

IN THE COURT OF CLAIMS OF OHIO

WAYNE GILREATH :
11681 Troy Road :
New Carlisle, Ohio 45344 : Case No. 2001-06525-AD

Plaintiff : MEMORANDUM DECISION

v. :

O.S.U. VETERINARY HOSPITAL :

Defendant :

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For Defendant: Julie D. Vannatta, Associate Legal Counsel
Office of Legal Affairs
Suite 209
33 West Eleventh Avenue
Columbus, Ohio 43201
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{¶1} Plaintiff, Wayne Gilreath, owned a nine and one-half year old dachshund, Cocoa, who suffered from end-stage renal disease. Plaintiff sought and received medical treatment for his dog at defendant, Ohio State University Veterinary Hospital. At various times between March 28, 2000 to July 20, 2000, plaintiff's dog received treatment at defendant's hospital. Plaintiff has alleged defendant's employee, Dr. Dennis J. Chew, was negligent in prescribing improper drug therapy to treat his dog's physical condition. The dog expired on July 20, 2000. Plaintiff has also alleged Dr. Chew made false representations about the efficacy of a drug prescribed for Cocoa and failed to disclose known contraindications about use of the drug. Plaintiff has suggested Renagel (sevelamer hydro-chloride), the drug prescribed for Cocoa, caused a vitamin K deficiency which created coagulation problems

leading to the dog's death on July 20, 2000. Consequently, plaintiff filed this complaint seeking to recover \$954.70, monies paid to defendant's facility for treatment, plus \$400.00, the estimated value of the dog, Cocoa.

{¶2} On March 28, 2000, plaintiff, Wayne Gilreath, brought his dachshund, Cocoa, to defendant's veterinary hospital to obtain a second opinion regarding Cocoa's diagnosis of chronic renal failure. This diagnosis of chronic renal failure (CRF) had been obtained from a veterinarian in Cincinnati identified as Dr. Valerius. Dr. Valerius had apparently made the CRF diagnosis

{¶3} after examining an analysis of Cocoa's blood work and performing an ultra-sound procedure. Once the CRF diagnosis was derived, Dr. Valerius recommended euthanasia. Plaintiff refused to authorize euthanasia of his dog and decided to pursue a course of treatment at defendant's facility. At the March 28, 2000 visit to defendant's hospital plaintiff's dog was examined by defendant's employee, Dr. Dennis Chew, and a diagnosis was developed from test procedure results. After reviewing Cocoa's test results Dr. Chew concluded the findings were consistent with a diagnosis of "renal failure of some variant." Dr. Chew also concluded plaintiff's dog exhibited hyperphosphatemia due to the renal failure. Cocoa's phosphorus level was tested at 8.0 mg/dl with 5.5 mg/dl representing a normal level in adult dogs. Other abnormal physical conditions were observed attributable to chronic renal failure. To treat Cocoa's elevated phosphorus level, Dr. Chew prescribed Alternagel in the amount of 2.5 ml orally twice daily. Dr. Chew made the following written prognosis and follow-up evaluation concerning control of the dog's phosphorus level:

{¶4} "PROGNOSIS: Cocoa's prognosis is guarded to fair at this point. We will know more when we receive the liver aspirate results and the Leptospirosis titer. Prognosis is slightly better for acute renal failure versus acute on chronic. Sequential blood work evaluations will allow us to differentiate between the two

types of renal failure based on the nature of any further recovery of renal function.

{¶5} FOLLOW-UP: Excellent control of serum phosphorus helps to reduce progressive chronic renal damage. Adjustment in dose or preparation of intestinal phosphate binding agents should be based on serum phosphorus levels. Though 'normal' ranges often show serum phosphorus as high as 7 or 8, these ranges include those for growing puppies. Adult values should be less than 6 or preferably less than 5.5."

{¶6} On May 4, 2000, approximately five weeks after Cocoa was initially treated at defendant's hospital, the dog was seen by Dr. Chew for a reevaluation. Test results indicated the dog was suffering from chronic renal failure which was not improving. Other physical problems were present that may or may not have been related to the dog's kidney function illness. Despite the Alternagel therapy Cocoa's phosphorus level had increased to 11.4 mg/dl from 8.0 mg/dl on March 28, 2000. The hyperphosphatemia was graded at "severe/persistent." To control the persistent hyperphosphatemia Dr. Chew added PhosLo, a calcium acetate phosphate binder to the Alternagel already being administered to Cocoa. Dr. Chew noted hyperphosphatemia as "a big risk factor for ongoing progressive renal failure." Dr. Chew wrote the following prognosis and follow-up:

{¶7} "PROGNOSIS: Guarded based on the initial further increases in creatinine and phosphorus as well as the decline in red cell mass.

{¶8} FOLLOW-UP: Repeat of BUN, creatinine, phosphorus two weeks after adding in the new phosphate binder is a good idea. We are maxing out on the doses of these drugs. If we do not get control of the serum phosphorus with this regimen, it may not be possible to do so."

{¶9} Dr. Chew next saw Cocoa on May 19, 2000. At this time it was reported the dog was doing relatively well, but had exhibited

decreased energy and loss of appetite. Furthermore, plaintiff related the dog had been having vomiting episodes for four days prior to the May 19, 2000 treatment at defendant's hospital. Plaintiff also acknowledged he stopped giving Cocoa Alternagel on May 16, 2000 when the dog's vomiting episodes started. Tests indicated Cocoa's phosphorus level had decreased to 7.9 mg/dl from 11.4 mg/dl. Dr. Chew decided to discontinue Alternagel and recommended Cocoa receive Renagel (sevelamer) as a substitute in an attempt to further reduce the dog's serum phosphorus. Renagel was identified as a new generation phosphate binder manufactured by the Genzyme Corporation. Cocoa was prescribed ½ of a 403 mg capsule daily. Dr. Chew admitted he did not have much experience using Renagel, but was unaware of "any major limiting side-effects." Dr. Chew recorded the following prognosis and follow-up based on the May 19, 2000 treatment:

{¶10} "PROGNOSIS: Guarded-her level of renal function (based on creatinine) is relatively stable; we are concerned with her vomiting, as uremia often does this. Vomiting and decreased food intake are major problems that limit quality and quantity of life in those with uremia. We are pleased for now that her anemia has not gotten worse (and maybe has gotten slightly better).

{¶11} FOLLOW-UP: Recheck serum phosphorus, calcium, BUN, creatinine, and albumin following the addition of sevelamer to her treatment. Further adjustments in intestinal phosphate binders may be needed."

{¶12} On June 6, 2000, after instituting the Renagel therapy, plaintiff brought Cocoa back to defendant's hospital. Plaintiff had discontinued giving his dog PhosLo as of May 31, 2000 due to diarrhea and vomiting. Testing revealed Cocoa's phosphorus level was 8.6 mg/dl, an increase from the May 19, 2000 recorded level. Although it appeared the dog's chronic renal failure was relatively stable, her anemia was progressing and her hyperphosphatemia remained persistent. Dr. Chew recommended increasing the dosage of

Renagel by 50% to attempt to better control Cocoa's serum phosphorus. This dosage increase exceeded the extrapolated maximum human dosage. Additionally, Dr. Chew noted he wanted to re-examine Cocoa in one month to, among other things, assess changes in the dog's serum phosphorus. Dr. Chew also indicated he would consider again prescribing Alternagel with the Renagel if Cocoa's phosphorus level was not controlled.

{¶13} On July 6, 2000, Cocoa was brought in to defendant's facility and assessed by defendant's personnel. Examinations and tests revealed the dog's renal function was deteriorating with damage to her tissues appearing inevitable. Cocoa's serum phosphorus was 13.8 mg/dl, a substantial increase over recorded levels on June 6, 2000 (8.6 mg/dl). Dr. Chew advised to increase the dose of Renagel to one capsule twice a day. A reexamination date was set at one month from July 6, 2000.

{¶14} On July 20, 2000, at approximately 9:35 a.m., plaintiff brought Cocoa to defendant's hospital. The dog displayed severe open mouth breathing with crackles and wheezing. She was rushed to an intensive care unit and placed under the direct care of defendant's employee, Dr. Stephen DiBartola, who was assisted by Catherine Moreau, a veterinary student. It was noted Cocoa bled excessively from her jugular vein following a needle puncture. Among other measures taken, a 25 mg dose of vitamin K was administered to the dog. At approximately 11:30 a.m., Cocoa went into respiratory and cardiac arrest. Cocoa was resuscitated. However, at 11:45 a.m., the dog again suffered cardiac arrest and expired.

{¶15} Catherine Moreau, the veterinary student who assisted with treating plaintiff's dog, recorded her observations regarding Cocoa's condition on July 20, 2000. Moreau reported the dog's open mouth breathing with crackling and wheezing lung sounds may have resulted from 1) a coagulopathy causing intratracheal and/or intrapulmonary hemorrhage, 2) uremic pneumonitis, or 3) concurrent

congestive heart failure. Moreau noted, the coagulopathy (excessive bleeding) may have been due to lowered vitamin K absorption, manifested by a vitamin K deficiency leading to decreased blood clotting factors as a side effect of Renagel use. Moreau reasoned the preceding physical scenario was "most likely," because Cocoa's blood platelet count was tested in the normal range. However, Moreau indicated platelet dysfunction could not be ruled out as a cause of the dog's coagulopathy.

{¶16} On August 21, 2000, plaintiff sent a letter to defendant's facility chronicling his recollection of conversations with Dr. Chew regarding Cocoa's treatment. The letter was addressed to three individuals: Richard Bednarski, Administrator of defendant's veterinary hospital, Glenn F. Hoffsis, Dean of defendant's veterinary hospital, and Bob Sherding, Chairman of defendant's veterinary hospital. Plaintiff, in the letter, expressed a number of grievances and dissatisfactions he experienced with Dr. Chew as Cocoa's attending veterinarian.

{¶17} Initially, plaintiff, in the August 21, 2000 letter, referenced a conference he had with Dr. Chew where Renagel was first mentioned as a medication to lower Cocoa's serum phosphorus. Plaintiff stated Dr. Chew offered Renagel as an alternative to PhosLo and Alternagel mentioning he had used the drug successfully in cats, but had no experience using Renagel in the treatment of dogs. Plaintiff asserted Dr. Chew's comment about Renagel was, "it won't hurt Cocoa, but may not help, I don't know."

{¶18} Plaintiff related Renagel was prescribed for Cocoa by Dr. Chew on May 19, 2000. Plaintiff pointed out Dr. Chew wrote he was unaware of any major limiting side effects for use in dogs such as Cocoa. Plaintiff maintained Dr. Chew did not make a full disclosure about Renagel. Consequently, plaintiff implied he was duped into approving Renagel in an attempt to lower his dog's phosphorus levels.

{¶19} After Cocoa's Renagel dosage was increased by 50% on and

after June 6, 2000, plaintiff noticed the dog experienced swallowing difficulties. Plaintiff attributed this dysphagia to increased Renagel use, Dr. Chew did not. Plaintiff stated Dr. Chew ascribed the swallowing difficulties to chronic renal failure.

{¶20} Plaintiff contended Cocoa's treating veterinarian, Dr. Stephen DiBartola, made several comments on July 20, 2000, the day the dog died. Plaintiff stated Dr. DiBartola informed him that Cocoa was having blood clotting difficulties after blood was drawn from the dog's neck. Plaintiff indicated Dr. DiBartola made a research assessment after being told Cocoa was ingesting Renagel. According to plaintiff, Dr. DiBartola said Renagel blocked vitamin k absorption in the gut similar to Warfarin, an anticoagulant drug.

Plaintiff suggested Dr. DiBartola believed Cocoa was suffering from a vitamin K deficiency which had created coagulation problems by causing faulty formation of various blood clotting factors. Plaintiff insisted Dr. DiBartola said Cocoa was definitely not afflicted with disseminated intravascular coagulation (DIC).

{¶21} Plaintiff explained he spoke with Dr. Chew by telephone during the afternoon of July 20, 2000. Plaintiff maintained Dr. Chew acknowledged it was a possibility vitamin K deficiency contributed to the coagulation problems Cocoa experienced. Plaintiff asserted Dr. Chew admitted it didn't dawn on him to give Cocoa a vitamin K supplement because publications addressing Renagel use in humans did not list vitamin K deficiency as a major adverse effect. Plaintiff stated Dr. Chew said no literature existed on the efficacy of Renagel in veterinary medicine but he had hoped the drug would be efficacious or at least safe. Plaintiff asserted that when he expressed his belief Renagel hastened the death of his dog, Dr. Chew replied, "its possible, I can't deny that. You may be right and I'm taking that under advisement for any future use of Renagel."

{¶22} Plaintiff submitted literature about Renagel usage and effects published by Genzyme Corporation, the manufacturer of the

drug. Plaintiff contended Dr. Chew had access to this publication and either disregarded warnings or didn't understand admonitions about the use of Renagel. The Genzyme publication states under the title Indications and Usage: "The safety and efficacy of Renagel Capsules in ESRD (end-stage renal disease) patients who are not on hemodialysis have not been studied." Plaintiff reasoned Cocoa should not have been given Renagel because the dog was not receiving hemodialysis. Additionally, the Genzyme literature under the heading Precautions, General states: "The safety and efficacy of Renagel Capsules in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders, or major GI tract surgery have not been established. Consequently, caution should be exercised when Renagel Capsules are used in patients with these GI disorders." Plaintiff implied Cocoa's difficulty swallowing was related to starting Renagel therapy. Plaintiff contended Dr. Chew ignored protests about Renagel exacerbating swallowing difficulties. Furthermore, the Genzyme document states under the title Precautions, General: "In preclinical studies in rats and dogs, sevelamer hydrochloride (Renagel) reduced vitamin D, E, K, and folic acid levels at doses of 6-100 times the recommended human dose." Based on this information, plaintiff argued his dog should have been given a vitamin K supplement as long as Renagel was being ingested.

{¶23} On September 5, 2000, Dr. Richard M. Bednarski, DVM, MS, the Director of defendant's veterinary hospital, responded by letter to plaintiff's written charges and allegations concerning the treatment of Cocoa by defendant's personnel. Dr. Bednarski wrote he had spoken to both Dr. Chew and Dr. DiBartola about their involvement in providing medical care for plaintiff's dog. Dr. Bednarski acknowledged Dr. Chew stated it was unlikely Renagel would hurt Cocoa or any other dog. Accordingly, Dr. Bednarski expressed the opinion Renagel did not hurt Cocoa and may have helped the dog live longer. Additionally, Dr. Bednarski stated Dr.

Chew could not make any connection between the use of Renagel and Cocoa's swallowing difficulty. Dr. Bednarski explained the vitamin deficiency issue involving Renagel use was not highlighted in the Genzyme publication. Dr. Bednarski pointed out the Genzyme literature revealed studies on dogs and rats established vitamin levels, including vitamin K, were reduced when dosages of Renagel were received by these animals at 6 to 100 times the recommended dosage.

{¶24} Further information conveyed is recorded verbatim from Dr. Bednarski's letter to plaintiff:

{¶25} "Without a necropsy and more detailed blood work, it will not be possible to say with certainty why Cocoa died. She was having respiratory difficulties that could have been the result of pneumonia, uremic pneumonitis, pulmonary embolism, and/or metabolic acidosis. The best hypotheses is that she was suffering from uremic pneumonitis associated with mineralization (very high phosphorus and PTH levels.

{¶26} According to Dr. Chew, you repeatedly asked him to do everything possible to save your dog. Dr. Chew told you on several occasions that her time would be limited if we were not able to control the serum phosphorus levels. We were not able to adequately decrease the serum phosphorus levels despite the use of amphojel (aluminum hydroxide), calcium acetate, or sevelamer.

{¶27} The admonition in the PDR about the use of sevelamer in non-dialysis patients is true. In human medicine they don't pay as much attention to phosphorus dynamics early on as we do in veterinary medicine. Since we don't have access to chronic dialysis treatments, we try to do everything possible to avoid any progression of renal disease. Excellent phosphorus control is the only thing that we have that may actually do this.

{¶28} Regarding the need to run clotting tests: There is no mention of clinical bleeding in the package insert. The toxicology studies mention that vitamin K levels were lowered, but to what

level and if any bleeding occurred was not stated. These animals received 5 to 10 times the recommended dose. Uremic dogs can bleed for a variety of reasons including uremic vasculitis, GI ulcers, poor platelet function, and in some instances poorly characterized coagulopathy. It has not ever been our standard of care to run coagulation panels on uremic patients. Animals with CRF frequently have coagulopathies. To blame the coagulopathy entirely or even in part on the sevelamer is unfair."

{¶29} On October 3, 2000, plaintiff sent a response letter to Dr. Bednarski's letter. This letter from plaintiff was addressed to the Board of Trustees of Ohio State University. Any information contained in this letter neither adds nor detracts from the issues presented to the court.

{¶30} Plaintiff filed a statement from his spouse, Linda Gilreath. In the statement Linda Gilreath attested defendant's employees, Dr. Dennis J. Chew and Dr. Stephen DiBartola, both admitted to her that Cocoa's blood clotting difficulties and death were directly associated with administering Renagel. The trier of fact has given this statement the proper weight it deserves.

{¶31} Defendant filed an investigation report denying any liability in this matter. Defendant acknowledged plaintiff, Wayne Gilreath, on March 28, 2000, brought his dachshund, Cocoa, to the veterinary hospital of Ohio State University to obtain a second opinion regarding a diagnosis of chronic renal failure (CRF). Plaintiff's dog was treated for CRF by defendant's hospital staff between March 28, 2000 and July 20, 2000 when the dog died of heart failure (cardiopulmonary arrest). Part of Cocoa's treatment plan at defendant's facility included the regular administration of the medicine Renagel (sevelamer hydrochloride), a phosphorus buildup inhibitor. Defendant's employee, Dr. Dennis J. Chew, was the primary veterinarian treating plaintiff's dog for CRF at defendant's hospital. Contrary to plaintiff's allegations, defendant has strenuously denied Dr. Chew provided any veterinary

services falling below the standard of care for a professional in the field of practice. Defendant has denied the death of plaintiff's dog was causally related to any negligent acts or omissions on the part of defendant's personnel at the veterinary hospital.

{¶32} Defendant has asserted plaintiff failed to offer any proof his dog, Cocoa, received negligent care and treatment at defendant's facility. Defendant has contended plaintiff cannot produce evidence to establish defendant breached a duty owed to him which proximately caused injury to the dog, Cocoa. Furthermore, defendant contended proof of proximate causation in a claim of this type must be shown by the opinion of expert witnesses. See *Southall v. Gable* (1972), 33 Ohio Misc. 194. Defendant explained plaintiff did not provide competent testimony from a qualified veterinarian to prove a causal connection between the death of Cocoa and any professional conduct falling below the requisite standard of care on the part of defendant's veterinary staff. In the present claim, the only witnesses in the field of veterinary practice offering evidence, are defendant's personnel, who indicated no causal connection was found between negligent practice and the death of plaintiff's dog. Therefore, defendant argued plaintiff's claim should be denied.

{¶33} Additionally, defendant professed its employee, Dr. Chew, the primary veterinarian for Cocoa, is a trained professional who exercised reasonable skill at all times when treating plaintiff's dog. Defendant cited *Storozuk v. W.A. Butler Co.* (1964), 3 Ohio Misc. 60, for the proposition that, "liability for veterinary negligence is tested by the same standards as physicians and surgeons with respect to the exercise or lack of ordinary care." Defendant contended plaintiff, in order to prove liability, "must prove by a preponderance of the evidence that Dr. Chew failed to exercise reasonable skill in caring for Cocoa that ordinarily may be expected of a careful, skillful, and trustworthy veterinarian."

Defendant has insisted plaintiff has not established Dr. Chew's acts in treating Cocoa fell below the professionally recognized standard of care to invoke liability. Defendant asserted plaintiff's beliefs are not recognized proof of professional negligence.

{¶34} Defendant submitted an affidavit from Richard M. Bednarski, D.V.M., M.S., the Director of the Veterinary Teaching Hospital for The Ohio State University College of Veterinary Medicine. Dr. Bednarski, as an Associate Professor in the College of Veterinary Medicine at defendant university and a licensed veterinarian, is a qualified expert on the practice of veterinary medicine. Dr. Bednarski stated he reviewed all the records regarding treatment of plaintiff's dog at defendant's hospital. Records indicated Cocoa was brought to defendant's hospital initially on March 28, 2000 for a second opinion on a diagnosis of chronic renal failure (CRF). At that time the dog's prognosis was evaluated at not good to fair. Dr. Bednarski offered the following explanation and analysis which the court finds relevant to the instant action.

{¶35} "Chronic renal failure is not curable. It is a devastating disease, and a frequent factor in the death of dogs. Dialysis is usually reserved for those animals in acute renal failure in which there is a potential for recovery of kidney function when the temporary dialysis is discontinued.

{¶36} To the best of my knowledge, the University of California at Davis is the only veterinary college of twenty-seven veterinary colleges in the U.S. that has a dialysis program that treats dogs with chronic renal failure. It is very expensive (costing tens of thousands of dollars) and requires three sessions on the dialysis machines per week. Using dialysis to treat chronic renal failure is controversial. Most veterinary nephrologists are willing to perform acute dialysis, but not chronic dialysis due to costs and quality of life issues involved for those animals on chronic

dialysis.

{¶37} The Veterinary Hospital, like every other veterinary hospital except the University of California at Davis, does not have access to chronic dialysis treatments in treating animals with chronic renal failure, so the standard course of treatment is to try to do everything possible to avoid any progression of renal disease by controlling phosphorus levels with medications. Dr. Chew properly advised the Gilreaths on several occasions that Cocoa's time would be limited if the serum phosphorus levels could not be controlled.

{¶38} Since the Veterinary Hospital does not treat animals with chronic renal failure with dialysis, it does not give Renagel to dialysis patients as is most commonly given to people. The Veterinary Hospital's goal is to prevent progression of chronic renal failure by phosphorus control, not to control hyperparathyroidism late in the development of chronic renal failure that so commonly occurs in human dialysis patients. The Veterinary Hospital strives to control renal secondary hyperparathyroidism at much earlier stages of renal diseases (i.e., pre-dialysis or pre-renal transplantation).

{¶39} There is evidence in dogs (mild to moderate uremia) that phosphorus restriction (diet plus binders) allows for longer life and for better renal function and the development of less renal lesions. The benefits may be due to decreased mineralization of many tissues including the kidneys. We strive hard to get the serum phosphorus under control for this reason.

{¶40} Dr. Chew was not successful in controlling Cocoa's serum phosphorus levels with amphotojel or Phos-Lo. In addition, the first drug was discontinued because the Gilreaths thought it was making Cocoa sick.

{¶41} Renagel is a medication that Dr. Chew prescribed in an attempt to control Cocoa's phosphorus levels. Renagel is a phosphorus binder that has the advantage of not having calcium

(otherwise hypercalcemia is a potential side effect) and also does not deliver aluminum (a number of standard phosphorus binders contain aluminum that, in people, can be toxic to bones and nervous system). Phosphorus binders are a mainstay of treatment of chronic renal failure in veterinary patients.

{¶42} Renagel had been given to dogs as part of a toxicology study by Genzyme to get the drug licensed for use in humans. Since the other traditional drugs had failed to achieve phosphorus control in Cocoa, it was reasonable for Dr. Chew to try Renagel.

{¶43} Renagel is an inert drug with low possibility for side effects. Veterinarians frequently prescribe human-approved drugs in situations where it seems that there is a chance that the drug could help, and not much chance that the drug could hurt.

{¶44} It is not necessarily appropriate to infer the same contraindications in the use of Renagel in dogs as in humans, since species differences exist. The Veterinary Hospital has used the drug in several cats without known adverse events, and achieved good control of phosphorus levels in the blood.

{¶45} Although Dr. Chew might not have known the exact kind of side effects Renagel can cause in dogs, it was reasonable not to expect systemic effects from an inert compound that is not absorbed. Any drug can cause local upsets to the stomach (anorexia, vomiting). At six to one hundred times the recommended dosage, during an experiment, the measured levels of vitamins, including vitamin K, declined. The pharmaceutical literature does not state that any bleeding occurred in these dogs or how low the vitamin K levels actually went. Also, there is no evidence that Renagel, given at reasonable doses (below six to one hundred times the recommended dosage), caused any clinical signs, such as bleeding.

{¶46} Uremic poisoning can result in bleeding tendencies for a variety of reasons. (Uremic poisoning is a build up of toxins in the blood and is not an uncommon complication resulting from

chronic renal failure.) These include poor platelet function due to poisoning of the platelet metabolic machinery, gastrointestinal ulcers secondary to uremia, and in some cases, the development of disseminated intravascular coagulation (DIC).

{¶47} It has never been the Veterinary Hospital's standard of care to run coagulation panels on uremic patients. (A coagulation panel is a test of the blood's ability to clot. Certain diseases can cause the clotting factors in the blood to improperly function.

This can result in abnormal bleeding, often internally.) Dogs such as Cocoa with chronic renal failure often have bleeding problems due to poorly functioning platelets (the blood cells that initiate the blood clotting process) and it would be unfair to blame her bleeding problems entirely or even in part on the Renagel. Coagulation panels do not screen for poor platelet function but rather screen for other causes of poor blood clotting that are not typically associated with chronic renal failure. Therefore, it is not the standard of care to spend the client's money on a test that is not relevant to the dog's condition.

{¶48} Cocoa's bleeding tendency was noted in the terminal stages of a terminal disease in which it would not be surprising if some bleeding did occur. Cocoa may have developed disseminated intravascular coagulation in the very terminal stages of her life due to her kidneys finally completely failing. A coagulation panel was ordered on July 20, 2000, but Cocoa died before the coagulation panel was able to be performed.

{¶49} Cocoa's prognosis initially went from guarded to fair on March 28, 2000, to guarded, and finally to poor on July 6, 2000, (the visit before her death on July 20, 2000).

{¶50} Cocoa died on July 20, 2000, of cardiopulmonary arrest. At the time, she was having respiratory difficulties that could have been the result of pneumonia, uremic pneumonitis, pulmonary embolism, and/or metabolic acidosis. The best hypothesis is that she was suffering from uremic penumonitis associated with

mineralization (very high phosphorus and PTH levels). However, without the benefit of a necropsy and more detailed blood work, it is not possible to say with certainty the exact cause of her death.

Regardless, Cocoa's principal diagnosis was chronic renal failure and she was not responding well to treatment.

{¶51} I have consulted with Drs. Chew and DiBartola about Cocoa's treatment and care, and found no impropriety or failure to render the proper standard of care. Furthermore, Dr. DiBartola adamantly denied Mr. Gilreath's assertion that he 'emphatically stated that Cocoa wasn't suffering from DIC when he examined her lab result but rather vitamin K. deficiency brought on by the Renagel which created coagulation problems by faulty formation of Factors II, VII, IX and X.'

{¶52} Based upon my education, training, and expertise in the area of veterinary medicine, as well as my review of Cocoa's veterinary records, it is my opinion to a reasonable degree of medical probability that Dr. Chew's and Dr. DiBartola's care and treatment of Cocoa met the standard of care of a veterinarian using ordinary care, skill, and diligence under like or similar circumstances."

{¶53} In response to defendant's expert, plaintiff emphasized the progress notes recorded by Catherine Moreau, a senior veterinary student. These observations of Moreau, written on July 20, 2000, were compiled in conjunction with treating the terminally ill Cocoa. Moreau's notes contain this assessment: coagulopathy (excessive bleeding or venipuncture) may be due to decreased vitamin K absorption from a vitamin K deficiency causing lowered blood clotting factors as a side effect of Renagel use.

{¶54} Plaintiff offered these notes and observations of Catherine Moreau as evidence to establish Cocoa's death was caused by over medication of Renagel ordered by Dr. Chew. Defendant countered by asserting the notes of a veterinary student such as Catherine Moreau, "cannot be interpreted as an authoritative record

of diagnosis, care, and treatment as recommended by the attending veterinarian." The trier of fact gives the observations, suppositions, and deductions of a student, without accompanying supporting forensic analysis, the evidentiary weight such notes are entitled to carry. The trier of fact is also cognizant of the circumstances under which the notes of Catherine Moreau were drafted. The reference about Renagel in and of itself does not establish the immediate, secondary, or any indirect cause of death of plaintiff's dog. Evidence has shown plaintiff's dog was suffering from a progressively deteriorating treatable, but irreversible condition.

{¶55} Plaintiff presented his dog on March 28, 2000 to defendant's facility with the dog suffering from a moribund disease. Although ameliorative measures were utilized, there remained no doubt Cocoa's condition would only exacerbate to a point where death would result. Too many alternative factors have been presented to conclude over medication with Renagel killed Cocoa. Renagel overdose as a direct cause of death is purely speculative and improbable due to lack of supporting evidence. Insufficient evidence is available to prove cause of death let alone professional negligence.

{¶56} Plaintiff filed a response to defendant's investigation report wherein he repeated his opinions about Renagel and his dog's death. Plaintiff related Renagel was first administered to Cocoa on May 19, 2000. However, plaintiff contended he was not sufficiently or adequately informed about problems (side effects, safety, effectiveness) with the drug by Dr. Chew before he agreed to start a treatment regimen. Plaintiff explained Dr. Chew admitted on May 8, 2000 he didn't have experience with Renagel use in dogs. Plaintiff indicated he was assured by Dr. Chew Renagel would not hurt Cocoa, but may not help her. Furthermore, plaintiff stated he was informed by Dr. Chew that Chew was unaware of any major limiting side effects of Renagel. Plaintiff maintained the

statements of Dr. Chew concerning Renagel were deceptive. Plaintiff argued Dr. Chew deliberately withheld negative information about Renagel so plaintiff would agree to authorize initiation of the drug therapy.

{¶57} Plaintiff has asserted the literature about Renagel published by Genzyme should be persuasive, although the publication discusses the administration of Renagel in humans. Plaintiff has argued the persuasiveness of the literature due to the fact dogs were used in preclinical studies on Renagel as referenced in the Precautions section of the publication. However, plaintiff did not offer any supporting opinion evidence from a qualified veterinarian regarding problems, difficulties, dosage, professional judgment, discretion, warnings, or other information indicating Renagel in a certain dosage was deleterious to a healthy dog or a dog suffering from chronic renal failure. Plaintiff did point out Dr. Chew ordered Renagel for Cocoa in amounts exceeding the maximum human dosage. Plaintiff did not present evidence establishing the prescribing and administering set dosage amounts of Renagel for Cocoa fell below the requisite standard of care for an individual practicing veterinary medicine.

{¶58} Plaintiff attacked the opinions expressed by defendant's expert, Dr. Bednarski. Plaintiff disputed Bednarski's advisement that Renagel is an inert drug with low possibility for side effects. Plaintiff stated:

{¶59} "Defendant's Attachment 1 under Item 14 states, 'Renagel is an inert drug with low possibility for side effects.' That claim is clearly contradicted by the Genzyme Corporation under the heading of Contraindications. It states, 'Renagel Capsules are contraindicated in patients known to be hypersensitive to sevelamer hydrochloride or any of its constituents.' Nowhere in Genzyme's data do they make the claim that Renagel is an inert drug. Quite frankly, if it were inert there could exist no hypersensitivity to any of it's constituents."

{¶60} The opinion of plaintiff was unsubstantiated by any corroborating expert opinion.

{¶61} Plaintiff stated:

{¶62} "Defendant's Attachment 1 under Item 16 states in part, 'It was reasonable not to expect systemic effects from an inert compound that is not absorbed.' Again that claim is clearly contradicted by the Genzyme Corporation under the heading of Pharmacokinetics. It states, 'No absorption studies have been performed in patients with renal disease.'"

{¶63} The trier of fact disagrees with plaintiff that defendant's statement is in conflict with a pharmaceutical publication.

{¶64} Plaintiff stated:

{¶65} "Defendant's Attachment 1 under Item 16 states in part, 'At six to one hundred times the recommended dosage, during an experiment, the measured levels of vitamins, including vitamin K declined.' That statement is not in disagreement with the Genzyme literature. However what it doesn't say is even more remarkable, and that is that pharmaceutical companies always use healthy animals as well as healthy human volunteers in their preclinical studies to ensure the scientific results aren't askew. To use diseased animals in vitamin experiments would be totally unreliable since the drug manufacturer has clearly indicated that no absorption studies have been performed in patients with renal disease. This is in contrast with the study that claims that sevelamer hydrochloride is not systematically absorbed by healthy volunteers."

{¶66} Once again, plaintiff did not offer corroborating evidence to establish these assumptions. Furthermore, plaintiff's statement produces no proof his dog's death was related to any negligence on the part of defendant, or its employees.

{¶67} Plaintiff stated:

{¶68} "Defendant's Attachment 1 under Item 18 states in part, 'It has never been the Veterinary Hospital's standard of care to run coagulation panels on uremic patients.' Plaintiff's position is perhaps that's true under normal circumstances where drugs (phosphate binders) such as aluminum hydroxide (Alternagel) or calcium acetate (Phoslo) are being used where they already have a wealth of experience and know what to expect. However when using a new drug on a dog at the Veterinary Hospital that no one, including Dr. Chew had any experience, calls for extra vigilance. In this situation, a coagulation panel would have been both prudent and no nonsense good medicine. Further, it could and would have detected any problems with faulty formation of Factors II, VII, IX, and X. Obviously, Dr. DiBartola thought so for he had ordered one for Cocoa prior to her death on July 20, 2000."

{¶69} Plaintiff is not qualified to offer his opinions about standard of care regarding course of treatment. Plaintiff has failed to show the decisions described caused his dog's death.

{¶70} Plaintiff stated:

{¶71} "Defendant's Attachment 1 under Item 19 states in part, 'A coagulation panel was ordered on July 20, 2000, but Cocoa died before the coagulation panel was able to be performed.' How ironic that they would see fit to desire to run a coagulation panel as Cocoa lay dying but couldn't muster the decency, wisdom, or zeal to run a coagulation panel at some earlier juncture prior to Cocoa being at death's door. The only possible explanation for this is that Dr. Chew was in charge prior to July 20, 2000 and was asleep at the wheel as he certainly wasn't watching for icebergs. On July 20, 2000, Dr. DiBartola was in charge and showed concern about the Factors II, VII, IX, and X. This corroborates exactly what he reported to us on July 20, 2000 and which was written in the chart on the same date by senior student, Catherine Moreau. At this time, Dr. DiBartola had already reported to us that Cocoa's platelet count was 282, was in the normal range and that Cocoa

definitely wasn't suffering from DIC but rather Vitamin K deficiency brought on by the Renagel. The pieces all fit for again, if Dr. DiBartola had not been concerned about Factors II, VII, IX and X, he wouldn't have bothered to even order the coagulation panel."

{¶72} Plaintiff is not qualified to offer his opinions concerning diagnosis and course of treatment.

{¶73} Additionally, plaintiff has argued he did not receive adequate consultation from defendant's personnel when he agreed to the course of treatment for his dog. Specifically, plaintiff indicated he received incorrect advice from Dr. Chew about deleterious effects of Renagel. Plaintiff cited *Richard V. Staehle* (1980), 70 Ohio App. 2d 93 for the proposition that a plaintiff in a professional malpractice action may recover damages resulting from reliance on incorrect advice offered by the professional. Plaintiff argued the incorrect advice standard applied in *Richard*, *id.* was proven in the instant action. The court disagrees. In *Richard*, four qualified witnesses testified the defendant gave improper advice and this conduct fell below the standard of care for a professional. In the present action only plaintiff, an unqualified witness, has asserted Dr. Chew's advice was incorrect. Plaintiff has failed to produce requisite testimony to establish Dr. Chew offered incorrect professional advice let alone rendered any services falling below the professional standard of care in the field of veterinary medicine.

{¶74} Alternatively, plaintiff has charged Dr. Chew with not being honest in his assessment of plaintiff's dog and failing to disclose information; conduct thereby constituting a breach of contract or false representation. Plaintiff and his spouse both related they were informed by Dr. Chew on May 8, 2000 of the effects of Renagel therapy on their dog. Plaintiff and Linda Gilreath both asserted they heard Dr. Chew say, "If we do go there, meaning that I don't have any experience with it in dogs, but it

won't hurt Cocoa but may not help I don't know." Furthermore, both plaintiff and Linda Gilreath maintained Dr. Chew wrote on May 19, 2000, about Renagel, "we have very little experience with this product, but we do not know of any major limiting side effects." Also, both plaintiff and Linda Gilreath indicated Dr. Chew wrote on June 6, 2000, "increase the Renagel by 50% to see if we can gain better control of the serum phosphorus-this is beyond the extrapolated maximum human dosage (75 mg/kg/da is the usual maximum)." Plaintiff contended the information conveyed about Renagel from Dr. Chew amounted to an absolute warranty of safety. The court disagrees. Plaintiff has failed to prove defendant made any absolute warranty regarding the treatment of the dog Cocoa. Evidence has shown defendant entered into contracts with plaintiff to treat Cocoa for maladies presented. Defendant did not promise to cure the dog. No breach of contract was established.

{¶75} Plaintiff asserted defendant, through its employee, Dr. Chew, intentionally misled him regarding the course of treatment for his dog; conduct which plaintiff contends constituted actionable fraud or false representation. Plaintiff argued he has presented evidence demonstrating the elements of fraud or false representation. As stated in the syllabus of *Hershman v. Univ. of Toledo* (1987), 35 Ohio Misc. 2d 11, the requirements for proving fraud or misrepresentation are: (a) a false representation actual or implied, or a concealment of a fact material to the transaction; (b) knowledge of the falsity on the part of the person making the representation; (c) intent to mislead another into relying on the misrepresentation; (d) reliance, with a right to do so, by the party claiming injury, and (e) injury resulting from that reliance.

To prove his allegations of fraud or false representation, plaintiff offered a cassette tape recording and transcript of a July 20, 2000 conference between himself and Dr. Chew. Plaintiff alleged he was intentionally misled by Dr. Chew about potential problems arising from the Renagel therapy. Any representations

made by Dr. Chew about Renagel on either May 8, 2000, May 19, 2000 or July 20, 2000 as referenced in documents contained in the claim file do not prove any elements of fraud or false representation. Plaintiff has failed to show any comments about Renagel that Dr. Chew expressed constituted fraud or false representation.

{¶76} Additionally, in a situation based on the alleged fraud of a physician making representations to a human patient the Supreme Court of Ohio in *Gaines v. Preterm-Cleveland, Inc.* (1987), 33 Ohio St. 3d 54 stated:

{¶77} "A physician's knowing misrepresentation of a material fact concerning a patient's condition, on which the patient justifiably relies to his detriment, may give rise to a cause of action in fraud independent from an action in medical malpractice.

[Citations omitted.] The fraud action is separate and distinct from the medical malpractice action which stems from the surrounding facts where the decision to misstate the facts cannot be characterized as medical in nature."

{¶78} Although the instant claim is based on alleged malpractice of veterinary medicine as opposed to a medical claim involving a physician/patient relationship, the court concludes the *Gaines*, id. standard of independent fraud assertions applies. However, this court must determine if plaintiff's causes of action are in actuality solely grounded in allegations of veterinary malpractice. The decision to prescribe and administer medication to treat a dog for a physical malady involves the practice of veterinary medicine. Opinions expressed and comments made regarding drug therapy for dogs are veterinary in nature and do not create a distinct cause of action for fraud independent of plaintiff's malpractice claim.

{¶79} Plaintiff has suggested the affidavit of defendant's expert, Dr. Bednarski, should be disregarded by the trier of fact.

Plaintiff has reasoned Dr. Bednarski is not qualified to render an expert opinion in a claim of this type under the parameters of R.C.

2743.43. Plaintiff has contended, Dr. Bednarski, pursuant to statute, is incompetent to offer expert testimony in a medical claim as defined by R.C. 2305.11(D)(3).

{¶80} R.C. 2743.43 states:

{¶81} "(A) No person shall be deemed competent to give expert testimony on the liability issues in a medical claim, as defined in division (D)(3) of section 2305.11 of the Revised Code, unless:

{¶82} "(1) Such person is licensed to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery by the state medical board or by the licensing authority of any state;

{¶83} "(2) Such person devotes three-fourths of his professional time to the active clinical practice of medicine or surgery, osteopathic medicine and surgery, or podiatric medicine and surgery, or to its instruction in an accredited university.

{¶84} "(B) Nothing in division (A) of this section shall be construed to limit the power of the trial court to adjudge the testimony of any expert witness incompetent on any other ground."

{¶85} R.C. 2305.11(D)(3) states:

{¶86} "'Medical claim' means any claim that is asserted in any civil action against a physician, podiatrist, or hospital, against any employee or agent of a physician, podiatrist, or hospital, or against a registered nurse or physical therapist, and that arises out of the medical diagnosis, care, or treatment of any person. 'Medical claim' includes derivative claims for relief that arise from the medical diagnosis, care or treatment of a person." (Emphasis added.)

{¶87} After review of the statutes cited the court concludes neither R.C. 2743.43 nor R.C. 2305.11(D)(3) have any application in the instant claim. The present action is based on veterinary negligence and is excluded from the definition of "medical claim" set forth in R.C. 2305.11(D)(3). Consequently, since plaintiff's action is not a statutorily defined "medical claim", R.C. 2743.43

has no application.

{¶88} Plaintiff has consistently maintained Dr. Chew was negligent in treating his dog with Renagel by ignoring advisements regarding contraindications for use of the drug reported in a publication from the manufacturer of Renagel. Plaintiff referenced a May 8, 2000 meeting with Dr. Chew where Chew stated he believed Renagel, "won't hurt Cocoa, but may not help, I don't know." Dr. Chew explained to plaintiff Renagel was a newly approved phosphorus binder for use in human patients, which defendant's personnel had used successfully in cats. Dr. Chew also informed plaintiff he did not have personal experience using the phosphorus binder Renagel in dogs. Dr. Chew did not inform plaintiff of known deleterious effects of Renagel usage in dogs.

{¶89} Plaintiff submitted a cassette recording and typed transcript of a July 20, 2000 conversation he had with Dr. Chew shortly after Cocoa expired. During this conversation Dr. Chew suggested Cocoa suffered from a vitamin K deficiency which possibly contributed to her death since she bled into her lungs. The manufacturer's publication on Renagel related under the "Precautions" section that studies of the drug in rats and dogs revealed reduced vitamin K levels at dosages 6-100 times the recommended human dose. Cocoa was being administered Renagel at twice the recommended human dose. Among a multitude of possibilities, Dr. Chew acknowledged the blood clotting difficulties Cocoa experienced immediately prior to death could have been due to vitamin K deficiency as a side effect of ingesting Renagel. Plaintiff contended Dr. Chew was negligent by not ordering a vitamin K supplement for Cocoa, despite plaintiff's failure to show Cocoa's death was indirectly caused by a vitamin K deficiency due to Renagel therapy.

{¶90} Plaintiff emphasized the difference in comments Dr. Chew made on May 8, 2000 and July 20, 2000 concerning the use of Renagel in Cocoa. Chew indicated on May 8, 2000 he believed Renagel would

not hurt plaintiff's dog. On July 20, 2000, Chew expressed his opinion Renagel should not have caused bleeding in plaintiff's dog.

The court affords the differences in Chew's statements the proper weight they deserve. The court finds plaintiff has failed to establish Renagel caused or contributed to his dog's death. The court finds plaintiff has not proven from Chew's statements that his dog was negligently medicated despite Chew's inability to deny it was possible Renagel might have contributed to Cocoa's death.

{¶91} Both plaintiff and his spouse, Linda Gilreath, stated they talked with defendant's employee, Dr. Stephen DiBartola, about Cocoa on July 20, 2000. Both plaintiff and Linda Gilreath attested Dr. DiBartola made the following comments:

{¶92} "That Renagel blocked Vitamin K absorption in the gut similar to warfarin . . .

{¶93} That the Vitamin K. deficiency had created coagulation problems by faulty formation of Factors II, VII, IX, and X.

{¶94} That Cocoa had fluid in both lungs that was most likely blood. . .

{¶95} That Cocoa had definitely not been suffering from DIC but rather Vitamin K deficiency brought on by the Renagel which created coagulation problems by faulty formation of Factors II, VII, IX, and X."

{¶96} Defendant denied Dr. DiBartola made comments to plaintiff or his spouse concerning the effects of Renagel upon plaintiff's dog. Defendant denied Dr. DiBartola expressed any opinion based on hard evidence that Renagel caused coagulation problems in Cocoa. The case file is devoid of any statement of Dr. DiBartola regarding his involvement in treating Cocoa or recollections of any conversations with plaintiff about opinions, data analysis, critiques, or personal observations concerning Cocoa's cause of death.

{¶97} Veterinary negligence may be established if sufficient proof exists to show the injury to the animal was caused by

committing an act that a veterinarian of ordinary skill, care and diligence would not have done under similar circumstances, or by failure to perform in a manner that a veterinarian of ordinary skill, care and diligence would have performed under similar circumstances. *Turner v. Sinha* (1989), 65 Ohio App. 3d 30. Mere possibilities or conjectures are not sufficient to establish negligence. Plaintiff must prove defendant's employee was negligent and such negligence caused the death of plaintiff's dog.

In order for plaintiff to show Dr. Chew deviated from the standard of care for veterinarians in Ohio, there must be some causal connection between the death of Cocoa and Renagel treatment. Without a necropsy or expert opinion testimony plaintiff cannot prove a causal connection between Dr. Chew's drug therapy and the dog's death. The court concludes plaintiff has failed to offer sufficient proof to show Dr. Chew's course of action in prescribing Renagel was negligent. Plaintiff has failed to prove Renagel therapy caused a vitamin K deficiency in Cocoa which resulted in coagulation problems. Plaintiff has failed to prove the coagulation problems were the primary and immediate cause of death of his dog considering the extensive irreversible physical damage the dog experienced from chronic renal failure.

{¶98} Having considered all the evidence in the claim file and adopting the memorandum decision concurrently herewith;

{¶99} IT IS ORDERED THAT:

{¶100} 1) Plaintiff's claim is DENIED and judgment is rendered in favor of defendant;

{¶101} 2) Court costs are assessed against plaintiff.

DANIEL R. BORCHERT
Deputy Clerk

Sent to S.C. reporter 10/7/02