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AL MARGE VENES SEA STATE REPORT

Good afternoon, members of the jury. The evidence in this case will show that hospitals cannot expose a patient to an unreasonable risk of injury. If a hospital's doctor chooses to expose a patient to an unreasonable risk of injury the hospital is responsible for the harms and losses caused.

In this case, who are we suing and why? We are here to hold the hospital, University of Maryland Medical Systems and Dr. Burks who's at the trial table responsible for giving Mr. Allen a drug which caused his suffering and death. And I represent the Estate of Mr. Allen, his wife and all his children.

During the course of the trial you may hear medical terms. That's why Your Honor said don't google

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these terms because we're going to explain the terms to you and the terms you will hear are hyperkalemia. Hyperkalemia is a fancy medical term, the doctors will explain it. What it means is it's a patient with elevated potassium levels.

Potassium is a chemical that exists in the blood. When the potassium levels rise too high it interferes with the way the heart beats. The heart has to beat properly in a sequence in order so the heart muscles can squeeze so it can push the blood through your body. Elevated potassium levels interfere with that and can cause a potentially life-threatening situation.

Bialysis. Most of you know what dialysis is. Hemodialysis is where a patient whose kidneys are unable to filter the blood efficiently, a person is hooked up to a dialysis machine and the dialysis machine takes the impurities out of the blood and puts the clean blood back into the patient.

In this case, dialysis will be used to remove elevated potassium levels from Mr. Allen's blood when he was in the hospital. This is not Mr. Allen (indicating). This is just a patient and this is a dialysis machine. Dialysis is done every day in hospitals throughout the state of Maryland at University of Maryland Medical Center. There's a little diagram. In this case, Mr.

Dialysis (sic) already had -- Mr. Allen had dialysis on his chest, but oftentimes, they put it in the arm. It goes through a pump. It goes through a filtering device. The waste is taken out and the clean blood is put into the patient. Usually it takes two to three hours. And the best part of dialysis is it's safe. It's used every day.

Medical terms. Intestinal necrosis is a term you will hear throughout the trial. Intestines have to do with your bowels. Necrosis simply means dead tissue. And the bowel that we're talking about in this case is Mr. Allen's colon. This is a picture of a healthy colon (demonstrating.) It's not Mr. Allen's colon. It's just a representative picture. And this is a picture of a necrotic colon and this is what happened in this case and I'll tell you why.

Kayexalate is a drug. Her Honor mentioned that to you in opening to see if any of you knew about it. The doctors will explain and the evidence will show that Kayexalate is a liquid that you drink. It's also mixed with a chemical that's called Sorbitol. It's mixed with sorbitol so it can go through your intestines and remove the potassium from the blood. There;'s a number of ways to do it.

In 2009 and 2011, the Food and Drug

Administration issued a warning, a labeling warning that must go with this drug. Those labeling warnings warned of intestinal necrosis which is tissue death and bowel perforation which are known leading complications of this drug.

The symptoms of intestinal necrosis and bowel perforation are abdominal pain and a bloody stool. They have bloody diarrhea that occurs because the intestines are being eaten away from the inside out the evidence will show due to the Kayexalate and the sorbitol.

Kayexalate and sorbitol our experts and our doctors will tell you it's used only as a last resort to remove potassium when dialysis is not readily available. If dialysis is available, you don't need to give the patent Kayexalate.

And this is just an illustration of the human body. There's the liver (indicating.) There's the stomach (indicating.) There's the small intestines (indicating) and there is the colon (indicating.)

In this case, the doctors will tell you how Mr. Allen's colon was destroyed by the Kayexalate that was given by Dr. Burks. This is a cross section of the colon (indicating) and the colon, these are very thin linings. These linings are supplied by blood vessels because every organ in the body needs blood to survive. That's how the

colon can live. The blood goes to the colon. It supplies the oxygen to the colon.

Potassium. I told you the elevated potassium gets into the bloodstream. In this case, it was in Mr. Allen's bloodstream due to a condition called rhabdomyolysis and I'll explain that in a minute. What happens is when you drink the solution, it goes into the colon and through a chemical process it draws the potassium into the colon so it can go out of the body when we have a bowel movement. That's how the body (indiscernible at 2:32:0) when you drink Kayexalate. It all happens inside the intestines and the colon. Unfortunately, a known complication and when the Kayexalate and sorbitol are not absorbed, they go out when you have a bowel movement. And unfortunately, the known complications are and this is another term you'll hear, mucosal ulcerations.

Mucosal is simply the lining of the colon. What happens is when Kayexalate goes through it causes these blood vessels to constrict. It reduces the blood and then (indiscernible at 2:33:36.) And then you have bleeding and then you have a destruction of the colon which happened in this case. And you have the eroded colon wall. And in this case, there were Kayexalate crystals found within the colon. And the experts will

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testify this is what caused Mr. Allen's intestinal necrosis.

Now, Ms. Yeung is employed by the University of Maryland Medical Systems. She's a pharmacist and she's sitting right here in the second row. She will be the first witness that we will call and Ms. Yeung's job at the pharmacy at the hospital was to develop hospital guidelines for this very condition. Her and her team developed these guidelines. And the guidelines were based upon the literature that was available and she looked for expert opinions from pharmacy specialists at the hospital, physicians committee at the hospital, nephrologists at the hospital, therapeutic committee at the hospital and in accordance with the best practices of medicine. She developed the guidelines for the treatment of hyperkalemia.

And these guidelines that the hospital published and had available to any doctor who was working there said and you will see the guidelines, major complications of sedium polystyrene sulfonate, a fancy word for Kayexalate, major complications: Intestinal necrosis and bowel perforation. Exactly what happened in this case. The hospital knew about it before Dr. Burks administered the drug to Mr. Allen.

Now, on March 13, 2013, Mr. Allen's cholesterol

medication was changed by the hospital. They changed his medication because he was having kidney issues. He was at end stage kidney stage and end stage liver disease. He needed both a kidney and liver transplant. They were trying to manage his condition. They changed his medication to (indiscernible at 2:35:46) kidney function.

On March 10th, he was admitted to the Northwest Hospital with rhabdomyolysis. That means that the medication they gave him was breaking down the muscle tissues in the body. When muscle tissues break down potassium rise. That's how the excessive potassium got in his body.

And I know I may be going a little bit too fast because the doctors will explain this to you in great detail but that's how this happened.

On March 11th, he was admitted to University of Maryland Hospital. And Dr. Burks became Mr. Allen's attending physician. He was responsible for the care while he was there at the hospital from the time he was there. Mr. Allen had hemodialysis. Mr. Allen had hemodialysis on four days; Thursday (sic), Wednesday, Thursday, Friday, Saturday. He did not have hemodialysis on Sunday. What happened the next day was stunning and is why we're here.

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The next day on March 18th, Dr. Burks arrives

for his 7:00 a.m. shift. No blood was drawn from Mr. Allen that morning. Dr. Burks ordered a morning blood draw for Mr. Allen. The reason the doctor needs the blood test results is because when pathologists come by te determine whether someone needs dialysis they look at the blood tests, what's going on with the patient's body and that's how they know.

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Well, Mr. Allen didn't have a bloed drawn that merning. And at 12 c'clock neen he developed an irregular heartbeat. Remember I told you that potassium causes an irregular heartbeat. That's exactly what happened at 12 c'clock neen. New, Dr. Burks is faced with an emergency situation. So he has to new (indiscernible at 2:37:42) an emergency and he orders medication. He did order medication, three medications that were proper for the treatment of his heart condition. However, hemedialysis takes the potassium out. When the potassium drops the heart goes back to normal. But he also ordered Kayexalate and sorbitol and this is what he should not have ordered for Mr. Allen in this case.

What happened within approximately 14 hours after Mr. Allen was administered the Kayenalate with the sorbitel the dectors we had two bewel movements during

dialysis because right after they gave him Kayexalate he was in dialysis. He was supposed to get dialysis and that was proper. However, Kayexalate causes the bowel movement because that's how the potassium gets out of the system but he developed abdominal pain. He developed bloody stools.

Remember I told you abdominal pain and bloody stools were the classic symptoms of intestinal necrosis. His bowel started to die that evening. He had eight more bowel movements after the dialysis. These are all signs and symptoms of intestinal necrosis. Mr. Allen's bowel was dying inside of him because of the drug that he was administered.

What Mr. Allen experienced and the estate is named as a party in this case. The estate is named because Mr. Allen can't be here to say how horrible this was. The estate is in his place. However, you will hear evidence of what he experienced from testimony, from the medical chart, and from all the family who were there, his wife, Ms. Allen was there, every single day of his (indiscernible at 2:39:41). She was at his side every single day.

Intestinal bleeding and bloody stools. Ten bowel movements in 14 hours. Abdominal pain. Mr. Allen was crying out in pain. This is a man who his family in

35 years never saw him experience fear. They never saw him cry out in pain, never. This was serious. And they also because he had so many bowel movements they decided to put a rectal tube through him even though his family was there cleaning him up after every bloody bowel movement. The nurses weren't doing it, his wife, his sons were cleaning him up but then they put a rectal tube in him. He was transferred to the ICU on the next morning.

From the records that you'll see it looks like the first time pain medication was given to Mr. Allen was on March 19th at about two o'clock in the afternoon. He was in all this pain the entire night, the entire night suffering and dying.

On March 19th, Dr. Burks comes back. He gets off duty seven o'clock the night before. All this bloody stool and abdominal pain happened during the 7:00 p.m. to 7:00 a.m. He comes in in the morning and realizes what has happened and tells the family. Ms. Allen has been there the whole night. She witnessed the horrific suffering. Tells the family I'm sorry. I made a mistake. I gave your husband Kayexalate that caused injury to his colon, however, we caught it in time. We'll have to go surgery. We'll only be there for an hour or two and he'll be okay.

So Dr. Burks told the family made a mistake, but don't worry. He's going to be okay.

This is the last time Dr. Bucks spoke to this family. And you can imagine what happened the next day. Surgery. Let's go back to March 19th. Surgery takes seven hours, not one or two. His entire colon is removed. They left him open. What did the surgeon tell the family? Fray. Mr. Allen dies the next day with his (indiscernible at 2:42:23.)

New, what happened in this case is medical malpractice, but under Maryland law, we call it medical negligence. It's the same thing. The healthcare provider the evidence will show is negligent if the healthcare provider does not use the degree of standard of skills which a reasonably compatent healthcare provider engaged in a similar practice acting under a similar circumstances would use.

And that's a lot of fancy legal talk and it simply means Dr. Burks is negligent if he didn't use the care that a similar doctor such as him would use for treating Mr. Allen, he's negligent and he's responsible for the harms and the losses that it caused and the evidence will show that he is.

In this case, there's two allegations of negligence. One, he breached the standard of cars by

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ordering and administrating Kayexalate. The second most important claim, it's distinct, it's two separate. You will be deciding two separate acts of negligence.

The other act of negligence is that the hospital's doctors failed to obtain Mr. Allen's informed consent before administering Kayexalate sorbitol. And you might have heard the term "informed consent." If you've ever been to a doctor and had a procedure the doctor has to tell you what the procedure is about. They have to tell you what the risks are and the alternatives because then you have to decide as the patient whether you're going to accept those risks and undergo the procedure.

In this case, these are the elements of informed consent. You have to reveal the nature of the element, what the problem is. Dr. Burks failed to do that. Reveal the nature of the procedure. He failed to do that. Reveal the probability of success. How successful this Kayexalate would reduce potassium. He never did that. Reveal the alternatives. He never revealed the alternatives to Mr. Allen. And he didn't reveal the material risks. Material risks is something a reasonable person would find important they need to know when making a decision regarding accepting medical care.

And I asked Dr. Burks in his deposition did he

have this type of discussion with Mr. Allen. He said no. Questions we've asked before we brought this case to you. We had a couple questions we wanted answered. A big question was, did the Kayexalate cause Mr. Allen's intestinal necrosis?

This is Dr. Burks discharge summary for Mr. Allen (indicating.) One of the differential diagnosis that he rendered to Mr. Allen was, "Intestinal ischemia due to concomitant Kayexalate." It simply means caused by the drug. And that's Dr. Burks own writing. He wrote' this in the chart, Hospital critical care unit by the doctor. A critical care doctor examined Mr. Allen and found "necrosis due to Kayexalate."

There it is again. A hospital surgeon's report. The medical intensive care unit pointed out that the patient had received Kayexalate the night before. There were several case reports of necrosis level ischemia. Those are the fancy words that I told you. It simply means the colon is being eaten alive. Case reports. There are reported cases of this and he knew about it. And here's the hospital's autopsy from the dector who looked at the issues. "They may be suggestive of Kayexalate colitis. Colitis is the same destruction of the colon."

All throughout the chart they mention

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Kayexalate and they mention the association between the Kayexalate and what happened to Mr. Allen in this case.

And these are the pathology slides (indicating.) We had a pathologist look at the slides and they found from the tissues from the colon that was removed from Mr. Allen that Kayexalate crystals are right there in the tissue and this is dead issue and they will explain that to you. These are the dectors that will explain (indiscernible at 2:46:40) called to this trial and you will hear from them. Dr. Odze. He's a board certified pathologist. Here's what Dr. Odze says about

MR. GASTON: Thank you. Well, then what I would do -- you will hear testimony from the experts in this case, from three experts, Dr. Odze who is a beard certified pathologist, Dr. Lee who is beard certified in critical care medicine and internal care medicine and Dr. Goldstein who is a colon rectal surgeon.

These doctors, particularly Dr. Odze, Goldstein and Leo will testify that in their opinion that Kayexalate caused Mr. Allen's intestinal necrosis. You'll hear that from those witnesses in this trial.

Also, was Kayexalate urgently needed or even necessary? It wasn't urgently needed and it wasn't necessary and here's why. This is the order that Dr. Burks placed for Kayexalate. Routine priority. He didn't order it by a stat basis. He did not order it on an emergency basis.

And we found the hospital guidelines that define what routine is which means if you order routinely how long do they have to give it to the patient? The hospital guidelines say that for routine medication the dose will be available in the patient care area within two hours of the order being received by the pharmacy. So the pharmacy has two hours to get it to the patient.

Dr. Burks had to know that when he ordered it routine, so it wasn't urgent. It wasn't urgently needed. That's important because the Defense is going to claim he had to give it to him right away when it wasn't ordered urgently and they had two hours to administer it.

Also, it wasn't even necessary. The heart condition by that time was under control. The cardiac

alarm monitor that went off to notify Dr. Burks that there was a problem after he gave the initial medications it didn't go off anymore. It wasn't going off when the nurse came in and gave Mr. Allen (indiscernible at 2:49:06.) It was not. His heart condition was under control. He has no immediate effect on potassium levels.

And this is extremely important because the hospital guidelines and you'll see those and you'll hear from Ms. Young who is sitting behind me testify that for Kayexalate it doesn't start working for two hour and the duration of action isn't for another four to six. And this is the known complication, intestinal necrosis and bowel perforation. It's right on the guidelines. It doesn't work for two hours and there's no need to give it to him.

Mr. Allen's kidneys were already weak. He was in end stage kidney disease. He needed a transplant. And according to the FDA patients who have renal insufficiency that's what a bad kidney means, renal insufficiency, they're at risk for this exact type of complication. Dialysis is already on the way. They also started to immediately (indiscernible at 2:50:18.)

In order to write dialysis they ordered the inappropriate drug. There's no need for Kayexalats. It's only when it's the last resort. Was he going to die

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anyway? The Defense is going to ask you to believe that Mr. Allen was going to die anyway. And you will hear our experts, first off, if he's going to die anyway did he even == was he in the critical care physician in the hespital? I asked Dr. Burks. Did he have a need for a critical care physician before the 19th? And he's what Dr. Burks said. It's Page 28, Line 16 to 18 of his deposition,

(Video was played for the jury.)

(Video playback was stopped.)

MR. GASTON: They're claiming he's critically ill. He's going to die anyway. Even if he made a mistake, it didn't matter. Dr. Burks didn't find he was critically ill and Dr. Burks didn't seek consultation from a critical care physician.

Now, this is why we're here. This is Dennis Allen and this is his wife (indicating.) Mr. Allen was the founder and a pastor of his church. Shore Foundation Christian Ministry. And during the time of his life he and that of his wife who is taking over as the pastor started this ministry and started this church. Ne devoted is life to God and it happened 35 years ago. Before 35 years ago Mr. Allen was not making very good choices in his life. His wife will tell you that she met him 36 years ago. They went and found the Lord and

changed his whole life. His whole life changed. And this is some of his family (indicating.) And these are his children (indicating), Amanda and Sherrie who are in the courtroom (indiscernible at 2:52:29). Ruth who is also in the courtreom and that's her (indicating) and this is Daniel. The reason that Dennis and Daniel are dressed in religious attire is because they are ministers at the church that their father founded. Donna, another daughter. Sarah, another daughter. Cynthia, his wife. And pop and Shelly (indicating.) Shelly. Mr. Allen considered Shelly is daughter in every possible way even though Shelly was not his biological daughter. But he called her his daughter and Shelly called him his father (indiscernible at 2:53:19.)

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Now, in this case Your Honor will explain what the burden of proof is. And it's called a fancy word by a preponderance of the evidence. Lawyers make up fancy words just to feel important. We do it all the time. But preponderance of the evidence simply means we have to tip the scales. It's not like beyond any reasonable doubt in a criminal case. We just have to prove. And I believe Your Honor will instruct you at the end of the case, in order for us to prevail more likely than not the Kayexalate caused Mr. Allen's necrosis and caused his death and that is the elements of the burden of proof for

us.

Now, we are here for compensation for all the harms and losses caused by the hospital's negligence due to the doctor. It's called pain and suffering and mental anguish. Two aspects of the case.

Now, I told you that before. I'll go over it a little bit. From the time he was given the Kayexalate by Dr. Burks to the time of his death, so we're talking about 48 hours, the worst 48 hours of his life because he was dying. Intestinal bleeding and bloody stools with 10 bowel movements in 14 hours, abdominal pain, crying out in pain, rectal tube, the death of his colon, transferred to ICU, first pain medication not until March 19th. He told his family. He called his family and said get me out of here. Get me out of here. I'm dying. (Indiscernible at 2:55:09) he didn't know. Mr. Allen knew. His family didn't know, couldn't have known because they're net doctors.

Harms and losses. For the family members who are here they loss, the children loss a father and Mrs. Allen loss her husband. And here's a little bit about what Mr. Allen did throughout his life. When he raised his children he instilled upon them the values of hard work, the values of a good education, the values of compassion and love. He started a church, taught his

children how to sing, he taught his children to respect others and he had a relationship that was really remarkable. He was a pillar of this community. He would reach out to the less fortunate people in his community and offer them whatever he could, whatever he could because that's the type of man he was.

Now, the children den't have their father anymore and Mrs. Allen gees heme every night to an empty bed. He's not there anymore. And when you hear the testimony in this case from this family you will know why at the end of this case why the compensation the fair and accurate compensation that we're going to ask for is ten million dollars. Thank you very much.