279-10

STATE OF MAINE
WALDO, SS.

SUPERIOR COURT
CIVIL ACTION
Docket No. CV-06-39

Helen M. Cook, Personal Representative
Of the Estate of Sybil Lavway,
Plaintiff

v.

Decision and Judgment

Eastern Maine Medical Center,
Defendant

Helen M. Cook, the sister and personal representative of the estate of Sybil Lavway, maintains this claim for professional (nursing) negligence against Eastern Maine Medical Center (EMMC). The claim arises out of treatment provided by members of EMMC's nursing staff while Lavway recovered from cardiac surgery in the hospital's cardiac care unit (CCU) in September 2003. Cook alleges that Lavway sustained personal injury because of the improper administration and maintenance of an intravenous dopamine infusion. At a hearing held on the complaint, Cook and a representative of EMMC were present with counsel of record for the parties.[1] For the reasons set out below, while fully recognizing that this case is a close one, the court enters judgment in favor of Cook and against EMMC.

In order to establish a claim for medical negligence, the plaintiff must demonstrate the applicable standard of medical care, a departure from that standard and a causal connection between that negligence and the claimed damages. *See Ouellette v. Mehalic*, 534 A.2d 1331, 1332 (Me. 1988).

Several evidentiary issues remained outstanding following the trial. First, although a question arose concerning the measure of damages for medical expenses claimed in this action, the parties ultimately stipulated to the amount of those expenses, which are set out in a written stipulation filed on September 29, 2009. Second, EMMC

[1] The court has had this matter under advisement for longer than anticipated. The court thanks the parties and counsel for their patience during that period of time.

offered into evidence the transcribed testimony of James W. May, Jr. M.D. *See* defendant's exhibit 10. Cook objected to the exhibit on relevance grounds. The court has reviewed that transcript and admits the testimony over objection. Although May did not form a firm opinion about the cause of Lavway's injury, that he was unable to do so has some probative value.[2] Finally, Cook offered and the court admitted, over EMMC's objection, three notebooks containing medical records. *See* plaintiff's exhibits 3, 11 and 19. In assessing the evidence in this case, the court has referred only to those portions of those exhibits to which the parties themselves referred during trial. This includes records associated with Dr. Branch's examination of Lavway and several Maine Medical Center records relating to the procedure later performed by Dr. Atwood.

The central factual dispute in this case concerns the manner in which members of EMMC's nursing staff administered dopamine to Lavway. Dopamine is a medication used to improve the patient's cardiac and renal functioning. For those reasons, it was prescribed for Lavway following cardiac surgery performed on September 2, 2003. Dopamine, however is caustic. When administered intravenously, it can injure or destroy tissue if it extravasates, or leaks, into surrounding tissue. There is little disagreement between the parties that the standard of care calls for the provider to introduce dopamine into the patient through a central intravenous line, called a cordis, instead of through a peripheral line attached to the patient's arm. In fact, a cordis was inserted into Lavway's jugular vein, and that cordis was available to medical and nursing staff throughout the times relevant to this case. The use of a central intravenous line creates several important advantages over the use of a peripheral line. Most importantly for purposes of this action, the use of a cordis reduces the risk of damage to surrounding tissue. A cordis is secured to the patient more securely than a peripheral line, because it can actually be sewn to the patient's body. Also, compared to a peripheral line, the patient's movements are less likely to disturb the position of the central intravenous line and the integrity of its connection to the patient's body. In these ways, a cordis reduces the likelihood that the

[2] In the end, the court gives Dr. May's testimony no meaningful weight, largely because of his relative lack of experience dealing with dopamine extravasation injuries and because, as Cook argues, he did not form an opinion about the cause of the injury. This latter issue does not preclude the admissibility of his analysis, but it mitigates against its value.

dopamine will extravasate into tissue surrounding the IV site. Additionally, because a cordis provides a pathway into a blood vessel that is larger than ones used with peripheral IV lines, the medication becomes diluted and distributed into the patient's bloodstream more efficiently.

There are several circumstances where it is not inappropriate to administer a vesicant such as dopamine through a peripheral IV line. For example, in an emergency situation where a central line has not been inserted into the patient, use of a peripheral line is proper. Further, if the provider is able and willing to maintain a high level of vigilance to make sure that a peripheral line does not become displaced, then use of such a peripheral line may be an arguably acceptable medical practice. However, for the reasons set out below, none of these circumstances arose in Lavway's situation. Therefore, the standard of care, and proper nursing practice called for the introduction of the dopamine through the cordis.

In the event of a dopamine infiltration into surrounding tissue, one proper response is with the use of the medication Regetine. In fact, at the time of Lavway's admission, EMMC had Regetine protocol in place to be implemented in that situation. *See* plaintiff's exhibit 10. The evidence demonstrates that this protocol was proper. Under that protocol, the Regetine is to be used as soon as the extravasation became known but subject to an outside limit of twelve hours following the infiltration event. *See id.*

This evidence, which is not materially disputed, constitutes the background for Cook's contested liability claim. During the course of her admission in the CCU, Lavway developed a significant injury to her left forearm, which was the site of a peripheral IV. The essence of the parties' dispute is whether, as Cook alleges, that injury resulted from a dopamine infiltration, or whether, as EMMC contends, a cordis was used for the dopamine and the arm injury had some other non-actionable origin, such as a hemotoma.[3]

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[3] Cook also appears to be pursuing a claim that EMMC was negligent because of alleged shortcomings in its requirements for nursing records relating to medication administration. For example, Cook's expert criticizes EMMC for not imposing a requirement that the medical charts specify which IV routes were used for particular medications. Even if EMMC did not meet the standard of care for record-keeping, it

Lavway underwent the cardiac procedure on September 2, 1993, and was transferred to the CCU for recovery. The CCU has a small number of beds, with a nursing staff of no more than two patients per nurse. The nurses work in twelve-hour shifts from 7:00-7:00. Dopamine was first administered to Lavway beginning at 9:00 a.m. on September 3. *See* plaintiff's exhibit 6 and defendant's exhibit 5. (On the nursing flow sheets, such as plaintiff's exhibit 6, medications are referenced on page 1 and page 8. The latter page provides information about the period of time when a medication is administered and its dosage. The columns with letter headings correspond to the key at the top of the page, which lists the medications in use.) Lavway continued to receive dopamine until mid-afternoon on September 3. *See* plaintiff's exhibit 9.

Dean Harrison was the nurse primarily responsible for Lavway when she was received in the CCU on September 2. Although the nursing flow sheets reveal when Lavway received dopamine, they do not specify the insertion location of the IV used for that medication or any of the other medications prescribed to her. *See* note 3 *supra*. Until early the next morning, Lavway had at least three IV sites: the cordis in her jugular vein, a peripheral line in her right forearm, and a peripheral line in her left forearm, which is the location of the injury that is the focus of this suit.[4] The two peripheral lines were both 14 gauge, which is a relatively large bore tube. Because the record does not reveal which line was used for the dopamine during the period of the alleged infiltration, the court and the parties are left with the memory of the attending nurses, whose memories of the care they provided to Lavway are faint or non-existent (which is fully understandable because of the lapse of time), and with evidence of the routine procedures used by those nurses.

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could not be held liable for such a failing, because the absence of more detailed information in the nursing records was not the legal cause of any injury to Lavway. Those omissions from the record may affect the parties' ability to reconstruct events and, for the plaintiff, to prove her claim here, but EMMC cannot be held liable for any damages based on this issue.

[4] She also was received in CCU with an arterial line, which Harrison removed during his shift. Lavway also had a swans gans catheter, which can measure internal pressure values. Harrison removed the catheter. It is not clear to the court whether the catheter was part of the cordis system or a separate unit. The arterial line and catheter are not material to the claims here.

Harrison noted that during his shift, Lavway was "[i]mpulsive" and tried to "get up on her own." Lavway also did not understand restrictions on her activities and movements required of post-operative patients. *See* plaintiff's exhibit 6.

Jennifer Yanofsky followed Harrison as Lavway's primary CCU nurse, beginning her shift at 7:00 p.m. on September 2. When she began her shift, Lavway was still attached to three IV lines: the cordis and the two peripheral lines. Lavway also had a drain inserted in her leg. During a portion of the evening, Lavway was sitting up in bed, experiencing incisional pain. Yanofsky gave her Percocet. Just prior to midnight, Yanofsky saw that Lavway was "picking" at the leg dressing that covered the drain. *See* plaintiff's exhibit 6. In fact, Lavway was able to remove the drain before Yanofsky could intervene. The evidence indicates that the drain is of a significant size and difficult to remove. Lavway also was moving about by using her arms, to which the peripheral lines were attached. Yanofsky tried to explain to Lavway the importance of restricting her movements. Nonetheless, as is shown by Lavway's removal of the leg drain, it is evidence that Lavway continued to be defiant and too active.

The weight of the evidence suggests that at approximately this time, dopamine began to infiltrate into the tissue on Lavway's left arm proximate to the peripheral IV site.

The next activity noticed by Yanofsky occurred at 3:00 a.m. on September 3, when Lavway was awake and agitated. She acted impulsively and tried to pull herself out of bed. She was belligerent when the "staff," which presumably included Yanofsky herself, tried to dissuade her from moving about that way. Lavway then pulled out the IV from her left arm, "because," Lavway explained, "I wanted to." *See* plaintiff's exhibit 6. Because it appears that the dopamine had been administered to Lavway though the IV tube that she removed shortly after 3:00 a.m., the extravasation ended at that time. However, according to the nursing flow sheets, Lavway continued to receive dopamine after 3:00 a.m. This means that Yanofsky or another attending provider must have connected the line used for the dopamine to another IV site. As is noted below, the evidence demonstrates that this is an easy procedure. Lavway slept intermittently for the next few hours. At 6:30 that morning, she remained "very impulsive," *see id.*, and pulled out the IV line attached to her right arm. Lavway had now forcibly removed both

peripheral lines, and so only the central line remained attached to her. Lavway also removed all dressings from both arms and from her leg, where the drain had been attached. The nursing records indicate that Lavway even tried to remove staples, which may refer to the surgical incision in her chest.

Because Lavway was so agitated and uncooperative, Yanofsky called Lavway's sister, plaintiff Cook, who was staying nearby, along with her daughter (Lavway's niece), Sirena Bennett. Bennett volunteered to go to the CCU and, arriving at Lavway's bedside, found Lavway to be out of control. She had blood on her, she was sitting on the side of the bed, and she was screaming at the nurses, using profanities. Lavway did not recognize Bennett, although the two were close and had frequent contact. Bennett eventually was able to calm Lavway down. Bennett and Cook, who arrived later, stayed with Lavway through the day. At 7:00 a.m., Nurse Wendy Arno relieved Yanofsky in the CCU. The dopamine was discontinued at 3:00 p.m.

During the afternoon of September 3, Lavway began to complain about pain in her left forearm. Although Lavway tended to have a high pain threshold, the pain developed to the point where Lavway rubbed her arm continuously and where it caused her to cry. Sometime during the late afternoon, Arno looked at Lavway's left arm and saw, as she noted, that it revealed the visible symptoms of an "IV infiltrate." *See* plaintiff's exhibit 9. Arno also wrote that "there has not been one." She testified that in this written note, she intended to report that the condition of Lavway's arm appeared to her as the site of an IV infiltrate except that there was no IV present. The situation was of enough concern for Arno to call a physician, Dr. Hernandez, for a consultation. Dr. Hernandez examined Lavway's arm near the end of Arno's shift but did not order any medical intervention, except possibly for the application of warm packs.

The pain in Lavway's left arm continued into the evening, and at 7:30 p.m., she complained that "[i]t hurts bad." *See* plaintiff's exhibit 9. From the nursing noted entered that night, it appears that the pain may have waned at times, although at other times the attending nurse gave Lavway medication to relieve the pain. (Although the notes are not easy to read, they appear to indicate that the nurse gave Lavway Percocet.) Lavway remained confused and combative.

Several physicians were called in to assess Lavway's arm over the next several days. On September 7, a physician (whom Harrison identified as a Dr. Pietro, although the signature on the resulting physician progress note is not legible, *see* plaintiff's exhibit 8) "suspect[ed]" an IV extravasation. Dr. Branch examined Lavway two days later and concluded that Lavway had suffered an "[i]ntravenous infiltrate of the left forearm with what appears to be a subcutaneous small hemotoma." *See* plaintiff's exhibit 7, defendant's exhibit 4. By then, Lavway had developed an eschar at the site of the injury. An eschar is a hardening of the skin, which, for Lavway, involved all layers of the skin. It was surgically removed at Maine Medical Center on October 5. Significantly, on September 7, Dr. Branch prescribed Silvadene, which is a topical medication used to treat chemical burns. It is not used for hemotomas.

As is noted above, Cook alleges that the dopamine was administered to Lavway through the peripheral IV line attached to Lavway's left arm, that there was a dopamine extravasation, and that Lavway was injured as a result. EMMC's principal contention is that the CCU nurses exclusively used the cordis for the dopamine and that the arm injury therefore could not have been caused by that substance. As the court has also noted above, this is a close case because, although EMMC does not bear the burden of proof, there is legitimate affirmative evidence to support its contention. That evidence consists of two main points. First, the relevant attending nurses all professed to know and follow the standard of care, which prescribes that in the circumstances at issue here, a vesicant such as dopamine should be given to the patient through a central line because of the advantages of central line administration and the risks of peripheral IV administration. And in this case, there was no reason to administer the dopamine through a peripheral IV line. Indeed, it seems clear that even under Cook's theory of events, dopamine was administered to Lavway through the central line as early as 3:10 a.m. (when Lavway pulled out the first peripheral IV line, in her left arm) and no later than 6:30 a.m. (when Lavway pulled out the second peripheral IV line) on September 3. It is easy for a trained professional to switch a peripheral IV line to a central line – just as it is easy for a trained professional to switch an IV from a connection to central line over to a peripheral line.

The second and even stronger point supporting EMMC's argument is that the symptoms of a dopamine infiltration did not become evident until many hours had passed

after the alleged extravasation would have ended, which was no later than 3:10 a.m. on September 3, when Lavway pulled out the IV line at the location of the injury. In the case of a dopamine infiltration, the affected area is often swollen, blanched and cool at first, and then it becomes red. Also, the infiltrated area will become painful. Here, neither of the nurses who attended to Lavway noticed any signs of an infiltration until late afternoon on September 3. Lavway's niece, Bennett (who is trained as a CNA), helped clean the blood off of Lavway's arms and did not notice anything unusual, although she was observant enough to notice the hole where the IV had been inserted. Also, shortly after noon on September 3, Nurse Lori Strout assessed Lavway to determine if she was a good candidate for a PICC line, which is another type of IV. *See* defendant's exhibit 3. Strout is a resource nurse at EMMC who had particular training in IV use and management. Strout saw that Lavway had some areas of bruising on her arms and skin tears where the IV's had been used but, despite this examination, did not see the usual signs of a dopamine infiltration. Further, the records do not contain reports that Lavway complained of pain in her left arm, until approximately 5:00 p.m. on September 3. *See* plaintiff's exhibit 9.

The court has weighed this evidence, and, even though it is significant, it is outweighed by contrary evidence that the injury was caused by a dopamine infiltration. Cook's allegation of an extravasation finds strong support in the diagnostic evidence of several medical providers who were able to examine Lavway's arm directly. The earliest such report came from Arno, who knew the symptoms of an infiltration and could distinguish it from a hemotoma, which EMMC argues was the nature of the problem. Although Arno became defensive on the point during her trial testimony, she finally acknowledged that the physiological symptoms she saw matched a dopamine infiltration. The reservation she noted in her written record (". . . though there has not been one [an extravasation]") was based on the fact that, at the time, Lavway was not connected to an IV at that site. Nonetheless, the matter appeared to be sufficiently serious that she called in a physician, Dr. Hernandez, for a medical assessment. The parties have not pointed to any aspect of the medical record consisting of an independent report or note from Dr. Hernandez. It does appear that Dr. Hernandez did not take any action. However, the Regetine protocol was no longer an option because the IV line had not been used on

Lavway's left arm for more than fourteen hours, and so there may not have been any available treatment that Dr. Hernandez could have ordered.

Four days later, a different physician (Dr. Pietro, according to Harrison) examined Lavway and came to suspect that the injury was caused by an IV infiltration (rather than a hemotoma) and referred the matter to a specialist. That specialist was Dr. Branch, a plastic surgeon, who concluded that the injury was caused by an intravenous infiltration, although he also found an apparent small hemotoma. Importantly, he prescribed applications of Silvadene, which further confirms the nature of his opinion that Lavway had sustained a chemical burn rather than mere subcutaneous bleeding.[5]

Lavway underwent a debridement procedure on October 5. That procedure was performed by Dr. Attwood at Maine Medical Center. Dr. Attwood's testimony was presented in transcribed form. Although Dr. Attwood's treatment of Lavway did not focus on diagnosis or forensic issues, the condition of Lavway's arm injury was suggestive of an IV infiltration. Beyond this, he did not observe features of the injury that would suggest that it was a hemotoma. For example, Dr. Attwood did not observe coagulated blood, which he would expect to have found even a month after Lavway sustained the injury. The court places weight on this analysis.

The record contains several other references to a history of an extravasation. Such references are found, for example, in the EMMC discharge summary and in the physician's note prepared by Dr. Crofoot, who performed a skin graft on Lavway. The basis for the diagnostic information in those reports is not entirely clear, and so the court does not give that evidence significant weight.

Beyond the assessments of Nurse Arno and Drs. Pietro, Branch and Attwood, Arno's written note of an injury resembling an IV infiltration corroborates testimony presented by Bennett and Cook. Both stated that several days after September 3, they heard several nurses, whom they could not otherwise identify, state that Lavway's injury

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[5] In Dr. Branch's report, *see* plaintiff's exhibit 7, he refers to a "dobutamine" infusion. Dobutamine is a different medication from dopamine. There is no evidence that Lavway was prescribed the former. Because of the similarity of the words, the court attributes this reference to a stenographic error that does not affect the substance of the resulting diagnosis.

may have been caused by dopamine.[6] This evidence is significant for several reasons. First, although the specific basis for that conclusion is not revealed in this record, it appears to represent the assessment of trained observers who were in a position to have some knowledge, direct or indirect, about the situation. One would not expect EMMC employees in that position to make such remarks casually, particularly within earshot of the patient's family members. Second, it tends to demonstrate that despite the standard of care, which provides that except in unusual circumstances, dopamine should be administered to a patient through a cordis, there are instances when that standard of care is not followed. The evidence indicates that CCU patients usually have a central line implanted in them. For one or more CCU nurses to accept the prospect that Lavway was injured through a dopamine extravasation in her arm suggests the recognition that a cordis is not uniformly used for that medication.

The accounts of Lavway's demeanor during the relevant period of time leading up to her removal of the left arm IV also support Cook's claim here. The evidence reveals that a slow leak of IV fluids can develop if the patient moves around in a way that affects the placement of the needle in the receiving blood vessel. Here, Lavway engaged in a number of episodes of unruly and aggressive behavior during the day on September 2 and into the night. She was combative, confused and defied instructions by the nursing staff to restrict her movements. She was sufficiently active to be able to pull out the drain from her leg, which was a difficult maneuver. This created the opportunity for an extravasation.

Lavway's behavior also invoked a standard of care that required the nursing staff to use the central line as the means to administer the dopamine to her. As is noted above, there may be circumstances where, even if a central line is available, it is reasonable to use a peripheral line to administer a vesicant. Absent an emergency, such a circumstance, however, requires the patient to be someone who is quiet and whose behavior will not create an unreasonable risk that the peripheral IV might become dislodged or allow the medication to leak into surrounding tissue. Lavway clearly was not such a patient on September 2 and 3, and because of the nature of her behavior,

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[6] Cook's account of that conversation is the stronger of the two. She reports that one nurse told another that Lavway had dopamine in her arm.

reasonable nursing practices would not accommodate the use of the peripheral IV for the dopamine.

Finally, the court places some weight on evidence about the way Lavway's right and left arms healed after she pulled the IV lines from them. The circumstances of the two injuries were comparable: the general locations of the two IV sites were the same, and the needles were the same size. In fact, the resulting immediate trauma to the right arm was at least as significant as the tear to the IV site on her left arm. However, Lavway's right arm healed unremarkably. The left arm did not. The evidence suggests that the difference in those injuries is attributable to an outside factor, which is consistent with an infiltration.

For these reasons, the court finds that based on the totality of the record, the better explanation for Lavway's injury is a dopamine extravasation. The court acknowledges the existence of good arguments to the contrary pressed by EMMC. However, for some period of time prior to 3:15 a.m. on September 3, dopamine was either administered to Lavway through the peripheral IV line located in her left arm, or it was not. The delay in the onset of symptoms gives the court pause. Some of the initial symptoms may have dissipated in a subtle way. For example, because Lavway did not have much muscle mass in her arm, the swelling that normally accompanies an IV infiltration at the outset may not have been apparent. Further, because she was in such a confused and agitated state during some of the time after she pulled out the IV in her left arm, one can question her capacity to meaningfully report pain. She was able to do so later in the day on September 3, but she was badly incoherent for other parts of the day. In the conventional course, however, other objective symptoms would be noticeable. However, it is noteworthy that although Arno did not report symptoms until late afternoon on September 3, she also did not make note of injuries to Lavway's arms as observed by Strout mid-day on September 3. This may call into question the extent of Arno's written observations. Nonetheless, one would have expected reports that line up with the conventional progression of an extravasation injury. Yet, despite this and the other factors noted above, the greater weight of the evidence supports Cook's allegation that EMMC failed to meet the applicable standard of care and that this breach was the legal cause of injury to Lavway.

After Lavway was discharged from EMMC on September 10, she had ongoing problems with her left arm. It was painful, swollen, and the skin continued to harden. Lavway had several appointments with Dr. Branch. At the end of September, she was admitted to Maine Medical Center for several medical problems. Dr. Attwood debrided the arm injury through a surgical procedure performed in early October. Dr. Attwood's testimony shows that by the time he performed the surgery, the pain had largely subsided. Nonetheless, the procedure was warranted. At the end of October, a different physician grafted skin taken from Lavway's leg onto her left arm. *See* plaintiff's exhibit 17. Lavway's arm healed well from that course of treatment. However, she had some ongoing problems because the affected skin was tight, and she lost some strength in that arm. The treatment also left her with a substantial scar.

The ongoing effects of the arm injury were certainly not the only medical problems that Lavway faced until her death in April 2008. She suffered from congestive heart failure and other coronary problems, diabetes, and reflux disease. These conditions limited her activities and can only have affected her life profoundly. Nonetheless, the injury caused to her arm contributed in some measure toward those limitations, and the injury also caused her pain at first and then, after further treatment, a lesser level of discomfort. The scar was permanent.

The parties have stipulated that the reasonable and necessary medical expenses incurred attributable to Lavway's arm injury amounted to $21,719.

Based on this evidence, the court awards damages of $60,000.

The entry shall be:

For the foregoing reasons, judgment is entered for the plaintiff in the amount of $60,000, plus pre-judgment interest at the annual rate of 5.36%, post-judgment interest at the annual rate of 6.41%, and her costs of court.

Dated: October 19, 2010

Justice, Maine Superior Court