, there was more monitoring than I had remembered. That's -- that's -- and again, not to a substantial degree. It was probably in the ballpark.
>
> Q. When you reviewed the chart, did you determine whether what had been represented to you about Kellen Czyscon was accurate?
>
> A. Yes.
>
> * * * *
>
> Q. In terms of how you've looked at this, have you looked at it from the standpoint of a hospital pharmacist?

A. Yes, I have.

* * * *

Q. In looking at this and rendering your opinions, have you done it retrospectively or tried to do it prospectively?

A. I tried to take the approach of looking at it prospectively.

Q. Why is that?

A. Well, I guess if I had the advantage to do a lot of things differently, you know, years later or whatever, I may come up with different conclusions. So if I were to look at that -- if I put myself in the place of Mr. Engel at the time that I was presented with this, that's the position I guess I -- I was looking at this to say is there anything that I would know at that time prospectively that would indicate that -- that there should be a bad outcome from this.

* * * *

Q. You have been able to determine the definitions for neonate and infant as set forth in Exhibit 24; you've seen that?

A. Yes, I have seen that.

Q. How would you -- and do you have an -- strike that. Do you have an opinion to a reasonable certainty within your field as to what -- where Kellen Czyscon fell within that range?

A. This is the area that, as I would say, would -- is where I would be somewhat tainted from my experience. My experience at Children's Hospital -- as I said, we base a lot of things on weight. For example, our neonatal intensive care unit, if we had a patient who was even 3-1/2 kilograms, unless there were extenuating circumstances, that patient would not be in our NICU. Patient would, if they needed intensive care, probably be in our pediatric intensive care unit. That changed over time. In 1981, what was considered a neonate in a young patient was much larger than when I left in 1996. It was not uncommon for us to handle patients that were just slightly over a third of a pound -- excuse me -- third of a kilogram, I should say, 350 grams. And so the perspective that I have is at 4-1/2 kilograms, relative to my practice, that's a fairly large -- I mean a reasonable size infant. I don't disagree that the references here say four weeks and I certainly wouldn't disagree with that terminology. But the way we handled patients of 4 to 4-1/2 kilograms certainly would fit in an infant category.

Q. In that infant category, do you have an opinion, to a reasonable probability, as to whether a pharmacist in Mr. Engel's position should have filled that prescription as ordered by Dr. Martin?

A. Yes. In my opinion, a 4-1/2 kilogram at about four weeks of age that a -- a dose of a .1 milligram per kilo would be appropriate to fill.

Q. The pharmacist would have been meeting a standard of care in doing so?

A. I would -- yes, I would say it would be meeting appropriate professional judgment.

Q. At Children's Hospital, is that dose for that age and weight child unusual?

A. No.

Q. Of morphine sulfate.

A. That's correct.

* * * *

Q. You've heard references in the testimony today about pharmacy references, correct?

A. Yes.

Q. And you've heard references such as Harriet Lane. Do you recognize that as an authoritative pedia -- strike that -- an authoritative pharmacy handbook?

A. Yes.

Q. You've heard references to the dosing for infants as being .025 to 2.6 milligrams per kilogram per

hour?

A. Yes.

Q. That range --that dosage is .025 to 2.6 for an infant. Why such a large range?

A. It's because it's -- it's handled so variably by different patients. . . . The hundredfold range -- if you're asking me is, why is it so variable, it's because people are different. It -- it vastly differs on how patients both handle the drug and also respond as far as efficacy.

Q. You -- you talked about other factors. What factors do you take into consideration when determining infant neonate status?

A. Well, I think some that were mentioned here already today as far as the gestational age, what's the weight of the patient, are there other extenuating circumstances that would -- if you're looking at particularly this particular medication, are there things that -- you know, is there compromised either renal function or liver function? Those types of things take a look at. I think also if you're -- if you're looking to try and narrow down that range, I think there was a suggestion in the -- in the discussion today that if I have it for infants and children that it's the low end of that range is infant and the high end of the range is for children is -- is not accurate. That -- matter of fact, you probably would dose morphine on a per-kilogram basis less in a twelve-year-old than you would in a two-year-old.

* * * *

Q. Do you have an opinion to a reasonable probability in your field of expertise as to whether a pharmacist can expect monitoring of a patient when they're given this medication?

A. Yes, I believe it's routine for any patient getting morphine to have some monitoring in an institutional setting.

Q. You've had a chance to review the monitoring in the hospital chart?

A. Yes, I have.

Q. How would you characterize that monitoring?

A. In light of the '96 standards or in --

Q. In light of the '96 standards --

A. Okay. I would say that at least up until about 11 o'clock that -- that the monitoring was -- was adequate. There were, you know -- it started out, I believe it was mentioned already, every half hour to begin with and then hourly checks. There seemed to be a little drop in the documentation somewhere around, I think, between 11:00 and close to 2:00, somewhere in there.

Q. Do you have an opinion, from what you have seen, as to whether the compound was appropriately made and dispensed?

A. In my understanding it -- it was made appropriately and dispensed.

* * * *

Q. Okay. Do you have an opinion as to whether a pharmacist can, in determining dosage and at least evaluating dosages, can take into consideration past experience with doctors and how they dose or the -- the facility itself and how they dose?

A. I -- I think it can be helpful to -- where it's a borderline situation. My initial assessment I have to be -- have some level of comfort that we're in the ballpark. Then I believe that having a familiarity with the expertise of the -- of the prescribing physician will help determine whether or not the variance that you see is significant or not.

Q. Do you have an opinion as to whether Kellen Czyscon, with this dosage that he was given, had to be in the ICU and hooked up to a heart monitor?

A. I don't believe that was necessary.

* * * *

Q. Given your past experience prior to 1996, had physicians become more aggressive in the use of analgesics?

A. I would have to say in the -- in the early to middle 90's, there was a focus on pain management. It was popular to have pain management teams. Very specifically, in our institution there was a big concern about specifically circumcisions that had traditionally been treated -- been done, I should say, without any analgesia, and that the literature clearly stated that that should not -- that was not appropriate, that you should be providing analgesia for even simple procedures like circumcision.

Q. Let's turn to Mr. Rosowski's opinions, and I'd like to ask you about those. First of all, he was of the opinion that the dosage of .5 milligrams represented a substantial departure from the standard of care. Do you agree with that or disagree?

A. I disagree.

Dr. Watson's testimony was unequivocal and convincing.

There is no question that something went terribly wrong with the patient's pain treatment. There is some suggestion in this record that it may have been a failure to properly monitor the patient in the later hours of his life, but it would be inappropriate based upon this record to speculate in that regard. It may also have been that the variability between similar patients in terms of what Dr. Watson described as a vast difference in the way patients handle the drug may have led to this medical misadventure. In any event, the evidence in this case does not establish by a preponderance of the evidence that Mr. Engel's practice fell below the minimum standards for the practice of pharmacy, and this case must therefore be dismissed.

Dated this 28th day of April, 2000.

Respectfully submitted,

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Wayne R. Austin

Administrative Law Judge